

Fluoxetine 20mg capsules

(fluoxetine hydrochloride)

Eight important things you need to know about Fluoxetine capsules

- **Fluoxetine capsules treat depression.**
- 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 are 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 Fluoxetine capsules*.
- **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 side effects*.
- **Taking some other medicines with Fluoxetine capsules can cause problems.** You may need to talk to your doctor. See section 2, *Other medicines and Fluoxetine capsules*.
- **If you are pregnant or planning to get pregnant, talk to your doctor.** See section 2, *Pregnancy, breast-feeding and fertility*.

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.

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1 What Fluoxetine capsules are and what they are used for

Fluoxetine capsules belong 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 **irreversible, non-selective monoamine oxidase inhibitors (MAOIs, e.g. 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, or if you are pregnant (see 'Pregnancy, breast-feeding and fertility').
- are having Electroconvulsive Therapy (**ECT**).
- are taking **buprenorphine/naloxone**. The use of these medicines together with Fluoxetine capsules can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Fluoxetine capsules").

Medicines like Fluoxetine (so called SSRI/SNRI) 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 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 medicine. 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

Do not take Fluoxetine Capsules with:

- irreversible, non-selective monoamine oxidase inhibitors (MAOIs, e.g. iproniazid). Fluoxetine should only be started at least 2 weeks after stopping an irreversible non-selective MAOI. Do not take any irreversible non-selective MAOIs for at least 5 weeks after you stop taking Fluoxetine
- metoprolol (used for heart failure).

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

- medicines that may affect the heart's rhythm, e.g. Class IA 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 or certain antihistamines (astemizole, mizolastine), because taking one or more of these drugs with Fluoxetine capsules may increase the risk of changes in the electrical activity of the heart

- lithium, for mental illness
- linezolid and methylthioninium chloride (methylene blue) monoamine oxidase inhibitors (MAOI-As)
- neбиволol (used to treat high blood pressure)
- propafenone or flecainide (used to treat heart problems)
- atomoxetine (used to treat attention deficit hyperactivity disorder (ADHD))
- risperidone (used to treat psychotic disorders)
- diuretics (water tablets)
- desmopressin (used to reduce the amount of urine produced by the kidneys)
- mefloquine, chloroquine (anti-malaria)
- mequitazine, cyproheptadine (antihistamines)
- oxcarbazepine, carbamazepine or phenytoin for epilepsy or other conditions
- any other medicines for depression e.g. SSRIs (selective serotonin reuptake inhibitors)
- 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)
- L-tryptophan (an amino acid)
- buprenorphine/ naloxone (used to treat opioid overdose). These medicines may interact with fluoxetine and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.
- 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.

If you take Fluoxetine Capsules near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking Fluoxetine Capsules so they can advise you.

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, as 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.

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 (20mg) 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 (20mg) 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 the 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, joints or muscles) and signs such as jaundice (yellowing of the whites of the eyes and skin), life threatening irregular heart beat, 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.

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

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

Common (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
- ringing in the ears (tinnitus)
- low blood pressure
- shortness of breath
- difficulty swallowing
- hair loss
- increased tendency to bruising
- cold sweat
- painful urination
- feeling hot or cold
- feeling general discomfort or illness
- feeling abnormal
- memory problems
- nose bleeds
- sexual problems
- abnormal liver test results

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 the blood vessels)
- 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
- prolonged and painful erection
- rash, fever, joint pain, enlarged lymph nodes (serum sickness)
- blood spots, bruising and discolouring to skin (purpura)
- confusion
- speech problems
- aggression
- high level of prolactin in the blood (as seen in blood tests)

- confusion, hallucinations, drowsiness, fits, coma, difficulty breathing (syndrome of inappropriate high secretion of antidiuretic hormone (SIADH))
- 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)

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

Bone fractures - an increased risk of bone fractures has been observed in patients taking this type of medicine.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 you 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 Size 3 hard gelatine capsules, light green cap and yellow body. Markings are C on one half and FX on the other. Pack sizes are 30 capsules.

Marketing Authorisation Holder and Manufacturer
Accord, Barnstaple, EX32 8NS, UK

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