### Package leaflet: Information for the user

## Fluoxetine 20 mg/5 ml oral solution

#### Fluoxetine

# 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.

## Important things that you need to know about Fluoxetine 20 mg/5 ml Oral solution:

- Fluoxetine treats depression and anxiety disorders in adults (over 18 years). 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 18. See section 2, Children and adolescents aged 8 to 18 years.
- Tell a close friend or relative that you are taking Fluoxetine and ask them to read this leaflet. Ask them to tell you if they are worried that you are behaving differently whilst you are taking Fluoxetine. It is important that you receive the right treatment and you should see your doctor again if you feel any worse.
- 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 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 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.
- Taking some other medicines with Fluoxetine 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*, inside this leaflet.
- Seek medical help at once if you have difficulty in breathing, swelling of the face, lips, tongue or throat (that causes difficulty in swallowing or breathing), severe itching of the skin (with raised lumps) or fast, irregular heart beat and fainting which could be symptoms of a life-threatening heart condition (see section 4, *Possible side effects*).
- 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*.

Now read the rest of this leaflet. If you have more questions, ask your doctor or pharmacist (chemist). You may also find it helpful to contact a self-help group, or patient organisation, to find out more about your condition. Your doctor will be able to give you details.

#### 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. Content of the pack and other information

#### 1. What is Fluoxetine Oral solution is and what it is used for

Fluoxetine Oral solution contains the active substance fluoxetine which is one of a group of medicines called selective serotonin re-uptake inhibitors (SSRIs) antidepressants.

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 and above:

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 major depressive disorder only in
combination with a psychological therapy.

## **How Fluoxetine Oral solution 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 Oral solution 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.

#### 2. What you need to know before you take Fluoxetine Oral Solution

#### Do not take Fluoxetine Oral Solution if you:

- are allergic to fluoxetine or any of the other ingredients of this medicine (listed in section 6).
- taking other medicines known as irreversible, non-selective monoamine oxidase inhibitors (MAOIs), since serious or even fatal reactions can occur (e.g., iproniazid used to treat depression).
- combined with metoprolol in cardiac failure (see section Other medicines and Fluoxetine Oral Solution)

## Warnings and precautions

Talk to your doctor or pharmacist before taking Fluoxetine Oral Solution if any of the following applies to 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** 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, breast-feeding and fertility')
- are taking diuretics (water tablets) particularly if you are elderly
- ongoing ECT (electroconvulsive therapy)
- glaucoma (increased pressure in the eye)
- are taking medicines that thin the blood (see section Other medicines and Fluoxetine Oral Solution)
- are taking tamoxifen (used to treat breast cancer) (see section Other medicines and Fluoxetine Oral Solution)
- starting to feel restless and cannot sit or stand still (akathisia). Increasing your dose of fluoxetine may make this worse
- 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. You should contact your doctor immediately as treatment with Fluoxetine Oral Solution may need to be discontinued.
- 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).

Medicines like Fluoxetine 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.

Treatment with fluoxetine should only be started 2 weeks after discontinuation of an irreversible, Non-selective MAOI (for instance tranyleypromine).

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

**Do not** take any irreversible, non-selective 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.

#### 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.

#### 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, and if you are a patient under 18 years, your doctor may prescribe Fluoxetine Oral Solution 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 years 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 years 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 or pharmacist if you are taking, have recently taken or might take any other medicines.

Fluoxetine Oral Solution may affect the following medicines work (interaction):

- Metoprolol (for hypertension); there is an increased risk of excessive bradycardia (decrease heart rate).
- Mequitazine (for allergies); there is an increased risk of QT prolongation (abnormal ECG).
- Medicines that may affect the heart's rhythm, e.g. Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazine derviatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine), anti-malaria treatment particularly halofantrine, certain antihistamines (astemizole, mizolastine), because taking one or more of these drugs with Fluoxetine Oral Solution may increase the risk of changes in the electrical activity of the heart
- 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 drugs.
- Lithium, tryptophan, selegiline (MAOI-B); 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 checkups 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, nebivolol or encainide (for heart problems), carbamazepine (for
  epilepsy), atomoxetine or tricyclic antidepressants (for example imipramine, desipramine
  and amitriptyline) or resperidone (for 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.

- Anti-coagulants (such as warfarin), NSAID (such as ibuprofen, diclofenac), aspirin or other
  medicines which can thin the blood (including clozapine, used to treat certain mental
  disorders). Fluoxetine Oral Solution may alter the effect of these medicines on the blood. If
  Fluoxetine Oral Solution 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.
- Tamoxifen (used to treat breast cancer); because Fluoxetine Oral Solution 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 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.
- Cyproheptadine (for allergics); because it may reduce the effect of Fluoxetine Oral Solution.
- 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 Oral Solution. 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 Oral Solution may increase the risk of seizures when taken with these medicines.

#### 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 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.

In babies whose mothers took fluoxetine during the first few months of pregnancy, there have been some studies describing 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.

It is preferable not to use this treatment during pregnancy unless the potential benefit outweighs the potential risk. You and your doctor may decide that it is better for you to gradually stop taking fluoxetine while you are pregnant or before being 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 newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

If you take Fluoxetine Oral Solution 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 Oral Solution so they can advise you.

#### Breast-feeding

Fluoxetine is excreted in breast milk and can cause side effects in babies. You should only breast-feed if it is clearly necessary. If breast-feeding is continued, your doctor may prescribe a lower dose of fluoxetine.

#### **Fertility**

Fluoxetine has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

## Driving and using machines

Psychotropic drug such as Fluoxetine Oral Solution may affect your judgment or co-ordination. Do not drive or use machinery until you know how Fluoxetine Oral Solution affects you.

#### Fluoxetine Oral Solution contains sorbitol and benzoic acid

This medicine contains 1250 mg sorbitol in each 5 mL which is equivalent to 250 mg/mL

This medicine contains 2.5 mg benzoic acid in each 5 mL which is equivalent to 0.5 mg/mL.

#### 3. How to take Fluoxetine Oral Solution

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The label on the carton will tell you how much of the oral solution you should take and when.

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.

#### Adults

The recommended dose is:

<u>Depression:</u> The recommended dose is one 5 ml spoonful (20 mg) 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 5 ml spoonfuls (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 three 5 ml spoonfuls (60 mg) each day.

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

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

Treatment should be started and be supervised by a specialist. The starting dose is 10 mg each day (given as 2.5 ml of Fluoxetine Oral Solution). After 1 to 2 weeks, your doctor may increase the dose to 20 mg each day. The dose should be increased carefully to ensure that you receive the lowest effective dose. Lower weight children may need lower doses. If there is a satisfactory response to treatment, your doctor will review the need for continuing treatment beyond 6 months. If you have not improved within 9 weeks, your doctor will reassess your treatment.

#### **Elderly**

Your doctor will increase the dose with more caution and the daily dose should generally not exceed two 5 ml spoonfuls (40 mg). The maximum dose is three 5 ml spoonfuls (60 mg) 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, 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. Taking your medicine at the same time each day may help you to remember to take it regularly.

#### 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.

Make sure you do not run out of medicine.

You may notice the following effects (withdrawal 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 medicine, 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; 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 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
- **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.

## 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 or painful erection;
- irritability and extreme agitation.
- heart problems, such as fast or irregular heart rate, fainting, collapsing or dizziness upon standing which may indicate abnormal functioning of the heart rate.

### If you have any of the above side effects, you should tell your doctor immediately.

The following side effects have also been reported in patients taking 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
- rapid and irregular heartbeat sensations (palpitations)
- flushing
- yawning
- vomiting, indigestion (dyspepsia)
- · dry mouth
- · rash, urticaria, itching
- excessive sweating
- joint pain (athralgia)
- passing urine more frequently
- unexplained vaginal bleeding
- · feeling shaky or chills

## Uncommon (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
- low blood pressure
- · shortness of breath
- difficulty swallowing
- hair loss
- · increased tendency to bruising
- cold sweat
- · difficulty passing urine
- · feeling hot or cold
- abnormal liver test results
- ringing in the ears (tinnitus)
- memory impairment
- nosebleed (epistaxis)
- · unexplained bruising or bleeding
- thoughts of suicide or harming yourself

### Rare (may affect up to 1 in 1000 people)

- reduction in blood platelets, which increases risk of bleeding or bruising
- Condition in which the number of white blood cells called neutrophils is abnormally low.
- decrease white blood cells (leucopenia)
- · excessive release of antidiuretic hormone
- stuttering
- · aggression
- lung problem
- hepatitis
- Serious illness with blistering of the skin, mouth, eyes and genitals
- persistent erection
- high prolactin levels in the blood
- · difficulty passing urine
- · mucosal bleeding
- · low levels of salt in the blood
- · untypical wild behaviour
- hallucinations
- 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
- · pancreatitis (Inflammation of the pancreas, which causes severe pain in the abdomen and back

## Not known (frequency cannot be estimated from the available data)

 Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy, breastfeeding 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

Most of these side effects are likely to disappear with continued treatment.

In children and adolescents (8-18 years) – In addition to the possible side effects listed above, fluoxetine 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, 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: <a href="https://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a> 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 Oral Solution

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

This medicinal product does not require any special temperature storage conditions.

Store in the original package in order to protect from light.

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

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 to protect the environment.

## 6. Content 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 (E420), 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**

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