

**PATIENT INFORMATION LEAFLET
FLUOXETINE 20 mg / 5 ml ORAL SOLUTION**

Fluoxetine 20mg /5ml Oral Solution 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 20mg /5ml Oral Solution is not for use in children and adolescents under 18. See section 2, Use in children and adolescents aged 8 to 18 years.

Fluoxetine 20mg /5ml Oral Solution won't work straight away. Some people taking antidepressants feel worse before feeling better. Your doctor should ask to see you again in 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 20mg / 5ml Oral Solution.

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 20mg /5ml Oral Solution without talking to your doctor. If you stop taking Fluoxetine 20mg /5ml Oral Solution 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 20mg /5ml Oral Solution may make these feelings worse. See section 4, Possible side effects.

Taking some other medicines with Fluoxetine 20mg /5ml Oral Solution can cause problems. You may need to talk to your doctor. See section 2, Other medicines and Fluoxetine Oral Solution.

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

1. WHAT FLUOXETINE ORAL SOLUTION IS AND WHAT IT IS USED FOR

Fluoxetine is one of a group of medicines called selective serotonin reuptake inhibitors (SSRIs). These work by bringing the level of serotonin in the brain, back up to normal. Low levels of serotonin are thought to be a cause of depression and related disorders. This medicine is used to treat the following conditions:

Adults:

- Major depressive episodes
- Obsessive-compulsive disorder (OCD) an illness linked to anxiety in which you can become constantly troubled by persistent ideas (obsessions), that make you carry out repetitive rituals (compulsions);
- Bulimia nervosa (an eating disorder): Fluoxetine Oral Solution is used alongside psychotherapy for the reduction of binge-eating and purging activity.

Children and adolescents aged 8 years or over:

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLUOXETINE ORAL SOLUTION

Do not take Fluoxetine Oral Solution if you are:

- **allergic (hypersensitive) to fluoxetine**, or any of the other ingredients in the oral solution (these are listed in Section 6, Contents of the pack and other information). If you develop a rash or other allergic reactions (like itching, swollen lips or face, shortness of breath), stop taking the solution straight away and contact your doctor immediately.
- taking other medicines to treat depression, 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 nialamide, iproniazide, selegiline, phenelzine, moclobemide, linezolid, methylene blue, tranylcypromine, toloxatone and isocarboxazid. Treatment with fluoxetine should only be started 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). **Do not** take any MAOIs for at least 5 weeks after you stop taking Fluoxetine Oral Solution. If Fluoxetine Oral Solution has been prescribed for a long period and/or at a high dose, a longer interval needs to be considered by your doctor.
- Taking a medication called metoprolol

Warnings and precautions

Talk to your doctor or pharmacist before taking Fluoxetine Oral Solution if you:

- have **epilepsy or fits (seizures)** or experience an increase in seizure frequency, contact your doctor immediately as treatment with Fluoxetine Oral Solution may need to be discontinued
- have **mania or hypomania** now or in the past; if you have a manic episode, contact your doctor immediately as treatment with Fluoxetine Oral Solution may need to be discontinued
- suffer from **diabetes** (your doctor may need to adjust your dose of insulin or other antidiabetic treatment)
- have **liver problems**, as your doctor may need to adjust your dose
- have **heart problems**
- have a history of **bleeding disorders or you develop bruises or unusual bleeding or if you are pregnant (see 'Pregnancy')**
- are taking **diuretics** (water tablets) particularly if you are elderly
- have **glaucoma** (increase pressure in the eye)
- are receiving **ECT** (electroconvulsive therapy)
- are taking medicines that thin the blood (see 'Other medicines and Fluoxetine Oral Solution')
- are taking tamoxifen (used to treat breast cancer) (see 'Other medicines and Fluoxetine Oral Solution')
- start to feel restless and cannot sit or stand still (akathisia). Increasing your dose of fluoxetine may make this worse
- are taking irreversible non-selective Monoamine Oxidase Inhibitors (such as selegiline)
- start to experience fever, muscle stiffness or tremor; changes in your mental state, like confusion, irritability and extreme agitation as you may be suffering from

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'serotonin-syndrome' or 'neuroleptic malignant syndrome'. Although this syndrome occurs rarely it may result in potentially life threatening conditions. You should **contact your doctor immediately** as treatment with Fluoxetine Oral Solution may need to be discontinued.

Important information about Fluoxetine Oral Solution and thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

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

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Medicines like Fluoxetine 20 mg / 5 ml Oral Solution (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Children and adolescents

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 medicines. Fluoxetine Oral Solution 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 Oral Solution on growth, puberty, mental, emotional and behavioural development in this age group is available. Despite this, your doctor may prescribe Fluoxetine Oral Solution for patients under 18 for moderate to severe major depressive episodes in combination with psychological therapy because he/she decides that this is in your best interests. If your doctor has prescribed Fluoxetine Oral Solution for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform them if any of the symptoms listed develop or worsen when patients under 18 are taking Fluoxetine Oral Solution.

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

Other medicines and Fluoxetine Oral Solution

Tell your doctor if you are taking or have recently taken or might take any of the following medicines (up to 5 weeks ago) including medicines obtained without a prescription. Fluoxetine Oral Solution may affect the way some other medicines work (interaction) especially the following:

- Certain MAO-inhibitors (used to treat depression). Non-selective MAO-inhibitors and MAO-inhibitors type A (moclobemide) must not be used with Fluoxetine Oral Solution as serious or even fatal reactions (serotonin syndrome) can occur (see section 'Do not take Fluoxetine Oral Solution'). Some MAO-inhibitors type B (selegiline) can be used with Fluoxetine Oral Solution provided that your doctor monitors you closely.
- Lithium, tryptophan; there is an increased risk of serotonin syndrome when these drugs are taken with Fluoxetine Oral Solution. Your doctor will carry out more frequent check-ups.
- Phenytoin (for epilepsy); because Fluoxetine Oral Solution 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 Oral Solution.
- Tramadol (a painkiller) or triptans (for migraine); there is an increased risk of hypertension (raised blood pressure)
- Flecainide, propafenone or nebivolol (for heart problems), carbamazepine (for epilepsy), atomoxetine (attention-deficit hyperactivity disorder (ADHD)) tricyclic antidepressants (for example imipramine, desipramine and amitriptyline), risperidone (schizophrenia); because Fluoxetine Oral Solution may possibly change the blood levels of these medicines, your doctor may need to lower their dose when administered with Fluoxetine Oral Solution.
- Warfarin or other medicines used to thin the blood (including clozapine, used to treat certain mental disorders); Fluoxetine Oral Solution may alter the effect of these medicines on your blood. If treatment with Fluoxetine Oral Solution is started or stopped when you are taking warfarin, your doctor will need to perform certain tests.
- Tamoxifen (used to treat breast cancer); because Fluoxetine Oral Solution 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
- You should not take the herbal remedy St. Johns wort (Hypericum perforatum), while you are being treated with Fluoxetine Oral Solution since this may result in an increase in side effects. If you are already taking St. Johns wort when you start taking Fluoxetine Oral Solution, stop taking St. Johns wort and tell your doctor at your next visit.
- Metoprolol used to treat cardiac failure
- Cyproheptadine may reduce the antidepressant activity of fluoxetine
- Diuretics, desmopressin, carbamazepine and oxcarbazepine as these may lead to an increased risk of hyponatremia
- SSRIs, phenothiazines, butyrophenones, mefloquine, chloroquine, bupropion, tramadol as these may lead to an increased risk of seizures
- Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazine derivatives, pimozide, haloperidol), certain antimicrobial agents (e.g. sparflaxacin, moxifloxacin, erythromycin IV, pentamidine), anti-malaria treatment (halofantrine), antihistamines (astemizole, mizolastine) as these may affect your heart (QT interval prolongation)
- Mequitazine used to treat allergies

Fluoxetine Oral Solution with food and alcohol

Fluoxetine Oral Solution can be taken with or without food. You should avoid alcohol while you are taking this medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant and breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. 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. 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 sleeping. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Fluoxetine Oral Solution 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. 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.

Fluoxetine is excreted in breast milk and can cause side effects in babies. You should only breast-feed if it is clearly necessary.

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Customer: Kent Pharma **Originated by:** DOB (AWG)

Product: Fluoxetine 20mg/5ml Oral Solution

Dimensions: 300mm x 500mm

Item Code: AXP045FUI

Proof No and Date: 1 17/12/2020

Revision: PRAC update
ARTWORK FOR SUBMISSION
Supersedes: AXP045FUH

Colours



Black

If breast-feeding is continued, your doctor may prescribe a lower dose of fluoxetine. Abrupt discontinuation of therapy should be avoided during pregnancy.

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 of yet.

Driving and using machines

Fluoxetine Oral Solution may affect your judgment or co-ordination. Do not drive or operate machinery without advice from your doctor or pharmacist.

Fluoxetine Oral Solution contains sorbitol

If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicine.

3. HOW TO TAKE FLUOXETINE ORAL SOLUTION

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

Dosage: Your doctor will decide on the right starting dose for you and on any increase in the dose depending on your condition and whether you are taking any other medicines. The label on the carton will tell you how much of the oral solution you should take and when.

Adults:

Depression: The recommended dose is one 5ml spoonful (20mg) each day. Your doctor will review and adjust your dose if necessary within 3-4 weeks of the start of treatment. If required the dosage can be gradually increased up to a maximum of three 5ml spoonfuls (60mg) daily. The dose should be increased carefully to ensure 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 three 5ml spoonfuls (60mg) each day.

OCD: The recommended dose is one 5ml spoonful (20mg) each day. 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 three 5ml spoonfuls (60mg) daily. If no improvement is noted within 10 weeks, your doctor will reconsider your treatment.

Use in children and adolescents

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 10mg each day (given as 2.5ml of Fluoxetine Oral Solution). After 1 to 2 weeks, your doctor may increase the dose to 20mg each day. The dose should be increased carefully to ensure that you receive the lowest effective dose. Lower weight children may need lower doses. Your doctor will review the need for continuing treatment beyond 6 months, and treatment will be reassessed if no improvement is seen.

Elderly:

Your doctor will increase the dose with more caution and the daily dose should generally not exceed two 5ml spoonfuls (40mg). The maximum dose is three 5ml spoonfuls (60mg) daily.

Liver impairment:

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

If you take more Fluoxetine Oral Solution than you should:

If you have accidentally taken more than your prescribed dose, contact your nearest casualty department or tell your doctor or pharmacist immediately. Remember to take the pack and any remaining medicine with you. The most common signs and symptoms of overdose include nausea and vomiting, seizures, heart problems (like an irregular heartbeat and cardiac arrest), lung problems and change in mental condition ranging from agitation to coma.

If you forget to take Fluoxetine Oral Solution

It is important that you take your medicine every day. If you forget to take your medicine, just take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Fluoxetine Oral Solution

Do not stop taking Fluoxetine Oral Solution without asking your doctor first, even when you start to feel better. It is important that you keep taking your medicine. You may notice the following effects when you stop taking Fluoxetine Oral Solution: dizziness; tingling sensations 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 their symptoms on stopping Fluoxetine Oral Solution are mild and disappear within a few weeks. If you experience symptoms when you stop treatment, contact your doctor. When stopping Fluoxetine Oral Solution, your doctor will help you to reduce your dose slowly over one or two weeks – this should help reduce the chance of withdrawal effects. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines this medicine can cause side effects although not everybody gets them.

- If you get 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 medicine straight away and tell your doctor immediately
- If you get 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) stop taking the medicine 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 Oral Solution 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.

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 Oral Solution:

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

- difficulty in sleeping (insomnia)
- headache
- diarrhoea, feeling sick (nausea)
- feelings of weakness or tiredness (fatigue)

Common (may affect up to 1 in 10 people)

- not feeling hungry, weight loss
- anxiety, nervousness
- 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 (dysgeusia)
- uncontrollable shaking movements (tremor)
- blurred vision

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- rapid and irregular heartbeat sensations (palpitations)
- flushing
- yawning
- vomiting, indigestion (dyspepsia)
- dry mouth
- rash, urticaria, itching
- excessive sweating
- joint pain (arthralgia)
- passing urine more frequently
- unexplained vaginal bleeding
- feeling shaky or chills

Uncommon (may affect up to 1 in 100 people)

- suicidal thoughts
- 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
- low blood pressure
- shortness of breath
- difficulty swallowing
- hair loss
- increased tendency to bruising
- cold sweat
- difficulty passing urine
- feeling hot or cold
- memory impairment
- ringing in the ears
- nose bleeds
- gastrointestinal bleeding
- feeling unwell

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

- low levels of salt in the blood
- untypical wild behaviour
- hallucinations
- agitation
- panic attacks
- 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
- sensitivity to sunlight
- producing breast milk
- low levels of white blood cells (neutropenia, leucopenia)
- problems urinating
- confusion
- aggression
- stuttering
- muscle pain
- unexplained bruising or bleeding
- lung problems
- injury to the liver
- persistent and usually painful long-lasting erection
- heart problems (including palpitations)
- hypersensitivity reaction such as an itchy rash, joint pain and fever
- hepatitis, abnormal liver function test results

Very rare (May affect up to 1 in 10,000 people)

- reduction in blood platelets, which increases risk of bleeding or bruising

Bone fractures - An increased risk of bone fractures has been observed in patients taking this type of medicine. Most of these side effects are likely to disappear with continued treatment.

Not Known (cannot be estimated from available data)

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

Additional side effects in children and adolescents

In children and adolescents (8-18 years) – In addition to the possible side effects listed above, Fluoxetine Oral Solution may slow growth or possibly delay sexual maturity. Nose bleeds are 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 medicines.

5. HOW TO STORE FLUOXETINE ORAL SOLUTION

Keep all medicines out of the sight and reach of children.

Do not take this medicine after the expiry date shown on the carton. The expiry date is the last day of that month.

Store in the original package in order to protect from light. Do not use this medicine if you notice any signs of damage to the packaging which could affect the medicine.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Fluoxetine Oral Solution contains:

The active substance is fluoxetine (as hydrochloride). Each 5 ml of solution contains 20 mg of fluoxetine (as hydrochloride). The other ingredients are sorbitol liquid, propylene glycol, acesulfame potassium, benzoic acid, peppermint flavour and purified water.

What Fluoxetine Oral Solution looks like and the contents of the pack:

Fluoxetine Oral Solution is a clear colourless liquid with a peppermint flavour. Your medicine is supplied in an amber glass bottle, containing 70 ml of the solution.

Marketing Authorisation Holder:

Kent Pharma UK Limited, The Bower, 4 Roundwood Avenue, Stockley Park, Heathrow, United Kingdom, UB11 1AF.

Manufacturer responsible for batch release:

Kent Pharmaceuticals Limited, Crowbridge Road, Ashford, Kent, TN24 0GR, U.K.
Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

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