LUVOX® (fluvoxamine maleate) Tablets

Brief Summary of prescribing information (based on 8E1252 Rev 3/97)

**Maximum Dosage for Adults and Non-Pediatric Subjects**

When fluvoxamine maleate is administered in doses of 180 to 400 mg/day, treatment-related adverse events were observed with similar frequency in patients receiving fluvoxamine maleate and placebo. The adverse events most frequently reported during treatment with fluvoxamine maleate were: nausea (25%), anxiety (12%), abnormal dreams (11%), insomnia (10%), and dizziness (9%).

**Pediatric Use**

The efficacy of fluvoxamine for the treatment of Obsessive Compulsive Disorder was demonstrated in a 12-week multicenter placebo controlled study in children and adolescents (ages 8 to 17 years) with OCD. The study included 317 patients who were randomized to receive either fluvoxamine (n=154) or placebo (n=163). The efficacy of fluvoxamine in the treatment of OCD was demonstrated in a 12-week multicenter placebo controlled study in children and adolescents (ages 8 to 17 years) with OCD.

**Pediatric Use**


drug therapy. In children with OCD and depression, fluvoxamine was well tolerated, with a low incidence of adverse events compared to placebo.

**CNS Symptoms**

Fluvoxamine was associated with a low incidence of adverse events compared to placebo. These events included: nausea, anxiety, insomnia, dizziness, and drowsiness.

**Metabolism**

Fluvoxamine is extensively metabolized in the liver by two main pathways: the oxidative metabolic pathway and the glucuronidation pathway. The oxidative metabolic pathway is responsible for the formation of several active metabolites, including fluvoxamine N-desmethyl metabolite (M1), fluvoxamine N-glucuronide (M2), and fluvoxamine N-oxide (M3). These metabolites are mainly excreted in the urine and bile. The glucuronidation pathway results in the formation of a number of inactive glucuronides, which are then excreted in the urine.

**Drug Interactions**

Fluvoxamine is a substrate for CYP3A4 and a inhibitor of CYP2D6, CYP1A2, and CYP2C9. It is a potent inhibitor of P-glycoprotein and a moderate inhibitor of BCRP. Fluvoxamine is a non-selective serotonin reuptake inhibitor (SSRI) and has been shown to increase the levels of several neurotransmitters, including serotonin. It has been demonstrated to have no significant effect on the metabolism of other medications, which are not metabolized by the above enzymes.

**Adverse Reactions**

The most common adverse reactions reported during treatment with fluvoxamine maleate were nausea, anxiety, insomnia, dizziness, and drowsiness. These reactions were generally mild to moderate in intensity and tended to occur early in the treatment period. The frequency of these reactions was comparable between patients treated with fluvoxamine and those treated with placebo.

**Laboratory Tests**

There are no specific laboratory tests recommended. However, routine laboratory tests should be performed to monitor the patient's health and to detect any potential adverse effects of fluvoxamine treatment.

**Geriatric Use**

Approximately 200 patients participating in controlled pharmacology studies with fluvoxamine maleate were 65 years of age or over. No overall differences in safety were seen among these patients compared to younger patients, but greater sensitivity of some older individuals cannot be ruled out. Consequently, caution should be used when treating elderly patients with fluvoxamine.

**ADVERSE REACTIONS**

**Treatment of Obsessive Compulsive Disorder**

In pediatric patients (5-18 years) treated with fluvoxamine, the overall profile of adverse events was similar to that found in adults. The most commonly reported adverse events were nausea, anxiety, insomnia, dizziness, and drowsiness. The frequency of these adverse events was comparable between patients treated with fluvoxamine and those treated with placebo.

**Adverse Reactions in OCD Pediatric Patients**

In pediatric patients (5-18 years) treated with fluvoxamine, the overall profile of adverse events was similar to that found in adults. The most commonly reported adverse events were nausea, anxiety, insomnia, dizziness, and drowsiness. The frequency of these adverse events was comparable between patients treated with fluvoxamine and those treated with placebo.
Emerging from the profound anxiety of OCD

Low incidence of agitation

• 2% vs 1% for placebo

Low incidence of sexual dysfunction

• LUVOX® Tablets vs placebo*: decreased libido 2% vs 1%; delayed ejaculation 8% vs 1%; anorgasmia 2% vs 0%; impotence 2% vs 1%

Favorable tolerability profile

• Relatively low incidence of anticholinergic side effects in controlled trials of OCD and depression. LUVOX® Tablets vs placebo: dizziness 11% vs 6%; constipation 10% vs 8%; dry mouth 14% vs 10%

• The most commonly observed adverse events compared to placebo were somnolence 22% vs 8%; insomnia 21% vs 10%; nervousness 12% vs 5%; nausea 40% vs 14%; asthenia 14% vs 6%

• Concomitant use of LUVOX® Tablets and monoamine oxidase inhibitors is not recommended

*Parameters occurring ≥ 1% with fluvoxamine maleate.

Please see brief summary of prescribing information on adjacent page.