Package leaflet: Information for the user

Prozep® 20 mg/5 ml Oral Solution
fluoxetine

EIGHT IMPORTANT THINGS YOU NEED TO KNOW ABOUT PROZEP
Prozep 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.
Prozep is not for use in children and adolescents under 18. See section 2, Children and adolescents aged 8 to 18 years.
Prozep 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 Prozep.
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 Prozep without talking to your doctor. If you stop taking Prozep 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 Prozep may make these feelings worse. See section 4, Possible side-effects.
Taking some other medicines with Prozep can cause problems. You may need to talk to your doctor. See section 2, Taking other medicines.
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.

What is in this leaflet

1. What Prozep is and what it is used for

Prozep contains 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
- Bulimia nervosa: Prozep is 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. Prozep should be offered to a child or young person with moderate to severe major depressive disorder **only** in combination with psychological therapy.

How Prozep 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 Prozep 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 Prozep

Do not take Prozep:
- 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 reactions (like itching, swollen lips or face or shortness of breath), stop taking the oral solution straight away and contact your doctor immediately.**
- if you are 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). Treatment with Prozep 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 Prozep. If Prozep has 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 (to treat heart failure) because there is an increased risk of your heart beat becoming too slow.

Warnings and precautions
Talk to your doctor or pharmacist before taking Prozep if any of the following applies to you:
- heart problems;
- 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 Prozep might need to be discontinued;
- mania now or in the past; if you have a manic episode, contact your doctor immediately because Prozep might need to be discontinued;
- history of bleeding disorders, appearance of bruises or unusual bleeding, or if you are pregnant (see 'Pregnancy');
- ongoing treatment with medicines that thin the blood (see 'Other medicines and Prozep');
- epilepsy or fits. If you have a fit (seizures) or experience an increase in seizure frequency, contact your doctor immediately; Prozep might need to be discontinued;
- ongoing ECT (electro-convulsive therapy);
- ongoing treatment with tamoxifen (used to treat breast cancer) (see 'Other medicines and Prozep');
- starting to feel restless and cannot sit or stand still (akathisia). Increasing your dose of Prozep may make this worse;
- diabetes (your doctor may need to adjust your dose of insulin or other antidiabetic treatment);
- liver problems (your doctor may need to adjust your dosage);
- 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);
- ongoing treatment with diuretics (water tablets), especially if you are elderly;
- glaucoma (increased pressure in the eye).

Medicines like Prozep 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.

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 close friend or relative 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.
Prozep 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 Prozep 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 Prozep 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 Prozep 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 Prozep.
Prozep should not be used in the treatment of children under the age of 8 years.

Other medicines and Prozep
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Some medicines may be affected by Prozep or they may affect how well Prozep will work.
Do not take Prozep with:
- Certain **irreversible, non-selective monoamine oxidase inhibitors (MAOIs),** some used to treat depression. Irreversible, non-selective MAOIs must not be used with Prozep as serious or even fatal reactions (serotonin syndrome) can occur (see section 'Do not take Prozep'). Treatment with Prozep should only be started at least 2 weeks after discontinuation of an irreversible, non-selective MAOI (for instance tranylcypromine). **Do not** take any irreversible, non-selective MAOIs for at least 5 weeks after you stop taking Prozep. If Prozep has 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.
- **metoprolol** when used for heart failure; there is an increased risk of your heart beat becoming too slow.
- **pethidine** (a painkiller) because it increases the risk of serotonin syndrome when taken with Prozep

Prozep may affect the way the following medicines work (interaction):
- **tamoxifen** (used to treat breast cancer); because Prozep 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 methaemogobinaemia) 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** (for allergies); because taking this drug with Prozep may increase the risk of changes in the electrical activity of the heart.
- **phenytoin** (for epilepsy); because Prozep 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 Prozep.
- **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 Prozep. Your doctor will carry out more frequent check-ups.
- medicines that may affect the heart's rhythm, e.g. **Class IA and III antiarrhythmics, anti-psychotics** (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 Prozep 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). Prozep may alter the effect of these medicines on the blood. If Prozep 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 Prozep.
- **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 Prozep.
- **antidepressants** such as tricyclic antidepressants, 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 Prozep 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 Prozep may possibly change the blood levels of these medicines, your doctor may need to lower their dose when administered with Prozep.

Prozep with food, drink and alcohol
You can take Prozep 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 are pregnant, if you might be pregnant, or if you are 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. 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 Prozep while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking Prozep.
When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like fluoxetine may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the new born (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby, you should contact your midwife and/or doctor immediately.
Caution should be exercised when used during pregnancy, especially during late pregnancy or just before giving birth since the following effects have been reported in new born children: irritability, tremor, muscle weakness, persistent crying, and difficulty in sucking or in sleeping.
If you take Prozep 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 Prozep 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 drugs such as Prozep may affect your judgment or co-ordination. Do not drive or use machinery until you know how Prozep affects you.

Prozep contains sorbitol, benzoic acid and castor oil
- **Prozep contains** 2.2 g sorbitol in each 5 ml spoonful of fluoxetine oral solution, which is equivalent to 0.44 g/ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- **Prozep contains** 2.5 mg benzoic acid in each 5ml spoonful of fluoxetine oral solution which is equivalent to 0.5 mg/ml.
- **Prozep contains** 50 mg polyoxyl 40 hydrogenated castor oil in each 5 ml spoonful of fluoxetine oral solution which is equivalent to 10 mg/ml. Castor oil may cause stomach upset and diarrhoea.

3. How to take Prozep

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 medicine than your doctor tells you.

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- Take the solution with or without food, whichever you prefer.
- You should not drink **alcohol** whilst taking this medicine.

Adults

The recommended dose is:

- **Depression:** The recommended dose is 5 ml oral solution (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 15 ml oral solution (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:** The recommended dose is 15 ml oral solution (60 mg) daily.
- **Obsessive-compulsive disorder:** The recommended dose is 5 ml oral solution (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 15 ml oral solution (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/day (given as 2.5 ml Prozep). After 1 to 2 weeks, your doctor may increase the dose to 20 mg/day (5 ml).

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 10 ml oral solution (40 mg). The maximum dose is 15 ml oral solution (60 mg) daily.

Liver impairment

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

If you take more Prozep than you should

- If you take too much, go to your nearest hospital emergency department (or casualty) or tell your doctor straight away.
- Take the bottle of Prozep with you if you can.

Symptoms of overdose include: nausea, vomiting, seizures, heart problems (like irregular heart beat and cardiac arrest), lung problems and change in mental condition ranging from agitation to coma.

If you forget to take Prozep

If you miss a dose, do not worry. Take your next dose the next day 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 Prozep

- **Do not** stop taking Prozep 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 Prozep: dizziness; tingling feelings 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 any symptoms on stopping Prozep are mild and disappear within a few weeks. If you experience symptoms when you stop treatment, contact your doctor.

When stopping Prozep, 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 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 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 Prozep 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 sides effects (very common side effects that may affect more than 1 user in 10) 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.

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 Prozep:

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
- dizziness
- change in taste
- uncontrollable shaking movements
- blurred vision
- rapid and irregular heart-beat sensations
- flushing
- yawning
- indigestion, vomiting
- dry mouth
- rash, urticaria, itching
- excessive sweating
- joint pain
- passing urine more frequently
- unexplained vaginal bleeding
- feeling shaky or chills

Uncommon (may affect up to 1 in 100 people)

- feeling detached from yourself
- strange thinking
- abnormally high mood
- orgasm problems
- thoughts of suicide or harming yourself
- teeth grinding
- muscle twitching, involuntary movements or problems with balance or co-ordination
- memory impairment
- enlarged (dilated) pupils
- ringing in the ears
- low blood pressure
- shortness of breath
- nose bleeds
- difficulty swallowing
- hair loss
- increased tendency to bruising
- unexplained bruising or bleeding
- cold sweat
- difficulty passing urine
- feeling hot or cold
- abnormal liver test results

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

- low levels of salt in the blood
- reduction in blood platelets, which increases risk of bleeding or bruising
- reduction in white blood cell count
- untypical wild behaviour
- hallucinations
- agitation
- panic attacks
- confusion
- stuttering
- aggression
- 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
- hepatitis
- lung problems
- sensitivity to sunlight
- muscle pain
- problems urinating
- producing breast milk

Frequency not known

- 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 medicines.

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

In children and adolescent (8-18 years): In addition to the possible side effects listed above, Prozep 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: 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 Prozep

- Keep this medicine out of the sight and reach of children.
- Do not take this medicine after the expiry date which is stated on the bottle label and on the carton. The expiry date refers to the last day of that month.
- Do not use after one month from first opening the bottle.
- Do not store above 25°C. Store in the original container.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Prozep contains

- The active substance is fluoxetine hydrochloride. Each 5 ml of liquid contains 20 mg fluoxetine (as hydrochloride).
- Other ingredients are: glycerol (E 422), sorbitol (E 420), hydrogenated polyoxyl castor oil, benzoic acid (E 210), peppermint flavour and purified water. (See end of Section 2 for further information on sorbitol, benzoic acid and castor oil).

What Prozep looks like and contents of the pack

Prozep is a clear, colourless liquid with the odour of peppermint.

It is available in amber glass bottles of 70 ml with a tamper evident child resistant closure.

Marketing Authorisation Holder

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