



Fluoxetine belongs to a group of medicines known as selective serotonin reuptake inhibitors (SSRIs).

Fluoxetine is an antidepressant that influences the central nervous system.

USES:

Major depressive episodes.

${\bf Obsessisve\text{-}compulsive\ disorder.}$

Bulimia nervosa (compulsive eating).

Your doctor may have prescribed this medicine for a different purpose and/or different dosage from that given in the package leaflet. You must always follow the doctor's prescription and the instructions given on the label of the pack.

PRECAUTIONS:

Do not take Fluoxetine tablets.

If you have had any allergy reaction to fluoxetine or to any of the other ingredients in the product.

If you are taking a medicine to treat depression, known as non-selective monoamine oxidase inhibitors (MAOIs), since serious or even fatal reactions can occur.

Treatment with Fluoxetine should only be started 2 weeks after discontinuation of an irreversible MAOI (for example isocarbaxazide, phenelzine and selegiline).

However, treatment with Fluoxetine can be started the following day after dicontinuation of certain reversible MAOIs (for example moclobemide). Do not take any MAOIs for at least 5 weeks after you stop taking fluoxetine. If fluoxetine has been prescribed for a long period and/or at high dose, a longer interval needs to be considered by your doctor.

Take special care with Fluoxetine Tablet.

If you have diabetes Fluoxetine Tablet can raise or lower your blood sugar. The dose of your insulin or the antidiabetes medicine that you take by mouth may need to be adjusted.

If you have started having fits (seizures) or have epilepsy which is under control.

If you have reduced liver, kidney or heart function or have recently had heart attack you must tell your doctor, because it may be necessary to prescribe a lower dose for you.

If you have or have had mania.

If you start to lose weight.

If you get an allergic reaction such as itching, rash or swelling of the face, treatment with Fluoxetine Tablet 20mg must be stopped. If you have tendency to bleed.

If you are taking a herbal preparation containing St. John's Wort (taking a hypericum perforatum).

If you are receiving electric shock treatment.

Thoughts of suicide and worsening of your depression or anxiety disorder.

If you are depressed and/or have anxiety disorders you can somtimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

YOU MAY BE MORE LIKELY TO THINK LIKE THIS:

If you have previously had thoughts about killing or harming yourself.

If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behavior in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder and ask them to read this leaflet. You might ask them to tell you if they think that by taking Fluoxetine Tablet your depression or anxiety is getting worse, or if they are worried about changes in your behavior.

USE IN CHILDREN AND ADOLESCENTS UNDER 18 YEARS OF AGE :

Fluoxetine should normally not be used for children and adolescents under 18 years. Patients under 18 have an increased risk of side effects, such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behavior and anger) when they take this class of medicines.

Despite this, your doctor may prescribe fluoxetine for patients under 18 because he/she decides that this is in their best interests.

If your doctor has prescribed fluoxetine for patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms listed above develop or worsen when patient under 18 are taking fluoxetine. Also, the long-term safety effects concerning growth, maturation and congitive and behavioral development of fluoxetine in this age group have not yet been demostrated.

CONTRA INDICATIONS:

Certain other medicines can affect or be affected by Fluoxetine. Some of these medicines are :

Certain MAO-inhibitors (used to treat depression). Non-selective MAO-inhibitors (e.g. phenelzine) and MAO-inhibitors type A (e.g. moclobemide) must not be used with Fluoxetine Tablets as serious or even fatal reaction (serotonin syndrome) can occur. Some MAO-inhibitors type B (selegeline) can be used with Fluoxetine Tablets provided that your doctor monitors you closely. It is especially important that you ask your doctor for advice if you are taking medicine ti thin the blood (Warfarin) other medicines for depression (e.g. tricyclic antidepressants), or medicines containing tryptophan or lithium medicine for epilepsy (e.g. phenytoin or carbamzepine) pain-relieving medicines containing tramadol a natural remedy containing St. John's Wort (Hypericum perforatum) medicines containing flecainide or encainide (for irregular heart rhythm. Please tell your doctor or pharmacist. If you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Fluoretine Tablet with food and drink food :

The tablet may be taken with or between meals.

ALCOHOL :

The combination of Fluoxetine Tablet and alcohol is not recommended. Pregnancy, breast feeding and fertility. Always ask your doctor or pharmacist for advice before taking Fluoxetine Tablet. Pregnancy talk to your doctor as soon as possible if you're pregnant, If you might be pregnant, or if you are planning to become pregnant. In babies whose mothers took fluoxetine during the first few months of pregnancy, there have been some reports showing an increased risk of birth defects, in particular those affecting the heart. In the general population, about 1 in 100 babies are born with a heart defect. This increased to about 2 in 100 babies in mother who took fluoxetine. You and your doctor may decide that it is better for you to gradually stop taking fluoxetine while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking fluoxetine. Make sure your midwife and/or doctor know you are taking fluoxetine. When taken during pregnancy particularly in the last 3 months of pregnancy, medicines like fluoxetine may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the new born (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happened to your baby you should contact to your midwife and/or doctor immediately. Additional caution should be exercised especially during late pregnancy or just before giving birth since the following effects have been reported in new born children: irritability, tremor, muscle weakness, persistant crying and difficulty in suckling or in sleeping.

BREAST-FEEDING :

Fluoxetine is excreted in breast milk and can cause side effects. You should only breast-feed if it is clearly necessary. If breast-feeding is continued, your doctor may prescribe a lower dose of fluoxetine.

FERTILITY :

Fluoxetine has been shown to reduce the quality of sperm in animal studies. Theoratically, this could affect fertility, an impact on human fertility has not been observed as yet. Ask your doctor or pharmacist for advice before taking any medicine.

DRIVING AND USING MACHINES :

Fluoxetine can impair judgement, thinking capacity and motor skills. This should be taken into account in situations where increased alertness is necessary, e.g. when driving or operating hazardous machinery.

DOSAGE:

Always take fluoxetine tablet exactly as your doctor has advised you. You should check with your doctor or pharmacist if you are not sure. Take Fluoxetine Tablet with water.

The usual dose is:

DEPRESSION:

1 Tablet daily (20mg) obsessive thoughts and obsessive actions (OCD): Between 1 and 3 tablets daily (20-60mg)

BULIMIA:

3 tablets daily (60mg). If you take more Fluoxetine tablet than you should. When you have taken too much Fluoxetine than you should contact your doctor or a hospital. Symptoms of overdose: Nausea, vomiting, seizures, anxiety, restlessness and excessive Cheerfulness. If you forget to take Fluoxetine Tablet 20mg. Do not take a double dose to make up for a forgotten dose. If you stop taking Fluoxetine Tablet 20mg. Do not discontinue the treatment without consulting your doctor. When you stop taking Fluoxetine Tablet 20mg, withdrawl reactions, e.g. headache, nausea, anxiety and dizziness, can occur. These disorders are mild and temporary. When stopping treatment with Fluoxetine Tablet 20mg, your doctor will help you to reduce the dose slowly over one or two weeks in order to reduce the risk of withdrawl reactions. If you have any further questions on the use of this product, ask your doctor or pharmacist.

POSSIBLE SIDE EFFECTS:

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

BODY AS A WHOLE: Rash or allergic reaction, chills, sensitivity to sunlight, weight loss.

DIGESTIVE SYSTEM: Diarrhoea, nausea, vomiting, indigestion, difficulty swallowing or a change in taste, dry mouth, abnormal liver function tests have been reported rarely with very rare cases of hepatitis.

NERVOUS SYSTEM: Headache, sleep problem or unusual dreams, dizziness, loss of appetite, tiredness, abnormally high mood, uncontrolled movement, fits, extreme restlessness, hallucinations, untypical wild behaviors, confusion, agitation, anxiety, nervousness, not being able to concentrate or think properly, panic attacks, thoughts of suicide or harming yourself.

UROGENITAL SYSTEM: Difficulty passing urine or passing urine too frequently.

REPRODUCTIVE DISORDER: Poor sexual performance, prolonged erections, producing breast milk.

RESPIRATORY SYSTEM: Sore throat, shortness of breath. Lungs problems (including inflammatory processes of varying histopathology and/or fibrosis) have been reported rarely.

OTHER: Hair loss, yawning, blurred vision, unexplained bruising or bleeding, sweating, hot flushes, feeling dizzy when you stand up, joint or muscle pain, low levels of sodium in the blood. An increased risk of bone fractures has been observed in patients taking this type of medicine. **STORAGE:** Keep out of the reach and sight of children. Use by date do not use fluoxetine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Store at room temperature.

DISPOSAL :

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

FURTHER INFORMATION:

FLUOXETINE TABLETS CONTAIN:

The active substance is fluoxetine.

The other ingredients are Magnesium Stearate, Lactose, Starch, Sodium Starch Glycolate. Talcum. PVPK-30.

CONTENTS OF THE PACK FLOSTIN:

Tablets are blue round biconvax marked PH between two lines on one side.

AVAILABILITY:

The tablets are available in blister pack of 10's.

دھوپ، کری اوری سے تھوظ ریس تمام ادویات بچوں کی پہنچ سے دور رکھیر ڈاکٹر کی ہدایت کے مطابق استعمال کر ہ

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(pharmedic)
Manufactured by:

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