Nodep

Fluoxetine 20 mg Capsule

Presentation

Nodep : Each capsule contains Fluoxetine 20 mg (as Fluoxetine Hydrochloride BP).

Pharmacodynamic Properties

Fluoxetine is a selective competitive inhibitor of 5HT (serotonin) uptake in the presynaptic cleft and exerts little or no effect on re-uptake mechanisms for norepinephrine, dopamine or acetylcholine. The major metabolite norfluoxetine is similar in efficacy to the parent molecule.

Pharmacokinetic Properties

Fluoxetine is well absorbed from the gastrointestinal tract after oral administration. The bioavailability is not affected by food intake. It is highly protein bound (about 95%). Fluoxetine has a non-linear pharmacokinetic profile with first pass liver effect. Maximum plasma concentration is generally achieved 6 to 8 hours after administration. Fluoxetine is primarily metabolised by the liver to the active metabolite norfluoxetine (demethylfluoxetine), by demethylation. The elimination half-life of fluoxetine is about 4 days (2-7 days) and for norfluoxetine is about 7-9 days (4-15 days). Excretion is mainly (about 65%) via the kidneys.

Indications

The treatment of depressive disorder, particularly where sedation is not required
The treatment of bulimia nervosa
The treatment of obsessive compulsive disorder
Panic disorder
It is also used in combination with olanzapine for treatment of resistant depression and treatment of depression associated with bipolar disorder.

Dosage & Administration

Major depression: 20 mg once daily increased after 3-4 weeks if necessary and at appropriate intervals thereafter, max. 60 mg once daily (elderly usual max. 40 mg once daily but 60 mg can be used); Child (8-18 years) 10 mg once daily increased after 1-2 weeks if necessary, max. 20 mg once daily. Bulimia nervosa: adult (over 18 years) 60 mg once daily. Obsessive-compulsive disorder: Adult (over 18 years) 20 mg once daily; if inadequate response after 2 weeks increase gradually to max. 60 mg once daily (elderly usual max. 40 mg once daily but 60 mg can be used), Panic disorder: 10-60 mg/day. Resistant depression: 20-50 mg of fluoxetine and 5-20 mg olanzapine once daily in the evening. Depression associated with bipolar disorder: 20-50 mg fluoxetine and 5-12.5 mg olanzapine once daily in the evening.

Contraindications

- Monoamine oxide inhibitors
- Severe renal failure
- Hypersensitivity to fluoxetine

  Relative contraindications
- Cardiovascular disorders
- Liver disease
- Diabetic mellitus

Side Effects

Nausea, loss of appetite, diarrhea, dry mouth, trouble sleeping, dizziness, drowsiness, yawning, weakness, or sweating may occur. Serious side effects may occur: unusual or severe mental/mood changes (e.g., anxiety, mania), weight loss, change in sexual desire and ability, vision changes. Some other side effects include (tremor), fever/flu-like symptoms.

Precautions

Patient should take precaution if the patient is allergic to it; liver disease, kidney disease, stomach bleeding, diabetes, seizure disorder. If patient have diabetes, fluoxetine may affect blood glucose levels. Have to monitor blood glucose regularly. The dose of anti-diabetic medications may need to be adjusted. This drug may make patient dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages. Patient should not stop taking this medication without consulting with doctor.

Drug Interactions

Have to avoid taking MAO inhibitors (e.g., furazolidone, isocarboxazid, linezolid, moclobemide, phenelzine, procarbazine, selegiline) with or within 2 weeks of starting fluoxetine or at least 5 weeks after stopping it. Have to avoid taking thioridazine with this medication or within 5 weeks after stopping treatment. This drug should not be used with the following medications because very serious (possibly fatal) interactions may occur: astemizole, terfenadine. Other drugs may interact such as certain anti-anxiety drugs (e.g., alprazolam, diazepam, buspirone), other SSRI anti-depressants (e.g., citalopram, sertraline), tricyclic anti-depressants (e.g., amitriptyline, imipramine), anti-seizure drugs (e.g., carbamazepine, phenytoin), atomoxetine, dextromethorphan, isoniazid, lithium, meperidine, drugs to treat migraines (e.g., ergotamine, triptans), pentazocine, anticoagulants such as heparin or warfarin. Aspirin can increase the risk of bleeding in combination with this medication.

Pregnancy and Lactation

Fluoxetine use is not recommended during pregnancy.
Breast-feeding: Fluoxetine has been shown to pass into human milk. Therefore, breast-feeding is not recommended.

Overdose

Symptoms of overdose may include: persistent nausea/vomiting, fast/abnormal heartbeats, severe drowsiness, seizures, loss of consciousness, severe mental/mood changes.

Missed Dose

If patient miss a dose, have to take as soon as remember. If it is near the time of the next dose, have to skip the missed dose and resume usual dosing schedule. Double the dose is not recommended.

Storage Conditions

Store in a cool and dry place and away from light. Keep all medicines out of the reach of children.

Commercial Pack

Nodep: Each box contains 5 blister packs of 10 Capsules.

Manufactured by :

general **GENERAL** Pharmaceuticals Ltd.
Gazipur, Bangladesh

GENERAL Pharmaceuticals Ltd.
ISO 9001:2008 Certified Company
UKAS QUALITY MANAGEMENT 043