

PACKAGE LEAFLET: INFORMATION FOR THE USER

FLUSETIN

20 mg film-coated tablets

FLUOXETINE HYDROCHLORIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 or pharmacist • 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 or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

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1. WHAT FLUSETIN TABLET IS AND WHAT IT IS USED FOR

Fluoxetine belongs to a group of medicines called selective serotonin reuptake inhibitor (SSRI) antidepressants.

This medicine is used to treat the following conditions:

Adults:

- Major depressive episodes
- Obsessive-compulsive disorder (is a mental disorder most commonly characterized by intrusive, repetitive thoughts resulting in compulsive behaviours and mental acts that the person feels driven to perform).
- Bulimia nervosa (eating disorder): Fluoxetine 20 mg Tablet is used alongside psychotherapy for the reduction of binge-eating and purging (for example by making themselves vomit, by taking laxatives to get rid of the calories they have eaten).

Children and adolescents aged 8 years and above:

- Moderate to severe major depressive disorder: If the depression does not respond to psychological therapy after 4-6 sessions, Fluoxetine 20 mg Tablet should be offered to a child or young person with moderate to severe major depressive disorder only in combination with psychological therapy.

How Flusetin tablet works

Everyone has a substance called serotonin in their brain. People who are depressed or have obsessive-compulsive disorder or bulimia nervosa have lower levels of serotonin than others. It is not fully understood how Fluoxetine tablet and other SSRIs work but they may help by increasing the level of serotonin in the brain.

Treating these conditions is important to help you get better. If it's not treated, your condition may not go away and may become more serious and more difficult to treat.

You may need to be treated for a few weeks or months to ensure that you are free from symptoms.

2. What you need to know before you take Flusetin tablets***Do not take Flusetin tablets if you are:***

- allergic (hypersensitive) to fluoxetine or any of the other ingredients of Flusetin tablets. If you develop a rash or other allergic reactions (like itching, swollen lips or face or shortness of breath), stop taking the tablets straight away and contact your doctor immediately.
- taking other medicines used to treat depression, known as irreversible, non-selective monoamine oxidase inhibitors (MAOIs) or reversible monoamine oxidase inhibitors type A (MAOIs), since serious or even fatal reactions can occur. Examples of MAOIs include medicines used to treat depression such as nialamide, iproniazid, moclobemide, phenelzine, tranylcypromine, isocarboxazid, tolloxatone and also linezolid (an antibiotic) and methylthioninium chloride also called methylene blue (used to treat high levels of methaemoglobin in the blood).

Treatment with Flusetin tablets should only be started 2 weeks after discontinuation of an irreversible non-selective MAOI (for instance tranylcypromine).

However, treatment with fluoxetine can be started the following day after discontinuation of certain reversible MAOIs (for instance moclobemide)

Do not take any irreversible, non-selective MAOIs for at least 5 weeks after you stop taking Flusetin tablets. If Flusetin tablets has been prescribed for a long period and/or at a high dose, a longer interval needs to be considered by your doctor.

- Taking metoprolol (to treat heart failure) since there is an increased risk of your heart beat becoming too slow.

Warnings and precautions

Tell your doctor if any of the following applies to you:

- have epilepsy or fits (seizures) or experience an increase in seizure frequency, contact your doctor immediately; Flusetin tablets might need to be discontinued.
- mania now or in the past; if you have a manic episode, contact your doctor immediately because Flusetin tablets might need to be discontinued.
- diabetes (your doctor may need to adjust your dose of insulin or other antidiabetic treatment)
- liver problems (your doctor may need to adjust your dosage)
- heart problems
- low resting heart-rate and/or if you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets);

- glaucoma (increased pressure in the eye);
- ongoing treatment with diuretics (water tablets), especially if you are elderly
- ongoing ECT (electro-convulsive therapy) treatment
- history of bleeding disorders or you develop bruises or unusual bleeding
- ongoing treatment with medicines that thin the blood (see 'other medicines and Flusetin tablets')
- ongoing treatment with tamoxifen (used to treat breast cancer) (see 'other medicines and Flusetin tablets');
- starting to feel restless and cannot sit or stand still (akathisia). Increasing your dose of

Flusetin tablets may make this worse;

- appearance of fever, muscle stiffness or tremor, changes in your mental state like confusion, irritability and extreme agitation; you may suffer from the so-called "serotonin syndrome" or "neuroleptic malignant syndrome". Although this syndrome occurs rarely it may result in potentially life threatening conditions; contact your doctor immediately, Flusetin tablets might need to be discontinued.

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.

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 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 your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

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.
- Flusetin tablet 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 Flusetin tablets on growth, puberty, mental, emotional and behavioural development in this age group is available. Despite this, your doctor may prescribe Fluoxetine Tablet for patients under 18 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 Flusetin tablets 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 Flusetin tablets.

Flusetin tablets should not be used in the treatment of children under the age of 8 years.

Other medicines and Flusetin tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, (up to 5 weeks ago) including medicines obtained without a prescription.

Do not take Flusetin tablets with:

- Certain irreversible, non-selective monoamine oxidase inhibitors MAO-inhibitors (used to treat depression). Irreversible, Non-selective MAO-inhibitors and MAO-inhibitors type A (moclobemide) must not be used with Flusetin tablets as serious or even fatal reactions (serotonin syndrome) can occur (see section “Do not take Flusetin tablets”). Treatment with Flusetin tablets should only be started at least 2 weeks after discontinuation of an irreversible MAOI (for instance tranylcypromine). Do not take any irreversible, non-selective MAOIs for at least 5 weeks after you stop taking Flusetin tablets. If Flusetin tablets has been prescribed for a long period and/or at a high dose, a longer interval than 5 weeks may need to be considered by your doctor.
- metoprolol when used for heart failure; there is an increased risk of your heart beat becoming too slow.

Flusetin tablets may affect the way following medicines work (interaction)

- lithium, selegiline, St. John's wort, tramadol (a pain killer), triptans (for migraine) and tryptophan (used to treat mental illness): there is an increased risk of serotonin syndrome when these drugs are taken with Flusetin tablets. Your doctor will carry out more frequent check-ups.
- monoamine oxidase inhibitors A (MAOI-A) including moclobemide, linezolid (an antibiotic) and methylthioninium chloride also called methylene blue (used to treat high levels of methaemoglobin in the blood): due to the risk of serious or even fatal reactions (called serotonin syndrome). Treatment with fluoxetine can be started the day after stopping treatment with reversible MAOIs but the doctor may wish to monitor you carefully and use a lower dose of the MAOI-A drug. However, treatment with fluoxetine can be started the following day after discontinuation of certain reversible MAOIs (for instance moclobemide, linezolid, methylthioninium chloride (methylene blue)). Some MAO-inhibitors type B (selegiline) can be used with Flusetin tablets provided that your doctor monitors you closely.
- mequitazine (for allergies); because taking this drug with Fluoxetine Tablets may increase the risk of changes in the electrical activity of the heart.
- phenytoin (for epilepsy): because Flusetin tablets may influence the blood levels of this drug, your doctor may need to introduce phenytoin more carefully and carry out check-ups when given with Flusetin tablets.
- tramadol (a painkiller) or triptans (for migraine); there is an increased risk of hypertension (raised blood pressure).
- medicines that may affect the heart's rhythm, e.g. Class IA and III antiarrhythmics, antipsychotics (e.g. fentiazine derivatives, phenothiazine derivatives pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine), anti-malaria treatment particularly halofantrine, certain antihistamines (astemizole, mizolastine). Taking one or more of these drugs with Flusetin tablets may increase the risk of changes in the electrical activity of the heart.
- Flecainide, propafenone, nebivolol or encainide (for heart problems), carbamazepine (for epilepsy), atomoxetine tricyclic antidepressants (for example imipramine, desipramine and amitriptyline or risperidone for schizophrenia); because Flusetin tablets may possibly change the blood levels of these medicines, your doctor may need to lower their dose when administered with Flusetin tablet.
- tamoxifen (used to treat breast cancer), because Flusetin tablets may change the blood levels of this drug and a reduction of the effect of tamoxifen cannot be excluded, your doctor may need to consider different antidepressant treatments.
- Anti-coagulants such as Warfarin, NSAID (such as ibuprofen, diclofenac) or aspirin and other medicines used to thin the blood (including clozapine, used to treat certain mental disorders); Flusetin tablets may alter the effect of these medicines on the blood. If Flusetin tablets treatment is started or

stopped when you are taking warfarin, your doctor will need to perform certain tests, adjust your dose and check on you more frequently.

- cyproheptadine (for allergies); because it may reduce the effect of Flusetin tablets.
- drugs that lower sodium levels in the blood (including, drug that causes increase in urination, desmopressin, carbamazepine and oxcarbazepine); because these drugs may increase the risk of sodium levels in the blood becoming too low when taken with Flusetin tablets.
- anti-depressants such as tricyclic anti-depressants, other selective serotonin reuptake inhibitors (SSRIs) or bupropion, mefloquine or chloroquine (used to treat malaria), tramadol (used to treat severe pain) or anti-psychotics such as phenothiazines or butyrophenones; because Flusetin tablets may increase the risk of seizures when taken with these medicines.
- You should not start to take the herbal remedy St John's wort while you are being treated with Flusetin tablets since this may result in an increase in side effects. If you are already taking St John's wort when you start on Flusetin tablets, stop taking St John's wort and tell your doctor at your next visit.

Flusetin tablet with food, drink and alcohol

- You can take this medicine with or without food, whatever you prefer.
- You are advised NOT to drink alcohol with 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 or pharmacist for advice before taking this medicine.

Pregnancy

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.

Make sure your midwife and/or doctor know you are on Flusetin tablets. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Flusetin tablets 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 happens to your baby you should contact your midwife and/or doctor immediately.

In babies whose mothers took Flusetin tablets 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 mothers who took Flusetin tablets. You and your doctor may decide that it is better for you to gradually stop taking Flusetin tablets while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking Flusetin tablets.

Caution should be exercised when used during pregnancy, especially during late pregnancy or just before giving birth since the following effects have been reported in new born children: irritability, tremor, muscle weakness, persistent crying, and difficulty in sucking or in sleeping.

Breast-feeding:

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

Ask your doctor or pharmacist for advice before taking any medicine.

Fertility

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:

Your medicine can affect your judgement or co-ordination. Do not drive or use machinery without advice from your doctor or pharmacist.

3. HOW TO TAKE FLUSETIN TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Do not take more tablets than your doctor tells you.

Swallow the tablets with a drink of water. Do not chew the tablets.

Adults:

The recommended dose is:

- Depression: The recommended dose is 1 tablet (20 mg) daily. Your doctor will review and adjust your dosage if necessary within 3 to 4 weeks of the start of treatment. If required, the dosage can be gradually increased up to a maximum of 3 tablets (60 mg) daily. The dose should be increased carefully to ensure that you receive the lowest effective dose. You may not feel better immediately when you first start taking your medicine for depression. This is usual because an improvement in depressive symptoms may not occur until after the first few weeks. Patients with depression should be treated for at least 6 months.
- Bulimia nervosa: The recommended dose is 3 tablets (60 mg) daily.
- Obsessive Compulsive Disorder: The recommended dose is 1 tablet (20 mg) daily. Your doctor will review and adjust your dosage if necessary after 2 weeks of treatment. If required, the dosage can be gradually increased up to a maximum of 3 tablets (60 mg) daily. If no improvement is noted within 10 weeks, your doctor will reconsider your treatment.

Children and adolescents aged 8 to 18 years with depression:

Treatment should be started and be supervised by a specialist. The starting dose is 10mg/day

After 1 to 2 weeks, your doctor may increase the dose to 20mg/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.

Elderly:

Your doctor will increase the dose with more caution and the daily dose should generally not exceed 2 tablets (40 mg). The maximum dose is 3 tablets (60 mg) daily.

Liver impairment:

If you have a liver problem or are using other medication that might affect Flusetin tablets, your doctor may decide to prescribe a lower dose or tell you to use Flusetin tablet every other day.

If you take more Flusetin tablets than you should

Do not take more tablets than your doctor tells you to. If you ever take too many go to the nearest hospital casualty unit or tell your doctor immediately. Take the container and any remaining tablets with you to show to the doctor.

Symptoms of overdose include: feeling sick or being sick, seizures (fits), heart problems (from heart flutters to heart attack), problems with breathing and change in mental condition ranging from agitation to coma.

If you forget to take Flusetin tablets

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose and just carry on as before. Do not take a double dose to make up for a forgotten dose.

Taking your medicine at the same time each day may help you to remember to take it regularly.

If you stop taking Flusetin tablets

- Do not stop taking Flusetin tablets without asking your doctor first, even when you start to feel better. It is important that you keep taking your medicine.
- Make sure you do not run out of tablets.

You may notice the following effects when you stop taking Fluoxetine tablets: dizziness; tingling feelings like pins and needles; sleep disturbances (vivid dreams, nightmares, inability to sleep); feeling restless or agitated; unusual tiredness or weakness; feeling anxious; nausea/vomiting (feeling sick or being sick); tremor (shakiness); headaches.

Most people find that any symptoms on stopping Flusetin tablets are mild and disappear within a few weeks. If you experience symptoms when you stop treatment, contact your doctor.

When stopping Flusetin tablets, your doctor will help you to reduce your dose slowly over one or two weeks - this should help reduce the chance of withdrawal effects.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Flusetin tablet 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, stop taking the tablets straight away and tell your doctor immediately.
- If you feel restless and cannot sit or stand still, you may have akathisia (feeling of "inner restlessness", a constant urge to be moving); increasing your dose of Flusetin tablets may make you feel worse. If you feel like this, contact your doctor.
- Tell your doctor immediately if your skin starts to turn red or you develop a varied skin reaction or your skin starts to blister or peel. This is very rare.

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.
- heart problems, such as fast or irregular heart rate, fainting, collapsing or dizziness upon standing which may indicate abnormal functioning of the heart rate.

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

If you have any of the following symptoms and they bother you, or last for some time, tell your doctor or a pharmacist.

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

- sleep problems
- headache
- feeling sick (nausea)
- diarrhoea
- tiredness

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)
- unusual dreams, sleep problems, tiredness or sleepiness
- dizziness
- change in taste
- uncontrollable shaking movements
- blurred vision
- rapid and irregular heartbeat sensations
- flushing
- yawning
- indigestion, vomiting
- dry mouth
- 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
- thoughts of suicide or harming yourself
- teeth grinding
- muscle twitching, involuntary movements or problems with balance or co-ordination
- memory impairment
- enlarged (dilated) pupils
- ringing in the ears
- low blood pressure
- shortness of breath
- nose bleeds
- difficulty swallowing
- hair loss
- increased tendency to bruising
- unexplained bruising or bleeding
- cold sweat
- difficulty passing urine
- feeling hot or cold
- abnormal liver function test results

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

- low levels of salt in the blood
- reduction in blood platelets, which increases risk of bleeding or bruising
- untypical wild behaviour
- hallucinations
- agitation
- panic attacks
- confusion

- stuttering
- fits
- vasculitis (inflammation of a blood vessel)
- rapid swelling of the tissues around the neck, face, mouth and/or throat
- pain in the tube that takes food or water to your stomach
- hepatitis
- lung problems
- sensitivity to sunlight
- muscle pain
- problems urinating
- producing breast milk

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.

In children and adolescents (8-18 years)

In addition to the possible side effects listed above, Flusetin tablets may slow growth or possibly delay sexual maturity. Suicide-related behaviours (suicide attempt and suicidal thoughts), hostility, mania, and nose bleeds were also commonly reported in children.

Reporting of side effects

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

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

5. HOW TO STORE FLUSETIN TABLETS

Keep out of the sight and reach of children.

Do not store above 25°C. Store in the original package.

Do not use your tablets after the expiry date stated on the label or carton. The expiry date refers to the last day of that month.

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.

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