

FLEXIN CAPSULE

Fluoxetine Hydrochloride 20 mg.

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What Flexin is used for

Fluoxetine is used to treat the:

- Symptoms of depression.
- Premenstrual dysphoric disorder (PMDD) - (a condition in which a woman has severe depression symptoms, irritability, and tension before menstruation).
- Obsessive-compulsive disorder (OCD).

How Flexin works

It belongs to the class of drugs known as SSRI (selective serotonin reuptake inhibitor), compounds working by stimulating the activity of certain cells in the brain. It helps for the management of panic disorders, anxiety and related diseases.

Before you use Flexin

When you must not use it

- Hypersensitivity to Fluoxetine.
- Monoamine Oxidase Inhibitors: Cases of serious and sometimes fatal reactions have been reported in patients receiving an SSRI in combination with a monoamine oxidase inhibitor (MAOI).

Before you start to use it

The following should be considered:

Allergies-

Tell your doctor if you have ever had any unusual or allergic reaction to Fluoxetine. Also tell your health care professional if you are allergic to any other substances, such as foods, preservatives, or dyes.

Pregnancy-

Tell your doctor if you are pregnant or if you may become pregnant while you are taking this medicine.

Breast-feeding-

Fluoxetine passes into breast milk. Be sure you have discussed the risks and benefits of this medicine with your doctor.

Children

The use of Flexin in children is not recommended as safety and efficacy have not been established.

Seizures: Seizures are a potential risk with antidepressant drugs.

Mania: Antidepressants should be used with caution in patients with a history of mania/hypomania.

Liver / Kidney function: Fluoxetine is extensively metabolized by the liver and excreted by the kidneys.

Cardiac Disease: Clinical experience in acute cardiac disease is limited, therefore, caution is advisable.

Weight Loss: Weight loss may occur in patients taking Flexin capsules.

Diabetes: In patients with diabetes, dosage may need to be adjusted.

Suicide: patients should be closely monitored

Hemorrhage: There have been reports of cutaneous bleeding abnormalities.

Premenstrual Dysphoric Disorder

(PMDD): The effect of Flexin on PMDD symptoms is usually rapid, with improvement generally occurring during the 1st cycle of treatment, unlike the treatment of depression.

Taking other medicines

Please consult your doctor/pharmacist before taking the below medicines as they may have interaction with Flexin capsule.

Your doctor/pharmacist may have a more detailed list of interactive medicines.

- Monoamine Oxidase Inhibitors
- CNS-Active Medications
- Serotonergic Drugs
- Lithium and Tryptophan
- P450IID6 Isoenzyme.
- Half-Life.
- Plasma Concentrations:
- Warfarin:
- Electroconvulsive Therapy (ECT)
- Alcohol
- St. John's Wort

How to use Flexin

How much to use

For oral administration to adults only.

Depression, With or Without Associated Anxiety Symptoms: Adults and the Elderly: Recommended Dose: 20 mg/day.

Obsessive-Compulsive Disorder: Adults and the Elderly: Recommended Initial Dose: 20 mg/day.

Although there may be an increased potential for side effects at higher doses, a dose increase may be considered after several weeks if there is no response.

Premenstrual Dysphoric Disorder (PMDD):

Recommended Dose: 20 mg/day. Initial treatment should be limited to 6 months, after which patients should be re-assessed regarding the benefit of continued therapy.

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All Indications: The recommended dose may be increased or decreased. Doses >80 mg/day have not been systematically evaluated.

A lower or less frequent dose should be considered in patients with liver impairment, concurrent diseases, or who are taking multiple medications.

When to use it

Once daily, maybe administered with or without food.

This is only recommendation, for actual dosage please always refer to your doctor or pharmacists

How long to use it

Follow doctor's advice .

If you forget to use it

Take the missed dose as soon as possible as you remember it. However if it is almost time for the next dose ,skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one

If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Taking too many tablets may cause nausea, vomiting, seizures and signs of central nervous system excitation.

While you are using it

Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Flexin.

- Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

- Do not stop taking without consulting doctor first.
- Do not give your medicine to others who may be experiencing the same symptoms as you.

Things to be careful of

Effects on the Ability to Drive or Operate Machinery

This medicine may affect your ability to drive or use machines. Avoid driving a car or operating hazardous machinery until you are reasonably certain that your performance is not affected

Side Effects

Like all medicines, Flexin capsule can cause side effects, although not everybody gets them.

Among the side effects are rash, diarrhoea, nausea, vomiting ,headache, sleep abnormalities.

Visit your doctor or pharmacist immediately if you experience any side effects even if they are not listed here, after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of Flexin

Storage

Store below 25°C.Protect from light & moisture and KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

Disposal

Medicines should not be disposed of via waste water or household waste.

These measures will help you to protect the environment.

Ask your pharmacist how to dispose of medicines no longer required.

Products Description

How it looks like

Caramel Pink / Caramel Pink coloured, size '3' hard gelatin capsule.

Ingredients:

Active ingredient use is Fluoxetine Hydrochloride and inactive ingredients used are colloidal silicon dioxide, corn starch,lactose,magnesium stearate and microcrystalline cellulose

MAL Number.: MAL06041463A

Manufacturer and product registration holder

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