

Rare (seen in 1 to 10 in every 10,000 patients)

- Low levels of salt in the blood
- Untypical wild behaviour
- Hallucinations
- Agitation
- Aggression
- Panic attacks
- Vasculitis (inflammation of a blood vessel)
- Lung problems (inflammation of tissue)
- Muscle pain
- Confusion
- Serotonin syndrome
- 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
- Sensitivity to sunlight
- Producing breast milk
- Reduction in blood platelets, which increases risk of bleeding or bruising
- Stuttering
- Problems urinating
- Stevens-Johnson syndrome
- Liver problem (transaminases or gamma glutamyl transpeptidase increases)

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store FLUOXETINE CAPSULE

Do not store above 30°C. Store in the original outer carton. Do not put them into another container as they might get mixed up. Keep this medicine out of the sight and reach of children.

Do not use Fluoxetine Capsules after the expiry date which is stated on the blister and carton as EXP or EXP date.

Do not use this medicine if you notice description of the visible signs of deterioration.

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.

This leaflet does not contain all the information about your medicine. If you have any questions or you are not sure about anything ask your doctor or pharmacist.

6. Contents of the pack and other information

What Fluoxetine Capsule contains

- The active substance is Fluoxetine (as the hydrochloride).
- The other ingredients are dimeticono, pregelatinised starch, titanium dioxide (E171), erythrosine (E127), patent blue V and gelatine. The ink used to print on the capsules contains shellac, black iron oxide and propylene glycol.

What Fluoxetine Capsule looks like and contents of the pack

Fluoxetine Capsules are blue and white, and marked 'R9'. Your doctor may have given you this medicine before from another company and it may have looked slightly different. Either brand will have the same effect.

They are supplied in boxes of 14, 28, 30, and 70 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

RI Pharma Limited, First Floor, 6 St. John's Court, Upper Forest Way, Swansea Enterprise Park, Swansea, Wales SA6 8QQ.

Manufacturer: Pharmacare Premium Ltd, HHF 003, Hal Far Industrial Estate, Birzebbugia, BBG 3000

If you would like this leaflet in a different format please contact the licence holder at the following address: RI Pharma Ltd, 6, St. John's Court, First Floor, Upper Forest Way, Swansea Enterprise Park, Swansea, SA6 BQQ or email at info@ri-pharma.com

If you would like to have any further information or want to report any side effects, please email at info@ri-pharma.com

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PACKAGE LEAFLET: INFORMATION FOR THE USER

FLUOXETINE 20 MG CAPSULES

Fluoxetine 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 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. See section 4.

What is in this leaflet

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

1. What Fluoxetine Capsule is and what it is used for

The name of this medicine is Fluoxetine 20mg Capsule (referred to as Fluoxetine throughout this leaflet). Fluoxetine belongs to a group of medicines called SSRI (selective serotonin reuptake inhibitor) antidepressants.

It is used to treat the following conditions:

- Depression.
- Obsessive-compulsive disorder (also known as OCD).
- The eating disorder bulimia nervosa.

2. What you need to know before you take Fluoxetine Capsule

Do not take Fluoxetine Capsule if you are:

- Allergic (hypersensitive) to Fluoxetine or any of the other ingredients of Fluoxetine capsule (listed in section 6).
- The symptoms of an allergic reaction include itching, nettle rash, wheezing or swelling of the hands, throat, mouth or eyelids.

Taking any of the following medicines:

- Do not take Fluoxetine in combination with irreversible, non-selective monoamine oxidase inhibitors, since serious or even fatal reactions can occur. Examples of such MAOIs used to treat depression such as, iproniazide, and also linezolid (an antibiotic) and methylthioninium chloride also called methylene blue (used to treat high levels of methaemoglobin in the blood).
- Do not take Fluoxetine in combination with metoprolol used in the treatment of heart failure

If you think any of the above points apply to you, do not take the capsules. Talk to your doctor first and follow the advice given.

Warnings and precautions:

Tell your doctor before taking Fluoxetine capsules if any of the following points apply to you:

- If you suffer from epilepsy, fits, seizures or experience an increase in seizure frequency, contact your doctor immediately; Fluoxetine might need to be discontinued.
- If you have mania or have a history of mania contact your doctor immediately because Fluoxetine might need to be discontinued.
- If you have liver or kidney problems (your doctor may need to adjust your dosage).
- If you suffer from heart disease or if you have family history of QT prolongation.
- If you have 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).
- If you have diabetes (dosage of diabetic medicines may need to be adjusted).
- If you have had previous bleeding problems.
- If you are being treated with electroconvulsive therapy (ECT).
- If you have raised intraocular pressure or at risk of acute narrow-angle glaucoma.
- If you are taking medicines that thin the blood (see "Taking other medicines").
- If you have ongoing treatment with tamoxifen (used to treat breast cancer).
- If you starting to feel restless and cannot sit or stand still (akathisia). Increasing your dose of Fluoxetine may make this worse.
- If you have 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, since Fluoxetine might need to be discontinued.
- If you are already taking St. John's Wort, a herbal medicine for depression.

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 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

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Thoughts of suicide and worsening of your depression or anxiety disorder continued overleaf

about changes in your behaviour.

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

Children and adolescents

Fluoxetine is not recommended for children and patients under the age of 18.

Other medicines and Fluoxetine Capsule

If taken with some other medicines the effects of Fluoxetine or the effects of other medicines may be changed. Check with your doctor if you are taking any of the following:

- Monoamine oxidase inhibitors (MAOIs) used to treat depression. Some cases of serious or even fatal reactions can occur such as serotonin syndrome. Treatment with Fluoxetine 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 linezolid, methylnthionium chloride (methylene blue)). Similarly, at least 5 weeks should elapse after discontinuing fluoxetine treatment before starting an irreversible, non-selective MAOI.
- Metoprolol used in cardiac failure: there is an increased risk of metoprolol adverse events like bradycardia.
- Tamoxifen used to treat breast cancer, because Fluoxetine 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.
- Mequitazine: Risk of QT prolongation may be increased because of an inhibition of its metabolism by fluoxetine.
- Phenytoin (for epilepsy); 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 Fluoxetine
- Medicines known as 'Serotonergic drugs' such as lithium, tramadol, triptans, tryptophan, selegiline (MAOI- B).
- Medicines that may prolong the QT interval such as Class IA and III antiarrhythmics, antipsychotics (e.g. fenitiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine), anti-malaria treatment particularly halofantrine, certain antihistamines (astemizole, mizolastine).
- Cyproheptadine: Reduced antidepressant activity of fluoxetine.
- Medicines inducing hyponatremia (e.g. diuretics, desmopressin, carbamazepine and oxcarbazepine): may lead to an increased risk of hyponatremia, which is undesirable effect of fluoxetine.
- Medicine metabolised by CYP2D6 such as flecainide, propafenone and nebivolol, atomoxetine, carbamazepine, tricyclic antidepressants and risperidone as Fluoxetine is a strong inhibitor of CYP2D6 enzyme.
- Anticoagulants used to thin the blood e.g. Warfarin including aspirin or NSAID.
- The herbal remedy St John's Wort (Hypericum perforatum). If you already take a St John's Wort preparation, stop taking it and mention it to your doctor at your next visit.

Fluoxetine with food and drink and alcohol

You can take Fluoxetine capsule with or without food, whatever you prefer. It is not advisable to drink alcohol while you are taking Fluoxetine.

Pregnancy and breast-feeding and fertility

Pregnancy

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 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.

Make sure your midwife and/or doctor know you are on 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 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 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

Breast-feeding whilst taking Fluoxetine may lead to side effects in your baby. If you need to continue treatment, you should consider stopping breastfeeding or make sure that your doctor is aware that you are breastfeeding so that he can prescribe you an appropriate dose.

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

Fluoxetine may affect your judgement or co-ordination. Do not drive or use hazardous machinery unless you are sure that you are not affected.

3. How to take Fluoxetine Capsule

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Swallow the capsules whole with a drink of water. Do not chew the capsule.

Dosage in Adults

The recommended dose is given below:

- Depression: Initially one 20 mg Fluoxetine capsule per day. Your doctor may increase this to up to 60 mg (three capsules) per day.
- Obsessive-Compulsive disorder: Initially one 20 mg Fluoxetine capsule per day. Your doctor may increase this up to 60 mg (three capsules) per day.
- Bulimia nervosa: Three 20 mg Fluoxetine capsule per day.

Dosage in Elderly

Elderly patients may be more sensitive to the effects of Fluoxetine so your doctor may prescribe a smaller dose than that stated above, up to a maximum of 60 mg (three capsules) a day.

Patients who suffer from kidney and liver disease are likely to be given less frequent doses of Fluoxetine, such as one 20mg capsule every second day. If you are not sure how many capsules to take, ask your doctor or pharmacist.

Use in children and adolescents

Fluoxetine is not recommended for children and patients under the age of 18.

If you take more Fluoxetine than you should

An overdose of this medicine may be dangerous. If you have taken an overdose tell your doctor or go to the nearest hospital casualty department immediately.

If you forget to take Fluoxetine

If you forget a dose at the right time, do not worry. Take your next dose the next day at the usual time but do not take two doses at the same time.

If you stop taking Fluoxetine

- It may take a few weeks before this medicine starts to work. Do not stop taking Fluoxetine without consulting your doctor first. Fluoxetine should be taken for a period of at least six months unless your doctor tells you otherwise.
- When stopping taking Fluoxetine, your doctor will help you to gradually take less of the medicine.
- This will be over a period of weeks or months. This might be done by slowly reducing the amount of medicine you take each day, week by week.
- As you take less Fluoxetine you may notice some side-effects. Most people find that any effects are mild and go away within 2 weeks. Some people find that they are more severe and last longer. If you notice any effects when you are reducing Fluoxetine, your doctor may decide that you should come off it more slowly. If you notice any severe side-effects, talk to your doctor.
- The doctor may ask you to start taking a slightly higher dose again and then reduce it more slowly. If you have any further questions on the use of this medicine, ask your doctor.

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).**

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.

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

Very common (seen in more than 1 in every 10 patients)

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

Common (seen in 1 to 10 in every 100 patients)

- 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, vomiting
- Dry mouth
- Rash, urticaria, itching
- Excessive sweating
- Joint pain
- Passing urine more frequently
- Unexplained vaginal bleeding
- Feeling shaky or chills

Uncommon (seen in 1 to 10 in every 1,000 patients)

- Feeling detached from yourself.
- Nose bleeds.
- Thoughts of suicide or harming yourself.
- Ringing in the ears.
- Unexplained bruising or bleeding.
- Strange thinking.
- Low blood pressure.
- Shortness of breath.
- Abnormally high mood.
- Increased tendency to bruising.
- Difficulty swallowing.
- Orgasm problems.
- Cold sweat.
- Memory impairment.
- Teeth grinding.
- Difficulty passing urine.
- Hair loss.
- Feeling hot or cold.
- Difficulty passing urine.
- Muscle twitching, involuntary movements or problems with balance.