ZEELENT CAPSULES

(Fluoxetine 20 mg)

COMPOSITION

Each capsule contains Fluoxetine Hydrochloride equivalent to Fluoxetine 20 mg. Excipients: as per approved formulation.

DESCRIPTION & PHARMACOLOGY

Fluoxetine is a selective serotonin reuptake inhibitor (SSRI) antidepressant. It inhibits neuronal reuptake of serotonin (5-HT) in the central nervous system. Clinical benefit may require several weeks of continuous treatment.

INDICATIONS

Under appropriate prescribing supervision, fluoxetine is indicated for major depressive disorder, obsessive-compulsive disorder (OCD), bulimia nervosa and panic disorder, according to the locally approved product information. In combination with olanzapine, fluoxetine has additional specific indications; fluoxetine alone is not approved for bipolar depression.

DOSAGE & ADMINISTRATION

For adults with major depression, the usual initial dose is 20 mg orally once daily in the morning. For OCD, 20 mg daily is a common starting dose; for panic disorder, a lower 10 mg starting dose is commonly used before increasing to 20 mg. Bulimia nervosa treatment generally requires 60 mg daily. Dose adjustments are made by the prescriber based on indication and response.

ADMINISTRATION GUIDANCE

Swallow capsule with water, with or without food. Take at the same time each day. Do not increase dose or discontinue treatment without medical advice. Lower or less frequent doses may be needed in hepatic impairment, older patients or patients taking interacting medicines.

BOXED WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increase the risk of suicidal thoughts and behaviours in children, adolescents and young adults, especially early in treatment or following dose changes. Monitor for worsening depression, agitation, unusual behavioural changes or suicidal thinking. Seek urgent professional help if these occur.

CONTRAINDICATIONS

Hypersensitivity to fluoxetine or formulation components. Do not use with monoamine oxidase inhibitors (MAOIs), pimozide or thioridazine. Do not start fluoxetine until at least 14 days after stopping an MAOI; wait at least 5 weeks after stopping fluoxetine before starting an MAOI. Avoid use with linezolid or intravenous methylene blue unless specialist protocols apply.

SPECIAL POPULATIONS

Paediatric use is indication- and age-specific; use only as approved and supervised by a specialist. During pregnancy or breastfeeding, assess maternal benefit and infant risk individually with the treating clinician.

WARNINGS & PRECAUTIONS

SEROTONIN SYNDROME: Potentially life-threatening; symptoms include fever, agitation, tremor, muscle rigidity, hyperreflexia, diarrhoea and altered mental status. Seek emergency care. Screen for bipolar disorder before starting therapy; antidepressants can precipitate mania or hypomania.

Use cautiously in patients with seizure disorders, bleeding risk, glaucoma, significant liver disease or a history of low sodium. Hyponatraemia/SIADH, abnormal bleeding, QT prolongation and sexual dysfunction have been reported. Monitor as clinically indicated.

DRUG INTERACTIONS

Other serotonergic agents (e.g., tramadol, triptans, lithium, St John's wort and other antidepressants) increase serotonin-syndrome risk. NSAIDs, aspirin and anticoagulants may increase bleeding risk. Fluoxetine inhibits CYP2D6 and may affect medicines such as some antipsychotics and tricyclic antidepressants. Review all concurrent medicines.

ADVERSE REACTIONS

Common effects include nausea, diarrhoea, insomnia, headache, anxiety, nervousness, tremor, sweating, fatigue and sexual dysfunction. Serious events include suicidal behaviour, serotonin syndrome, seizures, mania, severe allergic reactions and clinically significant bleeding.

MISSED DOSE

Take a missed dose when remembered unless it is close to the next scheduled dose. Skip the missed dose if necessary; do not double the dose. Ask the prescriber if uncertain.

OVERDOSAGE

Overdose can cause nausea, vomiting, agitation, seizures, tachycardia, arrhythmias or altered consciousness. Seek immediate emergency medical care. Management is supportive; no specific antidote is available.

STORAGE CONDITIONS

Store in a dry place at controlled room temperature according to approved product specifications. Protect from excess heat and moisture. Keep out of reach of children. Do not use after expiry.

PRESENTATION

Zeelent Capsules 20 mg: pack of 10 capsules.

PATIENT ADVICE

Take regularly as prescribed; improvement may take several weeks. Attend follow-up appointments. Report new suicidal thoughts, severe restlessness, unusual mood elevation, fever with muscle stiffness or unexplained bleeding promptly. Do not abruptly stop or change treatment without consulting the prescriber.

THERAPEUTIC CLASS

Selective serotonin reuptake inhibitor (SSRI). Primary segment: Psychiatry; secondary: General Practice / Internal Medicine.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.