LUVOX (fluvoxamine maleate) 25 mg TABLETS, 50 mg and 100 mg SCORED TABLETS

Brief Summary of prescribing information (Based on Rev 8/97)

INDICATIONS AND USAGE

LUVOX maleate is indicated for the treatment of: Obsessive Compulsive Disorder (OCD), as defined in the DSM-IV. Obsessive Compulsive Disorder is characterized by recurrent and persistent thoughts, urges, or images that are ego-dystonic and, if acted on, lead to significant distress or impairment in social, occupational, or other important areas of functioning.

WARNINGS

In patients receiving another serotonin reuptake inhibitor drug in combination with fluvoxamine or another selective serotonin reuptake inhibitor (SSRI) or in combination with another medication that is also known to have a potential for serotonin syndrome or interactions with SSRIs, the following precautions should be considered. In some cases, the potential for serotonin syndrome has been demonstrated by fatal reactions.

Other Potentially Important Drug Interactions

See PRECAUTIONS - Drug Interactions. Benzodiazepines: Benzodiazepines modulated by hypnotics (e.g., lorazepam, temazepam, and midazolam) should be used with caution in combination with fluvoxamine. A pharmacological interaction of the benzodiazepines with fluvoxamine has been demonstrated by increased plasma concentrations of diazepam, temazepam and diazepam-conjugate UDP-glucuronide and has been associated with tachyphylaxis of the benzodiazepines.

Fluvoxamine has been demonstrated to be defiitively demonstrated that fluvoxamine is a potent IAIAA inhibitor. It is likely to be.
EFFECTIVE FIRST-LINE SSRI THERAPY FOR OCD...

EMERGING FROM THE PROFOUND ANXIETY OF OCD

The first SSRI indicated for OCD in children and adolescents

AVAILABLE IN 25-mg TABLETS

LUVOX® Tablets

1st-line SSRI therapy for obsessions and compulsions

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%

• For adults, 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%

• Adverse events in children and adolescents were similar to
those observed in adult studies. The most commonly observed
adverse events compared to placebo were: agitation 12% vs 3%;
hyperkinesia 12% vs 3%; depression 5% vs 0%; dysmenorrhea
7% vs 3%; flatulence 5% vs 0%; rash 7% vs 3%

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

Available in 25-mg tablets

Fluvoxamine maleate

25 mg TABLETS 50 mg & 100 mg SCORED TABLETS

First-line SSRI therapy for obsessions and compulsions

*Parameters occurring ≥ 1% with fluvoxamine maleate.