

Fluzac 20 mg Capsules

Fluoxetine (as hydrochloride)

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 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. See section 4.

What is in this leaflet

1. What Fluzac is and what it is used for
2. What you need to know before you take Fluzac
3. How to take Fluzac
4. Possible side effects
5. How to store Fluzac
6. Contents of the pack and other information



1 What Fluzac is and what it is used for

Fluzac contains fluoxetine which is one of 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
- Bulimia nervosa: Fluzac is used alongside psychotherapy for the reduction of binge-eating and purging.

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. Fluzac should be offered to a child or young person with moderate to severe major depressive disorder only in combination with psychological therapy.

2 What you need to know before you take Fluzac

Do not take Fluzac if you are:

- allergic to fluoxetine or any of the other ingredients of this medicine (listed in section 6). **If you develop a rash or other allergic reactions (like itching, swollen lips or face or shortness of breath), stop taking the capsules straightaway and contact your doctor immediately.**
- taking metoprolol (a medicine used in heart failure). The side effects of metoprolol may be increased including slowing your heart beat excessively.
- taking other medicines known as non-selective monoamine oxidase inhibitors 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, iproniazide, moclobemide, phenelzine, tranylcypromine, isocarboxazid, toloxatone and also linezolid (an antibiotic) and methylthionium chloride also called methylene blue (used to treat medicinal or chemical induced methaemoglobinaemia).

Treatment with Fluzac should only be started at least 2 weeks after discontinuation of an irreversible MAOI (for instance tranylcypromine).

However, treatment with fluoxetine can be started the following day after discontinuation of certain reversible MAOIs (for instance moclobemide), linezolid, methylthionium chloride (methylene blue)).

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Fluzac if any of the following applies to you:

- have epilepsy or fits (seizures) or experience an increase in seizure frequency, contact your doctor immediately; Fluzac might need to be discontinued
- mania now or in the past; if you have a manic episode, contact your doctor immediately because Fluzac 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)
- are taking diuretics (water tablets), especially if you are elderly
- are having ECT (electro-convulsive therapy) treatment
- have a history of bleeding disorders or you develop bruises or unusual bleeding or if you are pregnant (see Pregnancy and breast-feeding)
- are taking medicines that thin the blood (see 'Other medicines and Fluzac')
- ongoing treatment with tamoxifen (used to treat breast cancer) see 'Other medicines and Fluzac'
- start to feel restless and cannot sit or stand still (akathisia). Increasing your dose of Fluzac may make this worse.
- start to experience 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.** Fluzac might need to be discontinued.

Medicines like Fluzac (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

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 children aged less than 25 years with antidepressant 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 straightaway.**

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. Fluzac 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 Fluzac 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 Fluzac 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 Fluzac 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 Fluzac.

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

Other medicines and Fluzac

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

Fluzac may affect the way some other medicines work (interaction), especially the following:

- **Certain MAO-inhibitors** (some used to treat depression). Non-selective MAO-inhibitors and MAO-inhibitors type A must not be used with fluoxetine as serious or even fatal reactions (serotonin syndrome) can occur (see section 'Do not take Fluzac if you are'). Treatment with Fluzac should only be started at least 2 weeks after discontinuation of an irreversible MAOI (for instance tranylcypromine). However, treatment with fluoxetine can be started the following day after discontinuation of certain reversible MAOIs (for instance moclobemide, linezolid, methylthionium chloride (methylene blue)).
- **metoprolol** (used in heart failure) see section 'Do not take Fluzac if you are'
- **mequitazine** (an antihistamine); Fluzac may increase the risk of side effects associated with this medicine
- **phenytoin** (for epilepsy); because fluoxetine 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 Fluzac
- **lithium, selegiline, tramadol** (a painkiller), **triptans** (for migraine), **tryptophan, St. John's Wort** (a herbal remedy); there is an increased risk of serotonin syndrome when these drugs are taken with fluoxetine. Your doctor will carry out more frequent check-ups.
- medicines that may affect the heart's rhythm, e.g. Class 1A and III antiarrhythmics, antipsychotics (e.g. 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)
- **flecainide, propafenone or nebivolol** (for heart problems), **atomoxetine** (for ADHD), **carbamazepine** (for epilepsy), **tricyclic antidepressants** (for example imipramine, desipramine and amitriptyline) and **risperidone** (an antipsychotic); because fluoxetine may possibly change the blood levels of these medicines, your doctor may need to lower their dose when administered with Fluzac.
- **tamoxifen** (used to treat breast cancer), because Fluzac 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
- **warfarin, NSAIDs, aspirin** or other medicines used to thin the blood ; there is an increased risk of bleeding when taken with fluoxetine. If Fluzac treatment is started or stopped when you are taking these medicines, your doctor will need to perform certain tests.
- **cyproheptadine** (an antihistamine) may reduce the effect of fluoxetine
- fluzac may decrease the level of sodium in blood, use with other medicines that can also have this effect may lead to an increased risk (e.g. **diuretics, desmopressin** (for diabetes), **carbamazepine** or **oxcarbazepine** (for epilepsy))
- fluzac may increase the risk of seizures, use with other medicines that may have the same effect (e.g. other anti-depressants, **phenothiazine, butyrophenone** (anti-psychotic), **mefloquine** or **chloroquine** (anti-malaria medicine), **tramadol** (a painkiller)) may increase the risk.

Fluzac with food, drink and alcohol

You can take Fluzac with or without food, whichever you prefer.

You should avoid alcohol while you are taking this medicine.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any 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.

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, 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 Fluzac while you are pregnant. However depending on your circumstances, your doctor may suggest that it is better for you to keep taking Fluzac.

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.

When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Fluzac 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.

If you take Fluzac near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding

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shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking Fluzac so they can advise you.

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.

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

Fluzac may affect your judgment or co-ordination. Do not drive or use machinery without advice from your doctor or pharmacist.

3 How to take Fluzac

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The instructions will also be on the label on the pack. Do not take more capsules than your doctor tells you. Swallow the capsules with a drink of water. Do not chew the capsules.

Adults:

The usual dose is:

- **Depression:** The recommended dose is 1 capsule (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 capsules (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 capsules (60 mg) daily.
- **OCD:** The recommended dose is 1 capsule (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 capsules (60 mg) daily. If no improvement is noted within 10 weeks, your doctor will reconsider your treatment.

Use in children and adolescents aged 8 to 18 years with depression:

Treatment should be started and be supervised by a specialist. The starting dose is 10 mg/day. After 1 to 2 weeks, your doctor may increase the dose to 20 mg/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 capsules (40 mg). The maximum dose is 3 capsules (60 mg) daily.

Liver impairment:

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

If you take more Fluzac than you should

If you take too many capsules, go to your nearest hospital emergency department (or casualty) or tell your doctor straightaway.

Take the pack of Fluzac with you if you can. Symptoms of overdose include: nausea, vomiting, seizures, heart problems (like irregular heartbeat and cardiac arrest), lung problems and change in mental condition ranging from agitation to coma.

If you forget to take Fluzac

If you miss a dose, do not worry. Take your next dose the next day at the usual time. 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 Fluzac

Do not stop taking Fluzac 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 capsules.

You may notice the following effects when you stop taking Fluzac: 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 Fluzac are mild and disappear within a few weeks. If you experience symptoms when you stop treatment, contact your doctor.

When stopping Fluzac, 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 medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicine, 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, **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 Fluzac 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 or you experience a serious illness with blistering of the skin, mouth, eyes and genitals. This is 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.

The following side effects have also been reported in patients taking Fluzac:

Very common: may affect more than 1 in 10 people

- insomnia
- headache
- diarrhoea, feeling sick
- fatigue

Common: may affect up to 1 in 10 people

- not feeling hungry, weight loss
- anxiety, nervousness, restlessness, feeling tense
- decreased sex drive or sexual problems (including difficulty maintaining an erection for sexual activity)
- sleep problems, unusual dreams, tiredness or sleepiness
- poor concentration
- dizziness
- change in taste
- uncontrollable shaking movements
- blurred vision
- rapid irregular heartbeat sensations
- flushing
- yawning
- indigestion, vomiting
- dry mouth
- rash, hives, itching
- excessive sweating
- joint pain
- passing urine more frequently
- unexplained vaginal bleeding
- feeling shaky, chills

Uncommon: may affect up to 1 in 100 people

- feeling detached from yourself
- strange thinking
- abnormally high mood
- orgasm problems
- teeth grinding
- thoughts of suicide or harming yourself
- 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 weak, 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
- reduction in white blood cells or neutrophils in the blood
- untypical wild behaviour
- hallucinations
- agitation
- panic attacks
- confusion
- stuttering
- aggression
- 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
- inflammation of the liver
- lung problems
- sensitivity to sunlight
- muscle pain
- problems urinating
- producing breast milk

Frequency not known:

- heavy vaginal bleeding shortly after giving birth (postpartum haemorrhage), see Pregnancy and breast-feeding in section 2 for more information.

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, Fluzac 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 of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance; website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Fluzac

Keep this medicine out of the sight and reach of children.

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

Do not store above 25 °C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Fluzac contains

- The active substance is fluoxetine. Each capsule contains 20 mg of fluoxetine (as hydrochloride).
- The other ingredients are: pregelatinised maize starch, dimeticone 350
Capsule shell: gelatin, titanium dioxide (E171), yellow ferric oxide (E172) and patent blue V (E131)

What Fluzac looks like and contents of the pack

Capsules with an opaque light green colour PP/Alu or PVC/Alu blisters: 30 capsules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturer

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

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