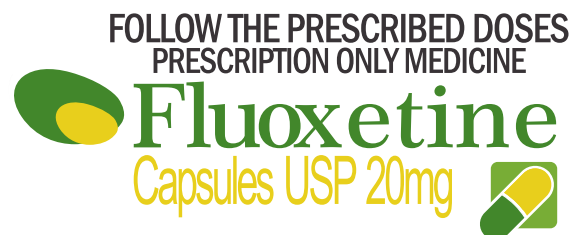


PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION



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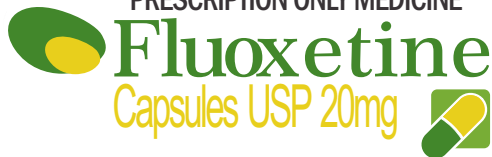
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**FOLLOW THE PRESCRIBED DOSES
PRESCRIPTION ONLY MEDICINE**



Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

• If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the leaflet.

See section 4.

Eight important things you need to know about Fluoxetine capsules

- Fluoxetine capsules treats depression and anxiety disorders.
- Like all medicines it can have unwanted effects. It is therefore important that you and your doctor weigh up the benefits of treatment against the possible unwanted effects, before starting treatment.

• Fluoxetine capsules is not for use in children and adolescents under 18. See section 2, Use in children and adolescents aged 8 to 18 years.

• Fluoxetine capsules won't work straight away. Some people taking antidepressants feel worse before feeling better. Your doctor

should ask to see you again a couple of weeks after you first start treatment. Tell your doctor if you haven't started feeling better.

See

section 3, How to take.

• Some people who are depressed or anxious think of harming or killing themselves. If you start to feel worse, or think of harming or killing yourself, see your doctor or go to a hospital straight away.

See section 2.

• Don't stop taking Fluoxetine capsules without talking to your doctor. If you stop taking Fluoxetine capsules suddenly or miss a dose, you may get withdrawal effects. See section 3 for further information.

• If you feel restless and feel like you can't sit or stand still, tell your doctor. Increasing the dose of Fluoxetine capsules may make these feelings worse. See section 4, Possible sideeffects.

Fluoxetine 20mg capsules (fluoxetine hydrochloride)

What is in this leaflet

- 1 What Fluoxetine capsules are and what they are used for**
- 2 What you need to know before you take Fluoxetine Capsules**
- 3 How to take Fluoxetine Capsules**
- 4 Possible side effects**
- 5 How to store Fluoxetine Capsules**
- 6 Contents of the pack and other information**

1. What Fluoxetine capsules are and what they are used for

Fluoxetine capsules belongs to a group of medicines called antidepressants that will relieve the symptoms of depression. It may also be used to treat the eating disorder bulimia nervosa and the condition obsessive-compulsive disorder.

2 What you need to know before you

take Fluoxetine Capsules

Do not take Fluoxetine capsules if you:

- are allergic to this medicine or any of the other ingredients (listed in section 6).
- are taking, or have taken within the last two weeks any monoamine oxidase inhibitors (MAOIs). MAOIs include phenelzine, tranylcypromine, isocarboxazid and iproniazid.

• are taking metoprolol for heart failure

Warnings and precautions

Talk to your doctor, pharmacist or nurse before

taking Fluoxetine Capsules if you:

- suffer from epilepsy or if you have had a fit in the past. Fluoxetine may increase the likelihood of an epileptic fit. If after taking Fluoxetine capsules, you develop a fit for the first time or get more fits than usual, seek medical advice from your doctor.
- have a history of mental illness known as mania or hypomania.
- suffer from heart, kidney or liver problems.
- have glaucoma (increased pressure in the eye)
- suffer from diabetes. Fluoxetine capsules may alter your blood sugar levels. Your doctor may need to alter the dose of your insulin or other diabetes control medicine.
- have a history of bleeding disorders or develop unexpected bruising, reddening under the skin or bleeding from any other part of the body.
- are having Electroconvulsive Therapy (ECT).

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes 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.

3. How to take Fluoxetine Capsules

Always take this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

You are advised not to drink alcohol with this medicine.

Swallow the capsule whole with a drink of water.

Fluoxetine capsules may be taken as a single or separate doses, during or between meals.

Doses: Adults:

- Depression: the recommended dose is one

capsule a day. Maximum daily dose should not exceed 60mg (3 capsules) a day.

- Bulimia: the recommended dose is 60mg (3 capsules) a day.
- Obsessive-compulsive disorder: the recommended dose is one capsule a day.

Maximum daily dose should not exceed 60mg (3 capsules) a day.

If you suffer from kidney or liver problems or are

elderly, your doctor may prescribe a different dose.

Children and adolescents aged 8 to 18 years with depression:

Treatment should be started and be supervised by a specialist.

The recommended starting dose is 10mg a day (given as 2.5ml

of Fluoxetine oral liquid). After 1 to 2 weeks, your doctor may

increase the dose to 20mg a day. The dose should be increased

carefully

to ensure that you receive the lowest effective dose.

Lower weight children may need lower doses. If there is a

satisfactory response to treatment, your doctor will review the

need for continuing treatment beyond 6 months. If you have not

improved within 9 weeks, your doctor will reassess your

treatment.

Fluoxetine may not make you feel any better for the first 2 weeks

or more. It should be taken for as long as your doctor tells you to.

If you take more Fluoxetine Capsules than you should

If you (or someone else) swallow a lot of capsules at the same

time, or you think a child may have swallowed any, contact your

nearest

hospital casualty department or tell your doctor immediately.

Signs of an overdose include feeling sick, being sick, seizures,

heart problems, lung problems, and signs of altered Central

Nervous

System status ranging from excitation to coma.

If you forget to take the Fluoxetine Capsules

Do not take a double dose to make up for a forgotten dose. If you

forget to take a dose take it as soon as you remember it and then

take the next dose at the right time.

If you stop taking the Fluoxetine Capsules

If you stop taking the capsules abruptly you may rarely develop

dizziness, feeling or being sick, pins and needles, insomnia,

intense dreams, weakness or loss of strength, agitation, tremor

(involuntary

shakiness), headache, anxiety, fits and heart problems. In most

cases, these symptoms are mild and short-lived. Talk to your

doctor before you stop taking the capsules and follow their

advice. Your

doctor may reduce your dose gradually at the end of treatment,

though this is often not necessary.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away (see Section 2).
- If you get a rash or allergic reaction such as itching, swollen lips/tongue or wheezing/ shortness of breath, rapid swelling of the tissue around the neck, face, mouth and/or throat, stop taking the capsules straight away and tell your doctor immediately.
- If you feel restless and cannot sit or stand still, you may have akathisia; increasing your dose of Fluoxetine may make you feel worse. If you feel like this, contact your doctor.
- Tell your doctor immediately if you have widespread skin rash –

circular, irregular red patches on the skin of the hands and arms (Erythema Multiforme), Severe form of skin rash with flushing, fever, blisters or ulcers (Stevens- Johnson Syndrome), Severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (Toxic Epidermal Necrolysis). This is rare. Bleeding from stomach or intestines e.g. black tarry stools, unexplained bleeding or bruising, fever, sore throat, tiredness which can be signs of decreased blood counts, hepatitis (inflammation of the liver causing yellowing of the skin or eyes or tiredness, pain in abdomen, joint or muscles) and signs such as jaundice yellowing of the whites of the eyes and skin, ringing or buzzing in the ears (tinnitus). Some patients have had:

- a combination of symptoms (known as "serotonin syndrome") including unexplained fever with faster breathing or heart rate, sweating, muscle stiffness or tremor, confusion, extreme agitation or sleepiness (only rarely);
- feelings of weakness, drowsiness or confusion mostly in elderly people and in (elderly) people taking diuretics (water tablets);
- prolonged and painful erection;
- irritability and extreme agitation.

If you have any of the above side effects, you should tell your doctor immediately.

Tell your doctor if you notice any of the following

side effects or notice any other effects not listed:

Very common (may affect more than 1 in 10 people)

- insomnia
- headache
- diarrhoea, feeling sick (nausea)
- fatigue

Common (may affect up to 1 in 10 people)

- not feeling hungry, weight loss
- nervousness, anxiety
- restlessness, poor concentration
- feeling tense
- decreased sex drive or sexual problems (including difficulty maintaining an erection for sexual activity)
- sleep problems, unusual dreams, tiredness or sleepiness
- dizziness
- change in taste
- uncontrollable shaking movements
- blurred vision
- rapid and irregular heartbeat sensations
- flushing
- yawning
- indigestion, being sick
- dry mouth

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 behaviour in young adults (less than 25 years old) 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 your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Use in children and adolescents aged 8 to 18 years: Patients under 18 have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines. Fluoxetine should only be used in children and adolescents aged 8 to 18 years for the treatment of moderate to severe major depressive episodes (in combination with psychological therapy) and it should not be used to treat other conditions. Additionally, only limited information concerning the long-term safety of Fluoxetine on growth, puberty, mental, emotional and behavioural development in this age group is available. Despite this, and if you are a patient under 18, your doctor may prescribe Fluoxetine for moderate to severe major depressive episodes, in combination with psychological therapy, because he/she decides that this is in your best interests. If your doctor has prescribed Fluoxetine for a 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

patients under 18 are taking Fluoxetine. Fluoxetine should not be used in the treatment of children under the age of 8 years.

Other medicines and Fluoxetine Capsules

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. Especially

- lithium, pimozide, haloperidol or phenothiazines (e.g. chlorpromazine) for mental illness.
- sparfloxacin, moxifloxacin, erythromycin IV, pentamidine (antibiotics, used to treat infections)
- halofantrine (used for anti-malaria treatment)
- iproniazid, linezolid and methylthionium chloride (methylene blue) (non-selective MAOI's – monoamine oxidase inhibitors)
- metoprolol (used for heart failure)
- nebivolol (used to treat high blood pressure)
- propafenone (used to treat abnormal heart rhythms)
- atomoxetine (used to treat attention deficit hyperactivity disorder (ADHD))
- risperidone (used to treat psychotic disorders)
- diuretics (water tablets)
- desmopressin (used to reduce amount urine produced by kidneys)
- oxcarbazepine (used to treat epilepsy)
- mefloquine, chloroquine (anti-malaria)
- astemizole, mizolastine, mequitazine, cyproheptadine (anti-histamines)
- flecainide or encainide for the heart.
- carbamazepine or phenytoin for epilepsy or other conditions.
- any other medicines for depression e.g. tricyclic anti-depressants, SSRI's (selective serotonin reuptake inhibitor).
- selegiline for Parkinson's disease.
- tramadol for pain relief.
- bupropion (used to help stop smoking)
- triptans (e.g. sumatriptan) for migraine or cluster headaches.
- medicines to thin the blood (e.g. warfarin).

- non-steroidal anti-inflammatory drugs (NSAIDs, e.g. ibuprofen).
- aspirin (for pain relief).
- tryptophan (an amino acid).
- tamoxifen (used to treat breast cancer).
- the herbal remedy St John's Wort (Hypericum perforatum).

This should not be taken at the same time as Fluoxetine capsules. Stop taking the St John's wort and mention it to your doctor at your next visit.

Fluoxetine capsules with food, drink and alcohol

- You can take Fluoxetine capsules with or without food, whatever you prefer.
- You should avoid alcohol while you are taking this medicine. Pregnancy, breast-feeding and fertility If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine. 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 newborn (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 happens to your baby you should contact your midwife and/or doctor immediately.

Caution should be exercised when used during pregnancy, especially during late pregnancy or just before giving birth, the following side effects have been reported in newborn children; irritability, tremor, muscle weakness, persistent crying and difficulty in breastfeeding or sleeping.

Talk to your doctor as soon as possible if you're pregnant, if you might be pregnant, or if you're planning to become pregnant. In babies whose mothers took fluoxetine during the first few months of pregnancy, there have been some reports suggesting an increased risk of birth defects 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 mothers 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. Breast-feeding is not recommended whilst taking fluoxetine.

Fluoxetine has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet. Driving and using machines Antidepressants can affect your judgement or coordination.

Do not drive or use machinery unless you are sure that you are not affected.

- rash, urticaria, itching
- excessive sweating
- joint pain
- passing urine more frequently
- unexplained vaginal bleeding
- feeling shaky or chills

Uncommon (may affect up to 1 in 100 people)

- feeling detached from yourself

- strange thinking
- abnormally high mood
- orgasm problems
- teeth grinding
- muscle twitching, involuntary movements or problems with balance or co-ordination
- enlarged (dilated) pupils
- low blood pressure
- shortness of breath
- difficulty swallowing
- hair loss
- increased tendency to bruising
- cold sweat
- difficulty passing urine
- feeling hot or cold
- feeling general discomfort or illness
- feeling abnormal
- memory problems
- nose bleeds
- sexual problems

Rare (may affect up to 1 in 1,000 people)

- low levels of salt in the blood
- untypical wild behaviour
- hallucinations (sensing (seeing, hearing or feeling) things that are not there)
- agitation
- panic attacks
- fits
- vasculitis (inflammation of a blood vessel)
- vasodilation (widening of the blood vessels)
- pain in the tube that takes food or water to your stomach
- sensitivity to sunlight
- sore throat
- over producing breast milk
- rash, fever, joint pain, enlarged lymph nodes (serum sickness)
- blood spots, bruising and discolouring to skin (purpura)
- confusion
- speech problems
- aggression
- reduced platelets in the blood, abnormal decrease in number of neutrophils in the blood, reduced white blood cells, high level of prolactin in the blood (as seen in blood tests)
- syndrome of inappropriate high secretion of antidiuretic hormone (SIADH) confusion hallucinations, drowsiness, fits, coma, difficulty breathing
- life threatening irregular heartbeat
- lung problems
- bruising
- muscle pain
- problems urinating
- elation or over excited mood
- bleeding from the mucous membranes such as eyes, mouth, anus

Not known (frequency cannot be estimated from the available data)

- headache
- abnormal liver function tests

Bone fractures - an increased risk of bone fractures has been

observed in patients taking this type of medicines. If you have any of the symptoms listed and they bother you, or last for some time, tell your doctor or a pharmacist. Most of these side effects are likely to disappear with continued treatment.

Additional side effects in children and adolescents: In children and adolescents (8-18 years) – In addition to the possible side effects listed above, Fluoxetine may slow growth or possibly delay sexual maturity. Nose bleeds were also commonly reported in children.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fluoxetine Capsules

Keep out of the sight and reach of children.

Do not store above 25°C

Do not use this medicine after the expiry date which is stated on the label/carton/bottle. The expiry date refers to the last day of that month.

DO NOT THROW AWAY ANY MEDICINE VIA WASTEWATER OR HOUSEHOLD WASTE. ASK YOUR PHARMACIST HOW TO DISPOSE OF MEDICINES NO LONGER USE. THESE MEASURES WILL HELP PROTECT THE ENVIRONMENT.

6. Contents of the pack and other information

What Fluoxetine capsules contain

- The active substance is 20mg fluoxetine as fluoxetine hydrochloride.
 - The other ingredients are pregelatinised maize starch, anhydrous colloidal silica, magnesium stearate and talc. The capsule shell contains: E104, E127, E132, E171 and gelatin. The printing ink contains: shellac glaze and iron oxide black (E172) and propylene glycol.
- What Fluoxetine capsules look like and contents of the pack
Fluoxetine capsules are hard gelatine capsules, light green cap and yellow body.

Pack sizes are 30 capsules & 500 Capsules.

Manufactured in India by:
TAJ PHARMACEUTICALS LTD.
Mumbai, India
Unit no 214.Old Bake house,
Maharashtra chambers of commerce lane,
Fort, Mumbai - 400001
at : Ahmedabad-382213, Gujarat, INDIA.
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This leaflet was last revised in April 2019.
Not all pack sizes may be marketed.

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