OXAMINE TABLETS

(Fluvoxamine Maleate 50 mg / 100 mg)

COMPOSITION

Each film-coated tablet contains Fluvoxamine Maleate 50 mg or 100 mg, as labelled. Excipients q.s.

DESCRIPTION AND PHARMACOLOGY

Oxamine contains fluvoxamine maleate, a selective serotonin reuptake inhibitor (SSRI). It inhibits neuronal reuptake of serotonin in the central nervous system. Its clinical effect develops gradually over several weeks.

INDICATIONS

Fluvoxamine maleate tablets are indicated for the treatment of obsessive-compulsive disorder (OCD), characterized by obsessions and/or compulsions causing significant distress or impairment. Other uses depend on locally approved product information and specialist assessment.

DOSAGE AND ADMINISTRATION

Adults with OCD: Recommended initial dose: 50 mg once daily at bedtime. Dose may be increased by 50 mg every 4-7 days according to response and tolerability, up to 300 mg/day. Total doses above 100 mg/day should generally be divided; give the larger portion at bedtime if unequal.

Treatment is individualized. Do not increase the dose or stop treatment without medical advice. A gradual taper is recommended on discontinuation.

USE IN CHILDREN

For OCD, reference prescribing information recommends starting 25 mg at bedtime in patients aged 8-17 years, with cautious titration. A 25 mg strength may be required; the 50 mg and 100 mg products must not be assumed suitable for obtaining this dose. Specialist supervision is essential.

CONTRAINDICATIONS

Hypersensitivity to fluvoxamine or any excipient. Do not co-administer with tizanidine, thioridazine, alosetron or pimozide. Do not use with monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping an MAOI; do not start an MAOI within 14 days after stopping fluvoxamine. Do not initiate in patients receiving linezolid or intravenous methylene blue.

WARNINGS AND PRECAUTIONS

Suicidality: Antidepressants may increase suicidal thoughts and behaviour in children, adolescents and young adults, especially early in treatment or following dose changes. Monitor for clinical worsening, unusual behaviour and suicidality.

Serotonin syndrome: May occur with fluvoxamine alone or with other serotonergic medicines. Watch for agitation, confusion, fever, sweating, tremor, muscle rigidity and diarrhoea; seek urgent medical care if suspected.

Screen for bipolar disorder; mania/hypomania may emerge. Use caution in patients with a seizure disorder, hepatic dysfunction, predisposition to bleeding, low serum sodium or untreated narrow angles (risk of angle-closure glaucoma).

Hyponatraemia, often associated with SIADH, may occur, particularly in older adults or with diuretics. Increased bleeding risk may occur with anticoagulants, antiplatelets and NSAIDs. Avoid abrupt withdrawal.

HEPATIC IMPAIRMENT / ELDERLY

Reduced clearance may require a lower initial dose and slower titration. Monitor closely.

DRUG INTERACTIONS

Fluvoxamine inhibits several hepatic CYP enzymes and can substantially increase concentrations of co-administered medicines. Contraindicated interactions include tizanidine, thioridazine, pimozide and alosetron. Check all prescription and non-prescription medicines before use.

Serotonergic medicines (including other SSRIs/SNRIs, tramadol, triptans, lithium, fentanyl, buspirone and St John's wort) increase serotonin-syndrome risk. NSAIDs, aspirin, warfarin and other antithrombotics may increase bleeding risk. Benzodiazepines and some antipsychotics may require monitoring or dose changes.

Caffeine effects may be enhanced; limit excessive intake. Alcohol should be avoided. Smoking changes may alter fluvoxamine exposure. Consult the prescriber or pharmacist before adding medicines.

PREGNANCY

Use only after assessment of maternal benefit and fetal/neonatal risk. Exposure late in pregnancy may be associated with neonatal adaptation symptoms and other complications. Do not stop abruptly on learning of pregnancy; consult the treating clinician.

LACTATION

Fluvoxamine passes into breast milk. Consider benefits of breastfeeding and maternal treatment and monitor the infant for adverse effects.

EFFECT ON DRIVING

Drowsiness, dizziness and impaired judgement can occur. Avoid driving or hazardous machinery until individual response is known.

ADVERSE REACTIONS

Commonly reported reactions include nausea, vomiting, dyspepsia, constipation, diarrhoea, loss of appetite, sweating, tremor, dizziness, somnolence, insomnia, nervousness, weakness and sexual dysfunction.

Serious reactions may include suicidal thoughts or behaviour, serotonin syndrome, abnormal bleeding, seizures, mania, severe hyponatraemia, angle-closure glaucoma and severe hypersensitivity reactions. Seek immediate medical attention for severe or unusual symptoms.

DISCONTINUATION

Stopping suddenly may cause dizziness, nausea, irritability, anxiety, sensory disturbances, headache and sleep disturbances. Taper gradually under medical supervision.

OVERDOSAGE

Overdose may cause nausea, vomiting, drowsiness, tachycardia, seizures, arrhythmia or other serious effects. Seek emergency medical attention immediately. No specific antidote is available; treatment is supportive with appropriate monitoring.

STORAGE CONDITIONS

Store according to the temperature and conditions stated on the approved pack. Protect from moisture and keep out of reach of children. Do not use after expiry.

PRESENTATION

Oxamine Tablets 50 mg: pack of 10 tablets.
Oxamine Tablets 100 mg: pack of 10 tablets.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.