



Package Leaflet: Information for the Patient

Fluoxetine 20 mg Dispersible Tablets

(fluoxetine)

Eight important things you need to know about Fluoxetine

Fluoxetine 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 is not for use in children and adolescents under 8. (See section 2, Children and adolescents aged 8 to 18 years).

Fluoxetine 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.

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 without talking to your doctor. If you stop taking Fluoxetine 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 may make these feelings worse. See section 4, Possible side-effects.

Taking some other medicines with Fluoxetine can cause problems. You may need to talk to your doctor. See section 2, Other medicines and Fluoxetine.

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 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.

The name of your medicine is "Fluoxetine 20 mg Dispersible Tablets" but will be referred as "Fluoxetine" in this leaflet.

What is in this leaflet

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

1. What Fluoxetine is and what it is used for

Fluoxetine dispersible tablets contain the active substance fluoxetine which is one of a group of medicines called selective serotonin re-uptake inhibitors (SSRI) antidepressants.

This medicine is used to treat the following conditions:

Adults:
- major depressive episodes
- obsessive-compulsive disorder
- the eating disorder Bulimia nervosa: Fluoxetine are 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. Fluoxetine should be offered to a child or young person with moderate to severe major depressive disorder only in combination with psychological therapy.

How Fluoxetine 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 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.

You must talk to a doctor if you do not feel better or if you feel worse after 70 days.

2. What you need to know before you take Fluoxetine

Do not take Fluoxetine
- 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 reaction (like itching, swollen lips or face or shortness of breath), stop taking the tablets straight away and contact your doctor immediately.
- if you are taking irreversible, non-selective monoamine oxidase inhibitors (MAOIs) like iproniazid since serious or even fatal reactions can occur (e.g. iproniazid used to treat depression)

  Treatment with Fluoxetine should only be started at least 2 weeks after discontinuation of an irreversible, non-selective MAOI

  Do not take any irreversible, non-selective MAOIs for at least 5 weeks after you stop taking Fluoxetine. If Fluoxetine have been prescribed for a long period and/or at a high dose, a longer interval needs to be considered by your doctor
- if you are taking metoprolol used in treatment of heart failure since there is an increased risk of your heartbeat becoming too slow.

Warnings and precautions

Talk to your doctor or pharmacist before taking Fluoxetine:
- if you have a, liver or kidney disorder. Your doctor may decide you need a lower dose
- 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
- The use of buprenorphine/opioids together with Fluoxetine can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Fluoxetine").
- 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 this medicine, you develop a fit for the first time or get more fits than usual, seek medical advice from your doctor immediately; Fluoxetine might need to be discontinued;
- if you have a history of mental illness known as mania or hypomania; if you have a manic episode, contact your doctor immediately because Fluoxetine might need to be discontinued
- if you suffer from or have a family history of heart problems or a condition which can increase the likelihood of you having heart problems (e.g. if you have low potassium or magnesium in your blood, conditions known as hypokalaemia or hypomagnesemia)
- if you suffer from diabetes. Fluoxetine may alter your blood sugar levels. Your doctor may need to alter the dose of your insulin or other diabetes control medicine
- if you 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')
- if you are having Electroconvulsive Therapy (ECT)
- if you are taking tamoxifen used for treatment of breast cancer. (See "Other medicines and Fluoxetine")
- ongoing treatment with medicines that thin the blood (see 'Other medicines and Fluoxetine Dispersible')
- if you have glaucoma (increased pressure in the eye); it may increase the risk of mydriasis (dilation of pupil of the eye)
- if you have an ongoing treatment with diuretics (water tablets), especially if you are elderly.

Talk to your doctor if you experience the following after taking Fluoxetine
- weight loss
- constant restlessness. A need to move constantly and not being able to stand or sit still for long periods. Increasing your dose of Fluoxetine may make this worse
- raised body temperature, muscle stiffness, confusion, irritation, extreme aggressiveness becoming worse especially if you are simultaneously taking tryptophan or other medicines to treat mental disorders; 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.
- a mixture of all above signs especially if you have taken iproniazid
- 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)
- rash, fever, redness, breathing difficulty, swelling of limbs. These could be signs of an allergic reaction. Stop taking Fluoxetine and tell your doctor if you experience any of these symptoms.

Sexual dysfunction

Medicines like fluoxetine (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 you first start taking 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.

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're a patient under 18, your doctor may prescribe this medicine 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 this medicine.

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

Other medicines and Fluoxetine

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

Do not take Fluoxetine with:
- Any irreversible, non-selective MAOIs for at least 5 weeks after you stop taking Fluoxetine. If Fluoxetine have 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
- Certain irreversible, non-selective monoamine oxidase inhibitors (MAOIs), some used to treat depression. Irreversible, non-selective MAOIs must not be used with Fluoxetine as serious or even fatal reactions (serotonin syndrome) can occur (see section "Do not take Fluoxetine"). Treatment with Fluoxetine should only be started at least 2 weeks after discontinuation of an irreversible, non-selective MAOI (for instance tranylcypromine)
- **metoprolol** when used for heart failure; there is an increased risk of your heartbeat becoming too slow.

Fluoxetine may affect the way the following medicines work (interaction):
- Treatment with Fluoxetine can be started the following day after discontinuation of certain reversible MAOIs (for instance moclobemide, linezolid, methylthioninium chloride (methylene blue)). Some MAOIs type B (selegeline) can be used with Fluoxetine provided that your doctor monitors you closely;
- tamoxifen; used to treat breast cancer; because Fluoxetine may change the blood levels of this drug, resulting in the possibility of a reduction in the effect of tamoxifen, your doctor may need to consider prescribing a different antidepressant treatment.
- **monoamine oxidase inhibitors A** (MAOI-A) including moclobemide, linezolid (an antibiotic) and methylthioninium chloride (also called methylene blue, used for the treatment of medicinal or chemical product induced methemoglobinemia): 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
- **mequitazine**; used to treat allergies; because taking this drug with Fluoxetine may increase the risk of changes in the electrical activity of the heart
- **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 Fluoxetine
- **lithium, selegiline, St. John's Wort, tramadol (a painkiller), triptans (for migraine) and tryptophan**; there is an increased risk of mild serotonin syndrome when these drugs are taken with Fluoxetine. Your doctor will carry out more frequent check-ups
- **buprenorphine/opioids**: 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.
- 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 may increase the risk of changes in the electrical activity of the heart
- **anti-coagulants** (such as warfarin), **NSAID** (such as ibuprofen, diclofenac), aspirin and other medicines which can thin the blood (including clozapine, used to treat certain mental disorders). Fluoxetine may alter the effect of these medicines on the blood. If Fluoxetine 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 Fluoxetine
- 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 Fluoxetine
- 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 Fluoxetine may increase the risk of seizures when taken with these Medicines
- flecainide, propafenone, nebivolol or encainide (for heart problems), carbamazepine (for epilepsy), atomoxetine or tricyclic antidepressants (for example imipramine, desipramine and amitriptyline) or risperidone (for schizophrenia); because Fluoxetine may possibly change the blood levels of these medicines, your doctor may need to lower their dose when administered with Fluoxetine.

Fluoxetine with food, drink and alcohol
- you can take Fluoxetine 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 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.

It is preferable not to use this treatment during pregnancy unless the potential benefit outweighs the potential risk. Thus, you and your doctor may decide to gradually stop taking Fluoxetine while you are pregnant or before being

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pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking 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 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 since the following effects have been reported in new born children: irritability, tremor, muscle weakness, persistent crying, and difficulty in sucking or in sleeping.

In babies whose mothers took this medicine 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 mother who took this medicine.

If you take Fluoxetine 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 so they can advise you.

Breast feeding:
Breast-feeding is not recommended whilst taking this medicine. 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
Psychotropic drugs such as Fluoxetine Dispersible Tablet can affect your judgement or co-ordination. Do not drive or use machinery unless you are sure that you are not affected.

Fluoxetine contains aspartame
Each dispersible tablet contains 4 mg of aspartame (E-951). Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Fluoxetine contains sodium benzoate
Each 20 mg dispersible tablet contains 0.002 mg of sodium benzoate (E-211). Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Fluoxetine contains benzyl alcohol
This medicine also contains benzyl alcohol in each 20 mg dispersible tablet. Benzyl alcohol may cause allergic reactions.

Ask your doctor or pharmacist for advice:

if you are pregnant or breast-feeding

if you have a liver or kidney disease

This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

Fluoxetine contains sodium
This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially ‘sodium-free’..

3. How to take Fluoxetine

Always take this medicine exactly as your doctor or pharmacist 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 tablet(s) with a half a glass of water or disperse the tablet(s) in half a glass of water and drink. Do not crush or chew the tablets.
You are advised NOT to drink alcohol with this medicine.
The recommended dose is-

Adults:
- **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.

The tablet may be divided in to equal doses.

If you suffer from kidney or liver problems or are elderly, your doctor may prescribe a different dose.

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 (half tablet) a day. After 1 to 2 weeks your doctor may increase the dose 20 mg 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 two weeks or more. It should be taken for as long as your doctor tells you to.

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 Fluoxetine, your doctor may decide to prescribe a lower dose or tell you to use Fluoxetine every other day.

If you take more Fluoxetine than you should
If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately.

Take the pack of Fluoxetine with you if you can.

Symptoms of an overdose include feeling sick, being sick, seizures, heart problems (like irregular heartbeat and cardiac arrest), lung problems and change in mental condition ranging from excitation to coma.

If you forget to take Fluoxetine
Do not take a double dose to make up for a forgotten dose. If you forget to take a dose then take the next dose at the usual time. Taking your medicine at the same time each day may help you to remember to take it regularly.

If you stop taking Fluoxetine
Do not stop taking Fluoxetine 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.

If you stop taking the tablets abruptly you may rarely develop dizziness, nausea/vomiting (feeling sick or being sick), tingling feelings like pins and needles, sleep disturbances (vivid dreams, nightmares, inability to sleep); feeling restless or agitated; unusual tiredness or weakness, tremor (shakiness), headache, and anxiety. In most cases, these symptoms are mild and short-lived. **Talk to your doctor** before you stop taking the tablets and follow their advice. Your doctor may reduce your dose gradually 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 medicines, this medicine can cause side effects although not everybody gets them.

Stop taking this medicine and talk to your doctor or go to a hospital immediately if you experience any of the following:
- 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; increasing your dose of Fluoxetine 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.

The most frequent side effects (very common: may affect more than 1 in 10 people) are insomnia, headache, diarrhoea, feeling sick (nausea) and fatigue.

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.
- bleeding from stomach
- excessively happy but may become angry or irritable.

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 Fluoxetine:

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
- disturbance in attention
- dizziness
- change in taste
- blurred vision
- Flushing
- Yawning
- indigestion, vomiting
- dry mouth
- rash, urticaria, itching
- excessive sweating
- joint pain
- feeling shaky or chills
- unexplained vaginal bleeding
- passing urine more frequently
- uncontrollable shaking movements
- rapid and irregular heartbeat sensations.

Uncommon (may affect up to 1 in 100 people)
- feeling detached from yourself
- strange thinking
- abnormally high mood
- sexual problems, including orgasm problems, occasionally persisting after treatment discontinuation
- thoughts of suicide or harming yourself
- teeth grinding
- muscle twitching, involuntary movements or problems with balance or co-ordination
- memory impairment
- enlarged (dilated) pupils
- low blood pressure
- shortness of breath
- nose bleeds
- gastrointestinal bleeding
- hair loss
- ringing in the ears
- increased tendency to bruising
- unexplained bruising or bleeding
- difficulty swallowing
- cold sweat
- difficulty passing urine
- feeling hot or cold
- abnormal liver function test results
- symptoms of tiredness, weakness, muscle pain, diarrhoea, loss of, appetite, nausea or vomiting trouble thinking clearly and seeing and hearing things that are not there. These could be signs of Syndrome of Inappropriate Antidiuretic Hormone Secretion.

Rare (may affect up to 1 in 1000 people)
- low levels of salt in the blood
- reduction in the number of white blood cells like neutrophils and leukocytes – report any signs of fever, tiredness as you may have an infection
- reduction in blood platelets which increases risk of bleeding or bruising
- pain in abdomen indicating inflammation of liver (hepatitis) as well as nausea, vomiting, production of dark urine, yellowing of skin and white of the eyes (jaundice)
- confusion
- stuttering
- aggressive behaviour
- fits
- agitation
- 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
- muscle pain
- problems urinating
- lung problems
- untypical wild behaviour
- hallucinations
- panic attacks
- vasculitis (inflammation of a blood vessel)
- sensitivity to sunlight
- producing breast milk.

Not known (frequency cannot be estimated from the available data)
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy 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 (aged 8 to 18 years) – in addition to the possible side effects listed above, this medicine 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. You can also report side effects directly via the Yellow Card Scheme Website: 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

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 carton and blister after ‘EXP’. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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

6. Contents of the pack and other information

What Fluoxetine contains
- ➡ The active substance is Fluoxetine (as hydrochloride)
- ➡ Each dispersible tablet contains Fluoxetine Hydrochloride equivalent to 20 mg of Fluoxetine.

The other ingredients are:

Tablet core: Silicified microcrystalline cellulose, Alginic acid, Hypromellose (3 cps), Peppermint NEAFCO flavour (contains: maize maltodextrin and hydroxypropyl cellulose), Flavour trusil apricot (contains: flavouring substances, natural flavouring preparations, natural flavouring substances, benzyl alcohol, propylene glycol-E1520, sodium benzoate-E211, gum arabic/acacia gum-E414, maize maltodextrin and citric acid-E330), aspartame, sodium lauril sulfate, silica colloidal hydrated and magnesium stearate.

What Fluoxetine looks like and contents of the pack
White to off white, uncoated, oval shaped, biconvex tablets with break line on both the sides. The tablet can be divided into equal doses.
Fluoxetine 20 mg dispersible tablets are available in OPA/Alu/PVC-Alu blisters
Packages contain 7, 10, **14**, 20, **28,** 30, **60**, 70 and 100 dispersible tablets.
Not all pack sizes may be marketed.

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