The Vancouver Island Health Authority has a full-time opportunity for an Emergency Room Physician at the West Coast General Hospital in Port Alberni.

You hold CCFP(EM) or FRCPC and will provide physician leadership as the Site Chief of the Emergency Department, lead all aspects of running the Department, and have the option of some shifts at our regional Emergency Department in Nanaimo. Grand River Hospital (GRH) provides the regional district stroke intervention program, as well as a full range of specialist services (excluding neurosurgery). GRH sees an average of 55,000 ED patients per year. Both departments have dedicated ultrasound machines and CEUS Independent Practitioners who can help train you toward IP status. Clinical Decision Units exist at both hospitals and both departments are supported by Nurse Practitioners. Both sites have Minor Treatment areas.

There is an equitable distribution of day, evening, night and weekend shifts between all members. Remuneration is under a competitive alternative-funding plan.

The successful candidate will be CCFP-EM, ABEM, or FRCPc certified. Physicians with emergency experience will also be considered. Applicants must be eligible for licensure in the Province of Ontario.

Interested individuals should submit inquiries and/or CV to:

Dr. Sam Hasan
Recruitment Coordinating Physician
Kitchener-Waterloo Emergency Medicine Associates
St. Mary’s General Hospital & Grand River Hospital
Email drhasan_sam@yahoo.com
Tel 519-749-4300 x3892 • Fax 519-749-4293
www.smgh.ca • www.grhosp.on.ca

It’s the Island calling

Emergency Room Physician • Port Alberni, Vancouver Island

The Vancouver Island Health Authority has a full-time opportunity for an Emergency Room Physician at the West Coast General Hospital in Port Alberni.

You hold CCFP(EM) or FRCPc and will provide physician leadership as the Site Chief of the Emergency Department, lead all aspects of running the Department, and have the option of some shifts at our regional Emergency Department in Nanaimo. Remuneration is fee-for-service with top-up to contract rate and a stipend for Site Chief leadership. Additional benefits include a $10,000 recruitment incentive, financial assistance with relocation costs, fee-for-service premium, annual retention premium and rural CME funding after 2 years (subject to eligibility).

The West Coast General Hospital is a modern, well-equipped facility, with 49 acute care beds plus a 3-bed ICU. Clinical specialties include anesthesiology, general surgery, urology, obstetrics/gynecology, internal medicine, pediatrics and radiology (CT Scanner and PACs imaging system). Academic affiliation with the University of British Columbia (UBC) and Island Medical School programs is available.

Port Alberni, a coastal community situated in the majestic Alberni Valley, is surrounded by breathtaking scenery and offers easy access to some of the best year-round recreational opportunities on Vancouver Island. Nanaimo is just under an hour’s drive away, with Victoria and Vancouver also within easy reach. Sprout Lake, on the outskirts of Port Alberni, is an idyllic location to base your family home.

To apply, please send your CV, cover letter and the names of three references to:

Brenda Warren, Manager Physician Recruitment
Email: physicians@viha.ca or Fax: 250.716.7747
As an Emergency Physician, you know minutes count.

Give us 10 minutes and we’ll show you how a career at Windsor Regional Hospital will enhance your life and your lifestyle.

From anywhere in Windsor, you are just minutes to a spectacular waterfront, NHL hockey, NFL football, MLB baseball, Broadway-class theatre, our international airport, more than 14 local wineries or to your own lakefront cottage! Windsor-Essex is one of the most reasonable cost-of-living locations in Canada.

Whether you’re a practicing Emergency Physician or you’ve just completed your residency, Windsor Regional Hospital (WRH) offers you the opportunity for a fantastic career as a full-time Emergency Department Physician in an award-winning health care facility. Our Emergency Department is equipped with state-of-the-art technology and staffed with qualified, dedicated professionals. Still not convinced? Just call us, and we’ll tell you about another 40,000 bonus reasons you should consider a career at Windsor Regional Hospital.

Windsor Regional Hospital is a large, multi-site health service organization providing Acute Medical and Surgical Services including Emergency, Family Birthing Centre, Neonatal Intensive Care, Paediatric Services, Critical Care (ICU/CCU), Regional Cancer Services (Inpatient Oncology, Windsor Regional Cancer Centre, Breast Health Centre), Children’s Mental Health, Complex Continuing Care, Specialized Mental Health/Addictions and Physical Rehabilitation Services to 400,000 people in Windsor and Essex County. WRH provides Acute and Continuing Care Services with over 600-beds on our multi-site locations.

Set aside 10 minutes for a personal conversation with:

Dr. Snezana Ninkovich
Deputy Chief, Emergency Medicine

FOR MORE INFORMATION:
(519) 254-5577 EXT. 52008
www.wrh.on.ca

WINDSOR REGIONAL HOSPITAL
OUTSTANDING CARE—NO EXCEPTIONS!

Emergency Medicine Locum & Permanent Positions

The Applicant
Candidates will be emergency specialists CCFP EM, FRCP or ABEM, or equivalent.

The Benefits
Compensation is via an Alternate Payment Plan. CMPA fees are reimbursed by the Saskatchewan Medical Association in accordance with their guidelines. Emergency physicians are independent contractors and have the opportunity to enjoy the financial benefits of incorporation.

Saskatoon Health Region (SHR)
SHR is one of the most integrated and complex health delivery agencies in Canada. We are the largest health region in Saskatchewan serving more than 300,000 residents in over 100 cities, towns and rural municipalities. Saskatoon Health region is the largest single employer in the province with over 11,000 staff and 780 physicians across the Region providing a complete range of health services to residents of central and northern Saskatchewan. The city’s three acute care hospitals comprise the tertiary teaching centre for the province.

The Opportunity
Come explore an opportunity to join an established group of ED Physicians. As a member of the Saskatoon Health Region Emergency Medicine team, you will be responsible for providing clinical medical services to individuals presenting to the emergency department, including trauma and paediatric care. Candidates will also have the opportunity to teach residents and medical students training at the University of Saskatchewan, College of Medicine. Locums are available starting June 2012 and throughout the following year. As well, we welcome applications for permanent positions.

The City
Saskatoon (pop. 250,000) is a thriving and growing city that radiates fun, excitement, and sophistication! The diversified economy is soaring!

To Apply:
If you are seeking a challenging career opportunity, please apply in confidence to:
Dr. James Stempien,
Head, Emergency Department
Saskatoon Health Region
1702 20th St. West.
Saskatoon, Saskatchewan. S7M 0Z9
Canada
Tel: (306) 655-5360
Fax: (306) 655-5555
Email: james.stempien@saskatoonhealthregion.ca

The University of Saskatchewan is committed to employment equity. Members of designated groups are encouraged to self-identify. (Aboriginal, persons with disabilities and visible minorities).
FULL TIME POSITIONS

CALGARY EMERGENCY DEPARTMENT

The Department of Emergency Medicine (Alberta Health Services – Calgary) is now accepting applications for FULL TIME EMERGENCY PHYSICIANS. Flexible start dates are available, beginning in January 2012.

The Calgary Department of Emergency Medicine encompasses two emergency medicine residency programs and three hospital sites seeing over 200,000 patients per year. A fourth hospital site, the South Health Campus will be opening in Summer 2012. In addition to a full spectrum of high acuity clinical medicine, trauma and cardiac care, we have active programs in human patient simulation and EM ultrasound, and Calgary is the home of STARS (Shock Trauma Air Rescue Society), one of North America’s longest operating rotary wing aero medical systems. The Calgary Department of Emergency Medicine has a growing academic program with research and teaching opportunities.

Calgary is a vibrant, multicultural city (population 1.2 million) near the Rocky Mountains, Banff National Park and Lake Louise with a full range of recreational, sports and cultural opportunities.

Alberta emergency physicians are among the highest paid in North America, and enjoy a flexible work/life balance while working is a highly supportive, collegial environment.

Requirements: CCFP (EM), ABEM or FRCPC certification is required, as well as eligibility for licensure in the province of Alberta.

Interested applicants should forward their curriculum vitae, cover letter and have 3 letters of recommendation sent to:

Scott H. Banks, MBA, CHRP, CITP
Zone Department Manager, Emergency Medicine
Foothills Medical Centre
Room C231, 1403 -29th St NW
Calgary, AB T2N 2T9

Email: scott.banks@albertahealthservices.ca
The life you’ve been working for…

Brant Community Healthcare System is a 350-bed acute care facility boasting comprehensive, state-of-the-art programs staffed by a dedicated and collegial staff whose first priority is high quality, patient-focused care.

Take this outstanding opportunity to experience the exceptional quality of life that is unique to Brantford, Ontario. Located in the picturesque Grand River Valley, our community offers outstanding recreational opportunities. In addition to local culture, arts, and entertainment, you can easily access the diversity of large urban centres such as Toronto, Hamilton, London, and Kitchener. Seven major universities are within commuting distance. We have the following opportunity available...

Emergency Medicine Physician

Presently ten career-oriented physicians supply primary coverage with a core of committed local family physicians providing secondary coverage seeing approximately 45,000 visits annually. We also run a parallel Urgent Care with volume of approximately 17,000. We enjoy comprehensive support from medical, surgical, paediatric, and psychiatric specialties as well as Emergency Department Echo with five certified master instructors and diagnostic imaging including MRI, CT scan, ultrasound, and a full regional laboratory. Candidates with certification in Emergency Medicine or the equivalent experience and certification in ACLS and ATLS are encouraged to apply. Part and full-time positions are available.

To submit your curriculum vitae and letter of interest, please contact:

Alice Preston
Medical Recruitment & Retention Specialist
Brant Community Healthcare System
200 Terrace Hill Street, Brantford, ON N3R 1G9
tel: (519) 751-5544 ext. 2354
e-mail: apreston@bchsys.org  fax: (519) 751-5575

www.bchsys.org
Do you want to bring a Roadshow to your city? We will come to your group! We take many of our Roadshows anywhere they are needed!

Contact Janice MacIsaac to find out all the details. Reach her at jmacisaac@caep.ca or 1-800-463-1158 ext. 20

AIME: Airway Interventions & Management in Emergencies

- September 27 - Whistler BC
- October 24 - Regina SK
- October 25 - Regina SK
- November 14 - Toronto ON

EDTU: Emergency Department Targeted Ultrasound

- June 28 - Ottawa ON
- July 11 - Halifax NS

ED STAT! ED Strategies for Teaching Any Time

- September 7 - Montreal QC
- October 11 - Stratford ON
- October 12 - Stratford ON

MSK: Musculoskeletal Injuries in Adults & Children in the ED

- November 13 - Charlevoix QC

ID: Infectious Disease Management in EM

- November 15 - Toronto ON

RB: Risky Business: Clinical Decision Making in EM

- November 13 - Charlevoix QC

* Roadshow dates are subject to change, check website for updates.
Registrar and Consultant positions available

**Working here**
This fully accredited 250 bed public hospital sees over 50,000 ED presentations annually with a 20% admission rate. Patient acuity has increased significantly in the last 12 months as the department continues to expand. Currently 1-2 patients are admitted to ICU each day with full resuscitation teams activated 2-3 times a week.

This is an exciting time to be part of the future growth and success of this ED. There are currently opportunities for a number of Emergency Physicians and Registrars to join the team and contribute to making this a leading national ED. Academic appointment with one of Australia’s leading universities can be offered and extensive research opportunities are available.

**Living here**
Do you want to escape the rat-race without compromising city living? Here you can have the best of both worlds. This city combines all the conveniences you would expect of a cosmopolitan capital with the beauty and peacefulness of country living. It is particularly great for families, offering Australia’s best education system and access to first-class national sports. Find out for yourself why Australia is ranked as one of the world’s most liveable countries.

**Making the move**
We know that moving to another country is a daunting experience. Wavelength’s team of recruitment, regulatory and migration consultants will be with you every step of the way to provide expert advice and management of the entire process.

“Having worked in many emergency departments, I would not hesitate to state that this hospital has the warmest culture of any hospital, and the ED has the strongest team spirit of any department I have experienced.”

Emergency Medicine Consultant

**Hear for yourself**
Contact us today for a recording of Wavelength’s webcast and listen to the hospital team and Wavelength recruitment specialists discuss this opportunity in more detail. This half hour briefing will give you an invaluable insight into the department and hospital, your career options, the registration and migration process and living in Australia.

Rare and desirable career opportunities like this do not come up often. If you are looking for a great career coupled with a fantastic lifestyle for both yourself and your family then contact Emma Gordon today for more information on +61 2 8353 9048 or email egordon@wave.com.au

wave.com.au
Specialists in medical recruitment
cyanide poisoning is high, Cyanokit® should be administered without delay. If clinical suspicion of cyanide intoxication exists, a confirmatory cyanide blood test must not delay treatment with hydroxocobalamin, it may be useful for documenting cyanide concentrations. While determination of blood cyanide concentration is not required and must not delay treatment with hydroxocobalamin, it may be useful for documenting cyanide poisoning. If a cyanide blood level determination is planned, it is recommended that the extent and duration of the interference is dependent on numerous factors such as the dose of hydroxocobalamin, analyte, analyte concentration, and analyte concentration in patients with impaired renal function is unknown.

Table 1. Common Signs and Symptoms of Cyanide Poisoning

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Signs</th>
</tr>
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<tbody>
<tr>
<td>Headache</td>
<td>Altered Mental Status (e.g., confusion, disorientation)</td>
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<tr>
<td>Confusion</td>
<td>Seizures or Coma</td>
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<tr>
<td>Dyspnea</td>
<td>Mydriasis</td>
</tr>
<tr>
<td>Chest tightness</td>
<td>Tachypnea/Hyperpnea (early)</td>
</tr>
<tr>
<td>Nausea</td>
<td>Bradypnea/Apnea (late)</td>
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<tr>
<td></td>
<td>Hypertension (early)/Hypotension (late)</td>
</tr>
<tr>
<td></td>
<td>Cardiovascular collapse</td>
</tr>
<tr>
<td></td>
<td>Vomiting</td>
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<tr>
<td></td>
<td>Plasma lactate concentration ≥8 mmol/L</td>
</tr>
</tbody>
</table>

In some settings, panic symptoms, including tachypnea and vomiting, may mimic early cyanide poisoning signs. The presence of altered mental status (confusion and disorientation) and/or mydriasis is suggestive of true cyanide poisoning, although these signs can occur with other toxic exposures as well.

Smoke inhalation: Not all smoke inhalation victims will necessarily have cyanide poisoning, and may present with burns, trauma, and exposure to additional toxic substances making a diagnosis of cyanide poisoning particularly difficult. Prior to the administration of Cyanokit® smoke inhalation victims should be assessed for the following:
- exposure to fire smoke in an enclosed area
- soot present around mouth, nose and/or oropharynx
- altered mental status

Use with Other Cyanide Antidotes: The safety of administering other cyanide antidotes simultaneously with Cyanokit® has not been established. If the decision is made to administer another cyanide antidote with Cyanokit®, these medicinal products must be administered concurrently in the same intravenous line (see DOSAGE AND ADMINISTRATION).

Geriatrics (≥ 65 years of age): Approximately 50 known or suspected cyanide victims aged 65 or older received hydroxocobalamin in clinical studies. In general, the safety and effectiveness of hydroxocobalamin in these patients was similar to that of younger patients. No adjustment of dose is required in elderly patients.

Pediatrics (< 18 years of age): Limited safety and efficacy data are available for pediatric patients. In infants and adolescents, the dose of Cyanokit® is 70 mg/kg (see DOSAGE AND ADMINISTRATION).

CONTRAINDICATIONS: None.

SPECIAL POPULATIONS: For use in special populations, see WARNINGS AND PRECAUTIONS. Special Populations.
methodology, analyzer, concentrations of cobalamins-(III) including cyanocobalamin and partially the time between sampling and measurement. Based on in vitro studies and pharmacokinetic data obtained in healthy volunteers the following table describes interference with laboratory tests that may be observed following a 5 g dose of hydroxocobalamin. Interference following a 10 g dose can be expected to last up to an additional 24 hours. The extent and duration of interference in cyanide-poisoned patients may differ according to the severity of intoxication. Results may vary considerably from one analyzer to another, therefore, caution is required when reporting and interpreting laboratory results.

Table 2. Laboratory Interference Observed with in vitro Samples of Hydroxocobalamin

<table>
<thead>
<tr>
<th>Laboratory Parameter</th>
<th>No Interference Observed</th>
<th>Artificially Increased&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Artificially Decreased&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Unpredictable&lt;sup&gt;c&lt;/sup&gt;</th>
<th>Duration of Interference</th>
</tr>
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<tbody>
<tr>
<td>Clinical Chemistry</td>
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<tr>
<td>Calcium</td>
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<td>Sodium</td>
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<td>Potassium</td>
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<td>Chloride</td>
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<td>Urea</td>
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<td>Gamma glutamyl transferase (GGT)</td>
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<td>Creatine</td>
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<tr>
<td>Total and conjugate bilirubin&lt;sup&gt;d&lt;/sup&gt;</td>
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<td>Triglycerides</td>
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<td>Cholesterol</td>
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<td>Total protein glucose</td>
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<td>Albumin</td>
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<tr>
<td>Albumin</td>
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<td>Alkaline phosphatase</td>
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<td>Alanine aminotrans-ferase (ALT)</td>
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<td>Amylase</td>
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<td>Phosphate</td>
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<td>Uric Acid</td>
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<td>Aspartate aminotrans-ferase (AST)</td>
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<td>Creatine Kinase (CK)</td>
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<td>Creatine Kinase isoenzyme MB (CK-MB)</td>
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<td>Lactate dehydrogenase (LDH)</td>
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<td>24 hours with the exception of bilirubin (up to 4 days)</td>
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<tr>
<td>Hematology</td>
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<td>Erythrocytes</td>
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<td>Hematocrit</td>
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<td>Mean corpuscular volume (MCV)</td>
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<td>Leukocytes</td>
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<td>Lymphocytes</td>
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<td>Monocytes</td>
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<td>Eosinophils</td>
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<td>Neutrophils</td>
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<td>Platelets</td>
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<td>12 – 6 hours</td>
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<td>Coagulation</td>
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<td>Activated partial thromboplastin time (aPTT)</td>
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<td>Prothrombin time (PT)</td>
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<td>Quick or INR</td>
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<td>24 – 48 hours</td>
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<td>Urinalysis</td>
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<td>pH (with doses ≥ 5 g)</td>
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<td>Glucose</td>
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<td>Protein</td>
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<td>Erythrocytes</td>
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<td>Leukocytes</td>
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<td>Ketones</td>
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<td>Bilirubin</td>
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<td>Urobilinogen Nitrile</td>
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<td>48 hours up to 8 days; colour changes may persist up to 28 days</td>
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</table>

<sup>a</sup> > 10% interference observed on at least 1 analyzer
<sup>b</sup> Artificially decreased using the diazo method
<sup>c</sup> Inconsistent results

Interference with hemodialysis machines: Because of its deep red colour, hydroxocobalamin may cause hemodialysis machines to shut down due to an erroneous detection of a ‘blood leak’. This should be considered before hemodialysis is initiated in patients treated with hydroxocobalamin.

ADVERSE REACTIONS (see Supplemental Product Information for full listing): Adverse Drug Reaction Overview: Serious adverse reactions with hydroxocobalamin include allergic reactions and increases in blood pressure (see WARNINGS AND PRECAUTIONS). A total of 347 subjects were exposed to hydroxocobalamin in clinical studies. Of these 347 subjects, 245 patients had suspected exposure to cyanide at the time of hydroxocobalamin administration. The remaining 102 subjects were healthy volunteers who had not been exposed to cyanide at the time of hydroxocobalamin administration. Most patients will experience a reversible red colouration of the skin and mucous membranes that may last up to 15 days after administration of Cyanokit®. All patients will show a dark red colouration of the urine that is quite marked during the three days following administration. Urine colouration may last up to 35 days after administration of Cyanokit®.

Post-Market Adverse Drug Reactions: The following adverse events have been reported in post-marketing surveillance. The relationship of these events to Cyanokit® use is not known. Smoke inhalation and cyanide exposure may have contributed to these events: abnormal laboratory tests, pulmonary edema, cardiac arrest, renal failure – in some cases requiring dialysis, and transient impairment of renal function. To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug, you may notify Health Canada by toll-free telephone: 1-866-234-2345.

DRUG INTERACTIONS (also see Supplemental Product Information: Overview): Due to its high molecular weight, hydroxocobalamin is unlikely to interact with or inhibit CYP450 enzymes at clinically relevant concentrations. It is therefore considered to have low potential to be involved in drug-drug interactions with drugs that are substrates of CYP450. Physical incompatibility (particle formation) and chemical incompatibility were observed with the mixture of hydroxocobalamin in solution with selected drugs that are frequently used in resuscitation efforts. Hydroxocobalamin is also chemically incompatible with sodium thiosulfate and sodium nitrite and has been reported to be incompatible with ascorbic acid. Therefore, these and other drugs should not be administered simultaneously through the same IV line as hydroxocobalamin (see DOSAGE AND ADMINISTRATION).

Drug-Drug Interactions: No formal drug-drug interaction studies with hydroxocobalamin have been done.

Drug-Food Interactions: No formal drug-food interaction studies with hydroxocobalamin have been done.

Administration

DOSAGE AND ADMINISTRATION: Dosing Considerations: Comprehensive treatment of acute cyanide intoxication requires support of vital functions. Cyanokit® should be administered in conjunction with appropriate airway, ventilatory and circulatory support. The safety of administering other cyanide antidotes simultaneously with Cyanokit® has not been established. If the decision is made to administer another cyanide antidote with Cyanokit®, these medicinal products must not be administered simultaneously through the same intravenous line.

Recommended Dose and Dosage Adjustment: In adults, the initial dose of Cyanokit® is 5 g administered as an IV infusion. Depending on the severity of the poisoning and the clinical response, a second dose may be administered by IV infusion. The maximum recommended total dose is 10 g. In infants and adolescents, the initial dose of Cyanokit® is 70 mg/kg body weight not exceeding 1 g. Depending on the severity of the poisoning and the clinical response, a second dose may be administered by IV infusion. The maximum recommended total dose is 140 mg/kg body weight not exceeding 10 g (Table 3).

Table 3. Initial Dosing Guidelines in Infants and Adolescents

<table>
<thead>
<tr>
<th>Body weight in kg</th>
<th>5</th>
<th>10</th>
<th>20</th>
<th>30</th>
<th>40</th>
<th>50</th>
<th>60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial dose in g</td>
<td>0.35</td>
<td>0.70</td>
<td>1.40</td>
<td>2.10</td>
<td>2.80</td>
<td>3.50</td>
<td>4.20</td>
</tr>
<tr>
<td>Initial dose in mL</td>
<td>14</td>
<td>28</td>
<td>56</td>
<td>84</td>
<td>112</td>
<td>140</td>
<td>168</td>
</tr>
</tbody>
</table>

Use in Renal and Hepatic Impairment: Although the safety and efficacy of hydroxocobalamin has not been studied in patients with renal or hepatic impairment, Cyanokit® is administered as emergency therapy in an acute, life-threatening situation only, and no dosage adjustment is required in these patients.

Administration: The initial dose of hydroxocobalamin for adults is 5 g (i.e., two 2.5 g vials or one 5 g vial) administered as an intravenous (IV) infusion over 15 minutes (approximately 15 mL/min). Depending upon the severity of the poisoning and the
The Cyanokit® 5 g vial is to be rocked or inverted for at least 60 seconds to mix the injection is not available, Lactated Ringer solution or 5% glucose can also be used. The Cyanokit® 2.5 g vial is to be rocked or inverted for at least 30 seconds to mix the solution. It must not be shaken as shaking the vial may cause foam and therefore may make checking reconstitution less easy.

2.5g Vial: Each 2.5 g vial is to be reconstituted with 100 mL of diluent using the supplied sterile transfer device. Sodium chloride 9 mg/mL (0.9%) solution for injection is the recommended diluent. Only when sodium chloride 9 mg/mL (0.9%) solution for injection is not available, Lactated Ringer solution or 5% glucose can also be used. The Cyanokit® 2.5 g vial is to be rocked or inverted for at least 60 seconds to mix the solution. It must not be shaken as shaking the vial may cause foam and therefore may make checking reconstitution less easy.

5 g Vial: Each 5 g vial is to be reconstituted with 200 mL of diluent using the supplied sterile transfer device. Sodium chloride 9 mg/mL (0.9%) solution for injection is the recommended diluent. Only when sodium chloride 9 mg/mL (0.9%) solution for injection is not available, Lactated Ringer solution or 5% glucose can also be used. The Cyanokit® 5 g vial is to be rocked or inverted for at least 60 seconds to mix the solution. It must not be shaken as shaking the vial may cause foam and therefore may make checking reconstitution less easy. Because the reconstituted solution is a dark red solution, some insoluble particles may not be seen. The intravenous infusion set provided in the kit must therefore be used as it includes an appropriate filter and is to be primed with the reconstituted solution. Repeat this procedure if necessary with the second vial.

Incompatibility Information: Physical incompatibility (particle formation) and chemical incompatibility were observed with the mixture of hydroxocobalamin in solution with selected drugs that are frequently used in resuscitation efforts. Hydroxocobalamin is also chemically incompatible with sodium thiosulfate and sodium nitrite and has been reported to be incompatible with ascorbic acid. Therefore, these and other drugs must not be administered simultaneously through the same IV line as hydroxocobalamin. Simultaneous administration of hydroxocobalamin and blood products (whole blood, packed red cells, platelet concentrate and/or fresh frozen plasma) through the same IV line is not recommended. However, blood products and hydroxocobalamin can be administered simultaneously using separate IV lines (preferably on contralateral extremities, if peripheral lines are being used).

Storage of Reconstituted Drug Product: Once reconstituted, hydroxocobalamin is stable for up to 6 hours at a temperature between 2°C and 40°C (35.6°F and 104°F). Do not freeze. Any reconstituted product not used by 6 hours should be discarded.

Supplemental Product Information

ADVERSE REACTIONS: Systematic collection of adverse events was not done in all clinical studies involving known or suspected cyanide-poisoning victims who were treated with hydroxocobalamin. The interpretation of causality in these studies is limited due to lack of a control group and due to circumstances of administration (e.g., use in fire victims).

Clinical Trial Adverse Drug Reactions: Because clinical trials are conducted under very specific conditions the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates.

Experience in Healthy Subjects: A double-blind, randomized, placebo-controlled, single-ascending dose (2.5, 5, 7.5, and 10 g) study was conducted to assess the safety, tolerability, and pharmacokinetics of hydroxocobalamin in 136 healthy adult subjects. Because of the dark red colour of hydroxocobalamin, the two most frequently occurring adverse reactions were chromaturia (red-coloured urine) which was reported in all subjects receiving a 5 g dose or greater; and erythema (skin redness), which occurred in most subjects receiving a 5 g dose or greater. Adverse reactions reported in at least 1% of the 5 g dose group and corresponding rates in the 10 g and placebo groups are shown in Table 5.

Table 4. Reconstitution

<table>
<thead>
<tr>
<th>Dose per Vial</th>
<th>Volume of Diluent to be Added to Vial</th>
<th>Approximate Available Volume</th>
<th>Nominal Concentration per mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5 g</td>
<td>100 mL</td>
<td>Approx. 100 mL</td>
<td>25 mg/mL</td>
</tr>
<tr>
<td>5 g</td>
<td>200 mL</td>
<td>Approx. 200 mL</td>
<td>25 mg/mL</td>
</tr>
</tbody>
</table>

Table 5. Incidence of Adverse Reactions Occurring in ≥ 1% of Healthy Subjects in 5 g Dose Group and Corresponding Incidence in 10 g Dose Group and Placebo

<table>
<thead>
<tr>
<th>Adverse Drug Reaction</th>
<th>5 g Dose Group</th>
<th>10 g Dose Group</th>
<th>Placebo</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5 g Dose Group</td>
<td>10 g Dose Group</td>
<td>Placebo</td>
<td>Placebo</td>
</tr>
<tr>
<td></td>
<td>N = 66</td>
<td>N = 22</td>
<td>N = 18</td>
<td>N = 6</td>
</tr>
<tr>
<td>Eye disorder</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Eye redness</td>
<td>2 (3)</td>
<td>0</td>
<td>1 (6)</td>
<td>0</td>
</tr>
<tr>
<td>Renal and Urinary Disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chromaturia (red coloured urine)</td>
<td>66 (100)</td>
<td>0</td>
<td>18 (100)</td>
<td>0</td>
</tr>
<tr>
<td>Pollakiuria (frequent urination)</td>
<td>1 (2)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue Disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Erythema</td>
<td>62 (94)</td>
<td>0</td>
<td>18 (100)</td>
<td>0</td>
</tr>
<tr>
<td>Rash*</td>
<td>14 (21)</td>
<td>0</td>
<td>3 (17)</td>
<td>0</td>
</tr>
<tr>
<td>Immune Disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Face edema</td>
<td>1 (2)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Pruritus</td>
<td>1 (2)</td>
<td>0</td>
<td>3 (17)</td>
<td>0</td>
</tr>
<tr>
<td>Urticaria</td>
<td>1 (2)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Investigations</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood amylase increased</td>
<td>1 (2)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Blood pressure increased</td>
<td>12 (18)</td>
<td>0</td>
<td>5 (28)</td>
<td>0</td>
</tr>
<tr>
<td>Lymphocyte percent decreased</td>
<td>5 (8)</td>
<td>0</td>
<td>3 (17)</td>
<td>0</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal discomfort</td>
<td>2 (3)</td>
<td>0</td>
<td>2 (11)</td>
<td>0</td>
</tr>
<tr>
<td>Flatulence</td>
<td>1 (2)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Loose stools</td>
<td>1 (2)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Nausea</td>
<td>4 (6)</td>
<td>1 (5)</td>
<td>2 (11)</td>
<td>0</td>
</tr>
<tr>
<td>Vomiting</td>
<td>2 (3)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Nervous System Disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td>2 (3)</td>
<td>0</td>
<td>1 (6)</td>
<td>0</td>
</tr>
<tr>
<td>Headache</td>
<td>4 (6)</td>
<td>1 (5)</td>
<td>6 (33)</td>
<td>0</td>
</tr>
<tr>
<td>General disorders and administrative site conditions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chest discomfort</td>
<td>3 (5)</td>
<td>0</td>
<td>2 (11)</td>
<td>0</td>
</tr>
<tr>
<td>Discomfort</td>
<td>1 (2)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Feeling hot and/or cold</td>
<td>2 (3)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Infusion site reaction</td>
<td>4 (6)</td>
<td>0</td>
<td>7 (39)</td>
<td>0</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Joint/back pain</td>
<td>2 (3)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Restlessness</td>
<td>2 (3)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dysepsia</td>
<td>1 (2)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Sore or dry throat</td>
<td>3 (5)</td>
<td>0</td>
<td>3 (17)</td>
<td>0</td>
</tr>
</tbody>
</table>

* Rashes were predominately acneiform.
Less Common Adverse Drug Reactions Occurring at a rate of less than 1%

Eye disorders: Swelling, irritation.

Gastrointestinal disorders: Dyspepsia, diarrhea, dysphagia, hematochezia.

General disorders and administration site conditions: Peripheral edema.

Immune system disorders: Allergic reactions including angioedema and skin eruption (see WARNINGS AND PRECAUTIONS).

Nervous system disorders: Memory impairment.

Respiratory, thoracic and mediastinal disorders: Pleural effusion.

Vascular disorders: Hot flush.

Experience in Known and Suspected Poison Victims: Four open-label, uncontrolled, clinical studies (one of which was prospective and three of which were retrospective) were conducted in known or suspected cyanide-poisoning victims. A total of 245 patients received hydroxocobalamin treatment in these studies. Systematic collection of adverse events was not done in all of these studies and interpretation of causality is limited due to the lack of a control group and due to circumstances of administration (e.g., use in fire victims). Adverse reactions reported in these studies listed by system organ class included:

Cardiac disorders: Ventricular extrasystoles, an increase in heart rates, electrocardiogram repolarization abnormality.

Adverse reactions common to both the studies in known or suspected cyanide poisoning victims and the study in healthy volunteers are listed in the healthy volunteer section of the Product Monograph only and are not duplicated in this list.

Abnormal Hematologic and Clinical Chemistry Findings: Cyanokit® may cause red discoloration of the plasma, which may cause artificial elevation or reduction in the levels of certain laboratory parameters (see WARNINGS AND PRECAUTIONS). White blood cell counts (WBC) showed a slight and transient increase in mean values from baseline at 2 to 12 hours after treatment in healthy subjects, and small decreases in serum sodium levels were also observed. Changed values generally remained within normal ranges. Other minor and transient changes in hematology and clinical chemistry findings were considered due to interference by hydroxocobalamin or due to individual variation.

DRUG INTERACTIONS: Drug-Herb Interactions: Interactions with herbal products have not been established.

Drug-Laboratory Interactions: Because of its deep red colour, hydroxocobalamin has been found to interfere with colourimetric determination of certain laboratory parameters (e.g., clinical chemistry, hematology, coagulation, and urine parameters). In vitro tests indicated that the extent and duration of the interference are dependent on numerous factors such as the dose of hydroxocobalamin, analyte, methodology, analyzer, hydroxocobalamin concentration, and partially on the time between sampling and measurement. Based on in vitro studies and pharmacokinetic data obtained in healthy volunteers, Table 2 describes laboratory interference that may be observed following a 5 g dose of hydroxocobalamin (see WARNINGS AND PRECAUTIONS). Interference following a 10 g dose can be expected to last up to an additional 24 hours. The extent and duration of interference in cyanide-poisoned patients may differ. Results may vary substantially from one analyzer to another; therefore, caution should be used when reporting and interpreting laboratory results.

OVERDOSAGE: For management of a suspected drug overdose, contact your Regional Poison Control Centre.

Limited data are available about overdose with Cyanokit® Doses as high as 15 g have been administered without reported specific dose related adverse reactions. If overdose occurs, treatment is directed to the management of symptoms. Hemodialysis may be effective in such a circumstance, but is only indicated in the event of significant hydroxocobalamin-related toxicity. Because of its deep red colour, hydroxocobalamin may interfere with the performance of hemodialysis machines (see WARNINGS AND PRECAUTIONS, Monitoring and Laboratory Tests).

Product Monograph available on request.

References: 1. CYANOKIT® (Hydroxocobalamin) Product Monograph, EMD Serono, October, 2011.

Cyanokit is a registered trademark of Merck Santé S.A.S.

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Mississauga, Ontario L5K 2N6 Canada
www.emdserono.ca
An affiliate of Merck KGaA, Darmstadt, Germany

EMD Serono
**Drug-Drug Interactions**

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**Potential Serotonergic Interactions:** Unless patients are carefully observed for signs and/or symptoms of serotonin syndrome, linezolid should not be administered to patients with carcinoid syndrome and/or patients taking any of the following medications: serotonin re-uptake inhibitors, tricyclic antidepressants, serotonin 5-HT1 receptor agonists (triptans), meperidine or bupropine (see **DRUG INTERACTIONS, Drug-Drug Interactions**).

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**General:** The use of antibiotics may promote the overgrowth of nonsusceptible organisms. Should superinfection occur during therapy, appropriate measures should be taken. ZYVOXAM Tablets, Injection and Oral Suspension have not been studied in patients with uncontrolled hypertension, pheochromocytoma, carcinoid syndrome or untreated hyperthyroidism. Large quantities of foods or beverages with high tyramine content should be avoided while taking ZYVOXAM (see **ADVERSE REACTIONS, DRUG INTERACTIONS, Drug-Food Interactions** for foods or beverages with high tyramine content). The safety and efficacy of ZYVOXAM given for longer than 28 days have not been evaluated in controlled clinical trials.

**Lactic Acidosis:** Lactic acidosis has been reported with the use of ZYVOXAM. Patients who develop recurrent nausea or vomiting, unexplained acidosis or a low bicarbonate level while receiving ZYVOXAM should receive immediate medical attention.

**Drug Interactions** (see also **DRUG INTERACTIONS, Drug-Drug Interactions**)

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**Serotonin Syndrome:** Very rare spontaneous reports of serotonin syndrome with co-administration of linezolid and serotonergic agents have been reported. Since there is limited experience with concomitant administration of linezolid and serotonergic agents (such as serotonin re-uptake inhibitors, tricyclic antidepressants and serotonin 5-HT1 receptor agonists), physicians should be alert to the possibility of signs and symptoms of serotonin syndrome (e.g., hyperpyrexia and cognitive dysfunction) in patients receiving such concomitant therapy (see **CONTRAINDICATIONS and ADVERSE REACTIONS, Drug-Drug Interactions, Serotonergic Agents**).

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**Gastrointestinal:** Clostridium difficile-associated disease (CDAD) has been reported with use of many antibacterial agents, including ZYVOXAM. CDAD may range in severity from mild diarrhea to fatal colitis. It is important to consider this diagnosis in patients who present with diarrhea, or symptoms of colitis, pseudomembranous colitis, toxic megacolon or perforation of colon subsequent to the administration of antibiotics. Treatment with antibacterial agents may alter the normal flora of the colon and may permit overgrowth of C. difficile. Clindamycin, included in this class, has been shown to suppress killing of C. difficile in vitro. CDAD may range in severity from mild diarrhea to fatal colitis. CDAD has been reported to occur over 2 months after the administration of antibacterial agents.

If the diagnosis of CDAD is suspected or confirmed, appropriate therapeutic measures should be initiated. Mild cases of CDAD usually respond to discontinuation of the causative antibacterial and supportive therapy. Severe cases may require surgical intervention, which may be required in certain severe cases (see **ADVERSE REACTIONS**).
Neurologic: Peripheral neuropathy has been reported primarily in patients treated for longer than the maximum recommended duration of 28 days with ZYVOXAM. When outcome was known, recovery was reported in only some cases following ZYVOXAM withdrawal. If symptoms of peripheral neuropathy such as numbness, tingling, pricking sensations or burning pain occur, the continued use of ZYVOXAM should be weighed against the potential risk. Convulsions have been reported to occur rarely in patients treated with ZYVOXAM. In most of these cases, a history of seizures or risk factors for seizures was reported.

Ophthalmologic: Optic neuropathy has been reported in patients treated with ZYVOXAM, primarily those treated for longer than the maximum recommended duration of 28 days. When outcome was known, recovery was reported in some cases following ZYVOXAM withdrawal. In cases of optic neuropathy that progressed to loss of vision, patients were treated for longer than the maximum recommended duration. Visual blurring has been reported in some patients treated with ZYVOXAM for <28 days. Visual function should be monitored in all patients taking ZYVOXAM for longer than the maximum recommended duration and in all patients reporting new visual symptoms regardless of length of therapy with ZYVOXAM. If patients experience symptoms of visual impairment, such as changes in visual acuity, changes in colour vision, blurred vision or visual field defect, prompt ophthalmologic evaluation is recommended. If optic neuropathy occurs, the continued use of ZYVOXAM in these patients should be weighed against the potential risks.

Special Populations: Pregnant Women: There are no adequate and well-controlled studies in pregnant women. ZYVOXAM should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Women: ZYVOXAM and its metabolites are excreted in the milk of lactating rats. Concentrations in milk were similar to those in maternal plasma. It is not known whether linezolid is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ZYVOXAM is administered to a nursing woman.

Pediatrics: There are insufficient data on the safety and efficacy of linezolid in children and adolescents (<18 years old) to establish dosage recommendations (see ACTION AND CLINICAL PHARMACOLOGY, Special Populations and Conditions, Pediatrics in the Product Monograph). Therefore, until further data are available, use of linezolid in this age group is not recommended.

Geriatrics: Of the 2046 patients treated with ZYVOXAM in phase II comparator-controlled clinical trials, 589 (29%) were ≥65 years and 253 (12%) were ≥75 years. No overall differences in safety or effectiveness were observed between these patients and younger patients.

Monitoring and Laboratory Tests: Complete blood counts should be monitored at least weekly in patients who receive linezolid, particularly in those who receive linezolid for longer than two weeks, patients who are at increased risk for bleeding, those with pre-existing myelosuppression, those receiving concomitant drugs that produce bone marrow suppression, or decreased hemoglobin levels or platelet counts or function, or those with a chronic infection who have received previous or concomitant antibiotic therapy (see WARNINGS AND PRECAUTIONS, Hematologic: Myelosuppression).

Visual function should be monitored in all patients taking ZYVOXAM for longer than the maximum recommended duration and in all patients reporting new visual symptoms regardless of length of therapy with ZYVOXAM. If patients experience symptoms of visual impairment, such as changes in visual acuity, changes in colour vision, blurred vision or visual field defect, prompt ophthalmologic evaluation is recommended (see WARNINGS AND PRECAUTIONS, Ophthalmologic).

ADVERSE REACTIONS (see full listing in Supplemental Product Information):

Adverse Drug Reaction Overview: The safety of ZYVOXAM Tablets and Injection was evaluated in 2046 adult patients enrolled in seven phase III comparator-controlled clinical trials, who were treated for ≥28 days. In these studies, 85% of the adverse events reported with ZYVOXAM were described as mild to moderate in intensity. The most common adverse events in patients treated with ZYVOXAM were diarrhea (incidence across studies: 2.8-11.0%), headache (incidence across studies: 0.5-11.3%) and nausea (incidence across studies: 3.4-9.6%). Other adverse events reported in phase II and phase III studies included oral moniliasis, vaginal moniliasis, hypertension, dyspepsia, localized abdominal pain, pruritus and tongue discolouration.

Postmarket Adverse Drug Reactions: Myelosuppression (anemia including pure red blood cell aplasia, leukopenia, panleukopenia and thrombocytopenia) has been reported during post-marketing use of ZYVOXAM (see WARNINGS AND PRECAUTIONS). Peripheral neuropathy and optic neuropathy sometimes progressing to loss of vision have been reported in patients treated with linezolid. These reports have primarily been in patients treated for longer than the maximum recommended duration of 28 days (see WARNINGS AND PRECAUTIONS).

Lactic acidosis (see WARNINGS AND PRECAUTIONS, General), convulsions (see WARNINGS AND PRECAUTIONS, Neurologic), angioedema and anaphylaxis have been reported. Very rare reports of bullous skin disorders such as those described as Stevens-Johnson syndrome have been received. Very rare spontaneous reports of serotonin syndrome with co-administration of linezolid and serotoninergic agents have been reported (see WARNINGS AND PRECAUTIONS, Drug Interactions).

These events have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to ZYVOXAM or a combination of these factors. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made and causal relationship cannot be precisely established.

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug, you may notify Health Canada by toll-free telephone: 1-866-234-2345.

DRUG INTERACTIONS (also see Supplemental Product Information: Overview: Drugs Metabolized by Cytochrome P450: Linezolid is not an inducer of cytochrome P450 (CYP) in rats. It is not detectably metabolized by human cytochrome P450 and it does not inhibit the activities of clinically-significant human CYP isozymes (1A2, 2C9, 2C19, 2D6, 2E1, 3A4). Therefore, no CYP450-induced drug interactions are expected with linezolid. Concurrent administration of linezolid does not substantially alter the pharmacokinetic characteristics of (S)-warfarin, which is extensively metabolized by CYP2C9. Drugs such as warfarin and phenytoin, which are CYP2C9 substrates, may be given with linezolid without changes in dosage regimen.

Drug-Drug Interactions: Monoamine Oxidase Inhibitor: Linezolid is a mild reversible nonselective inhibitor of MAO-A and MAO-B. Therefore, linezolid has the potential for interaction with adrenergic and serotoninergic agents. Studies in healthy volunteers have examined the effect of linezolid on the pharmacodynamic responses to tyramine, sympathomimetic amines and dextromethorphan (see CONTRAINDICATIONS).

Adrenergic Agents: A significant pressor response has been observed in normal adult subjects receiving linezolid and tyramine doses of >100 mg. Therefore, patients receiving linezolid need to avoid consuming large amounts of foods or beverages with high tyramine content. A reversible enhancement of the pressor response of either pseudophedrine HCl (PSE) or phenylpropanolamine HCl (PPA) is observed when linezolid is administered to healthy normotensive subjects. Some individuals receiving ZYVOXAM may experience a reversible enhancement of the pressor response to indirect-acting sympathomimetic agents, vasopressor or dopaminergic agents. Commonly used drugs such as phenylpropanolamine and pseudophedrine have been specifically studied. Initial doses of adrenergic agents, such as dopamine or epinephrine, should be reduced and titrated to achieve the desired response. A similar study has not been conducted in hypertensive patients. The interaction studies conducted in normotensive subjects evaluated the blood pressure and heart rate effects of placebo, PPA or PSE alone, linezolid alone and the combination of steady-state linezolid (600 mg q12h for 3 days) with two doses of PPA (25 mg) or PSE (60 mg) given 4 hours apart. Heart rate was not affected by any of the treatments. Blood pressure was increased with both combination treatments. Maximum blood pressure levels were seen 2 to 3 hours after the second dose of PPA or PSE, and returned to baseline 2 to 3 hours after peak.

Serotonergic Agents: A study to assess the potential interaction of linezolid with a serotonin-reuptake inhibitor (dextromethorphan) was conducted in healthy volunteers. No significant differences were found in the pharmacodynamic measures of temperature, digit symbol substitution, nurse-rated sedation, blood pressure or pulse when subjects were administered dextromethorphan with or without linezolid. The effects of other serotonin-reuptake inhibitors have not been studied. Very rare spontaneous reports of serotonin syndrome with co-administration of linezolid and serotoninergic agents have been reported. Since there is limited experience with concomitant administration of linezolid and serotoninergic agents, physicians should be alert to the possibility of signs and symptoms of serotonin syndrome (e.g., hyperpyrexia and cognitive dysfunction) in patients receiving such concomitant therapy (see CONTRAINDICATIONS).

Antibiotics: Aztreonam – The pharmacokinetics of linezolid or aztreonam are not altered when administered together. Gentamicin – The pharmacokinetics of linezolid or gentamicin are not altered when administered together.

Antacids: No studies have been conducted with antacids and chelating agents. Based on the chemical structure, concurrent administration with these agents is not expected to affect absorption of linezolid.

Drug-Food Interactions: Large quantities of foods or beverages with high tyramine content should be avoided while taking ZYVOXAM. Quantities of tyramine consumed should be <100 mg/meal. Foods high in tyramine content include...
those that may have undergone protein changes by aging, fermentation, pickling or smoking to improve flavour, such as aged cheeses (0-15 mg tyramine/28 g); fermented or air-dried meats (0.1-8 mg tyramine/28 g); sauerkraut (8 mg tyramine/224 g); soy sauce (5 mg tyramine/1 tsp); tap beers (4 mg tyramine/360 mL); red wines (0-6 mg tyramine/240 mL). The tyramine content of any protein-rich food may be increased if stored for long periods or improperly refrigerated.

Administration

DOSAGE AND ADMINISTRATION: Recommended Dose and Dosage Adjustment: The recommended dosage for ZYVOXAM Tablets, Injection and Oral Suspension for the treatment of infections in adults is described in Table 1. Doses of ZYVOXAM are administered every 12 hours (q12h).

Table 1. Dosage Guidelines for ZYVOXAM

<table>
<thead>
<tr>
<th>Infection*</th>
<th>Dosage and Route of Administration</th>
<th>Recommended Duration of Treatment (consecutive days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vancomycin-resistant Enterococcus faecalis (VREF) infections, including concurrent bacteremia</td>
<td>600 mg IV or oral q12h</td>
<td>14 to 28</td>
</tr>
<tr>
<td>Nosocomial pneumonia</td>
<td>600 mg IV or oral q12h</td>
<td>10 to 14</td>
</tr>
<tr>
<td>Complicated skin and skin structure infections: a) Except diabetic foot infections</td>
<td>600 mg IV or oral q12h</td>
<td>10 to 14</td>
</tr>
<tr>
<td>b) Non-Limb threatening diabetic foot infections, without concomitant osteomyelitis</td>
<td>600 mg IV or oral q12h</td>
<td>14 to 28</td>
</tr>
<tr>
<td>Community-acquired pneumonia, including concurrent bacteremia</td>
<td>600 mg IV or oral q12h</td>
<td>10 to 14</td>
</tr>
<tr>
<td>Uncomplicated skin and skin structure infections</td>
<td>400 mg oral q12h</td>
<td>10 to 14</td>
</tr>
</tbody>
</table>

* Due to the designated pathogens (see INDICATIONS AND CLINICAL USE).

Patients with infection due to MRSA should be treated with ZYVOXAM 600 mg q12h. In controlled clinical trials, the protocol-defined duration of treatment for all infections ranged from 7 to 28 days. Total treatment duration was determined by the treating physician based on site and severity of the infection, and on the patient’s clinical response.

No dose adjustment is necessary when switching from intravenous (IV) to oral administration. Patients whose therapy is started with ZYVOXAM Injection may be switched to ZYVOXAM Tablets or Oral Suspension at the discretion of the physician, when clinically indicated. ZYVOXAM may be taken with or without food.

Missed Dose: If a dose is missed, it should be taken as soon as possible. However, if it is almost time for the next dose, the missed dose should be skipped and the regular dosing schedule resumed. Doses should not be doubled.

Administration: Intravenous (IV): ZYVOXAM Injection should be administered by IV infusion over a period of 30-120 minutes. Do not use this IV infusion bag in series connections. Additives should not be introduced into this solution. If ZYVOXAM Injection is to be given concomitantly with another drug, each drug should be given separately in accordance with the recommended dosage and route of administration for each product. If the same IV line is used for sequential infusion of several drugs, the line should be flushed before and after infusion of ZYVOXAM Injection with an infusion solution compatible with ZYVOXAM Injection and with any other drugs) administered via this common line (see DOSAGE AND ADMINISTRATION, Compatible IV Solutions).

ZYVOXAM Injection: ZYVOXAM Injection is supplied as a ready-to-use sterile isotonic solution for IV infusion. As with all parenteral drug products, IV solutions should be inspected visually for clarity, particulate matter, precipitate and leakage prior to administration whenever solution and container permit. Solutions showing haziness, particulate matter, precipitate or leakage should not be used. ZYVOXAM Injection may exhibit a yellow colour that can intensify over time without adversely affecting potency. Discard unused portions.

Compatible IV Solutions: 5% Dextrose Injection, USP; 0.9% Sodium Chloride Injection, USP; Lactated Ringer’s Injection, USP.

Compatibility: Physical incompatibilities resulted when ZYVOXAM Injection was combined with the following drugs during simulated Y-site administration: amphotericin B, chlorpromazine HCl, diazepam, pentamidine isethionate, erythromycin lactobionate, phenytoin sodium and trimethoprim-sulfamethoxazole. Additionally, chemical incompatibility resulted when ZYVOXAM Injection was combined with ceftriaxone sodium.

Supplemental Product Information

Information for Patients

Patients should inform their physician or pharmacist if they:

- Have a history of high blood pressure.
- Are taking any cold or flu remedies or decongestants containing pseudoephedrine.
- Are taking any antihypertensives especially those known as serotonin re-uptake inhibitors.
- Are taking any other medicines, including those you have bought without a prescription.
- Have a history of anemia (low hematocrit), thrombocytopenia (low platelets), neutropenia (low white blood cells) or any other blood-related disorders.
- Have a history of bleeding problems.
- Ever had any unusual or allergic reaction to ZYVOXAM or its ingredients (such as preservatives or dyes).
- Are pregnant or trying to become pregnant.
- Are breastfeeding.
- Have a history of seizures or convulsions.

ADVERSE REACTIONS: Clinical Trial Adverse Drug Reactions: Because clinical trials are conducted under very specific conditions, the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug related adverse events and for approximating rates.

Phase III Clinical Trials: Table 2 shows the incidence of drug-related adverse events reported in at least 1% of adult patients in these trials by dose of ZYVOXAM.

Table 2. Incidence of Drug-Related Adverse Events Occurring in >1% of Adult Patients Treated with ZYVOXAM in Comparator-Controlled Clinical Trials

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>ZYVOXAM 600 mg IV PO q12h (n=1464)</th>
<th>Comparator (n=1537)</th>
<th>ZYVOXAM 600 mg q12h (n=1348)</th>
<th>All Other Comparators (n=1464)</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of patients with at least 1 drug-related adverse event*</td>
<td>25.4</td>
<td>19.6</td>
<td>20.4</td>
<td>14.2</td>
</tr>
<tr>
<td>% of patients discontinuing due to drug-related adverse events†</td>
<td>3.5</td>
<td>2.4</td>
<td>2.1</td>
<td>1.7</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>5.3</td>
<td>4.8</td>
<td>4</td>
<td>2.7</td>
</tr>
<tr>
<td>Nausea</td>
<td>3.5</td>
<td>3.5</td>
<td>3.3</td>
<td>1.8</td>
</tr>
<tr>
<td>Headache</td>
<td>2.7</td>
<td>2.2</td>
<td>1.9</td>
<td>1</td>
</tr>
<tr>
<td>Taste alteration</td>
<td>1.8</td>
<td>2</td>
<td>0.9</td>
<td>0.2</td>
</tr>
<tr>
<td>Urinary infections</td>
<td>1.6</td>
<td>1.3</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Fungal infection</td>
<td>1.5</td>
<td>0.4</td>
<td>0.1</td>
<td>0.5</td>
</tr>
<tr>
<td>Abnormal liver function tests</td>
<td>0.4</td>
<td>0</td>
<td>1.3</td>
<td>0.5</td>
</tr>
<tr>
<td>Vomiting</td>
<td>0.9</td>
<td>0.4</td>
<td>1.2</td>
<td>0.4</td>
</tr>
<tr>
<td>Tongue discoloration</td>
<td>1.1</td>
<td>0</td>
<td>0.2</td>
<td>0</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>1.1</td>
<td>1.5</td>
<td>0.4</td>
<td>0.2</td>
</tr>
<tr>
<td>Oral moniliasis</td>
<td>0.4</td>
<td>0</td>
<td>1.1</td>
<td>0.4</td>
</tr>
</tbody>
</table>

* The most commonly reported drug-related adverse events leading to discontinuation in patients treated with ZYVOXAM were nausea, headache, diarrhea and vomiting.

In controlled clinical trials, abdominal pain/stomach distension and abnormal hematology tests were also reported occurring at an incidence of at least 1%.

Less Common Clinical Trial Adverse Drug Reactions (<1%)

Adverse drug reactions that were possibly or probably related to ZYVOXAM with an incidence less than 1.0% but greater than 0.1% in controlled clinical trials were:

Body System

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metabolic and nutritional</td>
<td>100%</td>
</tr>
<tr>
<td>Amylease increased, Hyperglycemia, Hyperlipidemia, Lisspe High, Serum Cholesterol increased, ALT increased and ALP increased</td>
<td></td>
</tr>
<tr>
<td>Special senses</td>
<td>100%</td>
</tr>
<tr>
<td>Blurred vision, Tinnitus</td>
<td></td>
</tr>
<tr>
<td>Muscular-skeletal</td>
<td>100%</td>
</tr>
<tr>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td>100%</td>
</tr>
<tr>
<td>Hypertension, Pericarditis</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>100%</td>
</tr>
<tr>
<td>Constipation, Dry Mouth, Dysphagia, Gastritis, Glutathione, Increased Third, Strontium and Tongue Discoloration</td>
<td></td>
</tr>
<tr>
<td>Dermatologic</td>
<td>100%</td>
</tr>
<tr>
<td>Skin irritation, Urticaria, Inflammation, Rash, Skin reactions</td>
<td></td>
</tr>
<tr>
<td>Hypersensitivity, Malignant skin, Rash, Urticarial rash, Urticaria</td>
<td></td>
</tr>
</tbody>
</table>

In controlled clinical trials the pattern of drug-related adverse reactions by body system with an incidence less than 1.0% but greater than 0.1% were similar to comparators.
Serious adverse reactions in controlled clinical trials considered possibly or probably related to ZYVOXAM treatment with an incidence of less than 1% were: Heterotaxy, Kidney Failure, Liver Function Test Anomaly, Pancreatitis, Thrombocytopenia, Transient Ischemic Attack, and Wasting.

Phase IV Clinical Trials: In a phase IV computer-controlled study (Study 113) of adult diabetic patients with clinically documented complicated skin and skin structure infections ("diabetic foot infections"), most drug-related adverse events were rated as mild or moderate in intensity. 13.0% were rated as severe, with the exception of diarrhea (0.8%), each severe drug-related event was reported in no more than one patient.

Table 3. Frequencies of Study-Emergent Drug-Related Adverse Events Reported for ≥1% of Patients in Either Treatment Group (Study 113, linezolid in the treatment of adult diabetic patients with clinically documented complicated skin and skin structure infections ("diabetic foot infections"))

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Linezolid (n=241)</th>
<th>Comparator (n=120)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total reported</td>
<td>Patients reporting at least 1 drug-related AE</td>
<td>64 (26.6)</td>
</tr>
<tr>
<td>Digestive</td>
<td>Nausea</td>
<td>18 (7.5)</td>
</tr>
<tr>
<td></td>
<td>Vomiting</td>
<td>4 (1.7)</td>
</tr>
<tr>
<td>Hematologic and lymphatic</td>
<td>Anemia</td>
<td>11 (4.6)</td>
</tr>
<tr>
<td></td>
<td>Thrombocytopenia</td>
<td>9 (3.7)</td>
</tr>
</tbody>
</table>

* The information represents the number (%) of patients who reported a given study-emergent adverse event. Any patient with multiple reports of the same event was counted only once for that event.

1. All percentages are based on the number of ITT patients.

Less Common Clinical Trial Adverse Drug Reactions (<1%): In Study 113, adverse drug reactions that were possibly or probably related to ZYVOXAM with an incidence less than 1.0% but greater than 0.1% were:

<table>
<thead>
<tr>
<th>Body System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metabolic and nutritional</td>
</tr>
<tr>
<td>Healing Anomalous, Hypoglycemia, Hypokalemia, LIDH Increased</td>
</tr>
<tr>
<td>Special senses</td>
</tr>
<tr>
<td>Taste Perversion</td>
</tr>
<tr>
<td>Musculo-skeletal</td>
</tr>
<tr>
<td>None</td>
</tr>
<tr>
<td>Hematologic and lymphatic</td>
</tr>
<tr>
<td>Eosinophilia/Brusitis, Neutropenia</td>
</tr>
<tr>
<td>Respiratory</td>
</tr>
<tr>
<td>Diaphoresis</td>
</tr>
<tr>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Congestive Heart Failure, Disorder Peripheral Vascular</td>
</tr>
<tr>
<td>Digestive</td>
</tr>
<tr>
<td>Anemia, Bilary Pain, C difficile Colitis, Cholestasis, Jaundice, Gastrointestinal NOD, Gastrointestinal Bleeding, Hemolytic Anemia, Hypokalemia, LIDH Increased</td>
</tr>
<tr>
<td>Renal</td>
</tr>
<tr>
<td>Urogenital</td>
</tr>
<tr>
<td>Abnormal Laboratory Assay</td>
</tr>
<tr>
<td>Body as a whole</td>
</tr>
<tr>
<td>Abdominal Cramps, Abdominal Pain Localized, Anemia, Gastrointestinal Bleeding, Hemolytic Anemia, Hemorrhage, Hemoglobin, Hypokalemia, LIDH Increased</td>
</tr>
<tr>
<td>Skin</td>
</tr>
<tr>
<td>Dermatitis, Dermatosis Fungus, Rhema, Rash, Skin Ulcer</td>
</tr>
</tbody>
</table>

Abbreviations: NEC=nott elsewhere classified; NOS=not otherwise specified

In Study 113, serious drug-related events were reported for seven patients in the linezolid treatment group: congestive heart failure, peripheral vascular disease, biliary pain, cholecystitis, Cholestasis. 16.0% of patients who developed a substantially low platelet count (defined as less than 75% of lower limit of normal and/or baseline) was 2.4% (range among studies: 0.3 to 10.0%) with a comparator. Thrombocytopenia associated with ZYVOXAM and 1.5% (range among studies: 0.4 to 7.0%) with a comparator. Thrombocytopenia associated with ZYVOXAM has been associated with multiple reports of the same event was counted only once for that event.

In phase III trials: Abnormal Hematologic and Clinical Chemistry Findings: ZYVOXAM has been associated with thrombocytopenia when used in adults in doses up to and including 600 mg every 12 hours for up to 28 days. In phase II comparator-controlled trials, the percentage of patients who developed a substantially low platelet count (defined as less than 75% of lower limit of normal and/or baseline) was 2.4% (range among studies: 0.3 to 10.0%) with ZYVOXAM and 1.5% (range among studies: 0.4 to 7.0%) with a comparator. Thrombocytopenia associated with ZYVOXAM has been associated with multiple reports of the same event was counted only once for that event.

In a phase IV computer-controlled study (Study 113) of adult diabetic patients with clinically documented complicated skin and skin structure infections ("diabetic foot infections"), most drug-related adverse events were rated as mild or moderate in intensity. 13.0% were rated as severe, with the exception of diarrhea (0.8%), each severe drug-related event was reported in no more than one patient.

Table 4. Percent of Adult Patients who Experienced at Least One Substantially-Abnormal* Hematology Laboratory Value in Comparator-Controlled Clinical Trials with ZYVOXAM

<table>
<thead>
<tr>
<th>Laboratory Assay</th>
<th>ZYVOXAM 400 mg q12h</th>
<th>Comparator</th>
<th>ZYVOXAM 600 mg q12h</th>
<th>Comparator</th>
<th>All Other Comparators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin (g/L)</td>
<td>0.9</td>
<td>0.9</td>
<td>7.1</td>
<td>6.6</td>
<td></td>
</tr>
<tr>
<td>Platelet count (10⁹/L)</td>
<td>0.7</td>
<td>0.8</td>
<td>3.0</td>
<td>1.8</td>
<td></td>
</tr>
<tr>
<td>Mean platelet volume (fL)</td>
<td>0.2</td>
<td>0.2</td>
<td>2.2</td>
<td>1.3</td>
<td></td>
</tr>
<tr>
<td>Neutrophils (%)</td>
<td>0.9</td>
<td>0.9</td>
<td>2.2</td>
<td>1.2</td>
<td></td>
</tr>
</tbody>
</table>

* <75% (<50% for neutrophils) of Lower Limit of Normal (LLN) for values normal at baseline; <75% (<50% for neutrophils) of lower limit of normal for values abnormal at baseline.

Table 5. Percent of Adult Patients who Experienced at Least One Substantially-Abnormal* Serum Chemistry Laboratory Value in Comparator-Controlled Clinical Trials with ZYVOXAM

<table>
<thead>
<tr>
<th>Laboratory Assay</th>
<th>ZYVOXAM 400 mg q12h</th>
<th>Comparator</th>
<th>ZYVOXAM 600 mg q12h</th>
<th>Comparator</th>
<th>All Other Comparators</th>
</tr>
</thead>
<tbody>
<tr>
<td>AST (U/L)</td>
<td>1.7</td>
<td>1.7</td>
<td>3.0</td>
<td>2.6</td>
<td>4.8</td>
</tr>
<tr>
<td>ALT (U/L)</td>
<td>1.7</td>
<td>1.7</td>
<td>9.6</td>
<td>9.3</td>
<td></td>
</tr>
<tr>
<td>LDH (U/L)</td>
<td>0.2</td>
<td>0.2</td>
<td>1.8</td>
<td>1.5</td>
<td></td>
</tr>
</tbody>
</table>
The power of ZYVOXAM for the complexity of MRSA in cSSSIs\textsuperscript{1}

**ZYVOXAM**: Available in Tablet, Powder Oral Solution and IV\textsuperscript{1}

**High bioavailability\textsuperscript{1}**
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**Offers convenient and flexible dosing\textsuperscript{1}**
- From hospital to home – seamless transition from IV-to-oral therapy without dosage adjustment or reduction in efficacy.

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ZYVOXAM Tablets, Injection and Oral Suspension are indicated for the treatment of adult patients with the following infections, when caused by susceptible strains of the designated aerobic Gram-positive micro-organisms: Complicated skin and skin structure infections, including non-limb-threatening diabetic foot infections, without concomitant osteomyelitis, caused by \textit{Staphylococcus aureus} (methicillin-susceptible and -resistant strains), \textit{Streptococcus pyogenes} or \textit{Streptococcus agalactiae}. ZYVOXAM has not been studied in the treatment of necrotizing fasciitis or decubitus ulcers.

Uncomplicated skin and skin structure infections caused by \textit{Staphylococcus aureus} (methicillin-susceptible strains only) or \textit{Streptococcus pyogenes}.

ZYVOXAM is not indicated for treatment of Gram-negative infections. It is critical that specific Gram-negative therapy be initiated immediately if a concomitant Gram-negative pathogen is documented or suspected. ZYVOXAM Tablets, Injection and Oral Suspension should not be used in patients taking or within 2 weeks of taking any medicinal product which inhibits monoamine oxidases A or B. Unless patients are monitored for potential increases in blood pressure, ZYVOXAM should not be administered to patients with uncontrolled hypertension, pheochromocytoma, thyrotoxicosis or patients taking directly or indirectly acting sympathomimetic agents, vasopressive agents or dopaminergic agents. Unless patients are carefully observed for signs and/or symptoms of serotonin syndrome, ZYVOXAM should not be administered to patients with carcinoid syndrome or patients taking serotonin re-uptake inhibitors, tricyclic antidepressants, serotonin 5-HT\textsubscript{1} receptor agonists (triptans), neuropeptide or buspirone.

The most common clinical trial adverse events in patients treated with ZYVOXAM were (incidence across studies): diarrhea (2.8\% to 11.0\%); headache (0.5\% to 11.3\%); and nausea (3.4\% to 9.6\%).

Lactic acidosis has been reported with the use of ZYVOXAM. Patients who develop recurrent nausea or vomiting, unexplained acidosis or a low bicarbonate level while receiving ZYVOXAM should receive immediate medical attention.

Myelosuppression has been reported in patients receiving linezolid. In cases where the outcome is known, when linezolid was discontinued, the affected hematologic parameters have risen toward pretreatment levels. Complete blood counts should be monitored at least weekly in patients who receive linezolid, particularly in those who receive linezolid for longer than two weeks, patients who are at increased risk for bleeding, those with pre-existing myelosuppression, those receiving concomitant drugs that produce bone marrow suppression, or decreased hemoglobin levels or platelet counts or function, or those with a chronic infection who have received previous or concomitant antibiotic therapy. Discontinuation of therapy with ZYVOXAM should be considered in patients who develop or have worsening myelosuppression. Visual function should be monitored in all patients taking ZYVOXAM for longer than the maximum recommended duration and in all patients reporting new visual symptoms regardless of length of therapy with ZYVOXAM.

Please see Product Monograph for complete Warnings and Precautions, Dosage and Administration. Product Monograph available on request.

\textsuperscript{*} Clinical significance is unknown.
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Isser Dubinsky

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