

Package Leaflet: Information for the user

Prozamel 20mg Hard Capsules

Fluoxetine (as hydrochloride)

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 Prozamel Capsules are and what they are used for
2. What you need to know before you take Prozamel Capsules
3. How to take Prozamel Capsules
4. Possible side effects
5. How to store Prozamel Capsules
6. Contents of the pack and other information

1. What Prozamel Capsules are and what they are used for

Prozamel Capsules belong to a group of anti-depressant medicines called selective serotonin reuptake inhibitors (SSRIs). They work by regulating the activity of certain nerves.

Prozamel Capsules are used to treat:

Adults:

- Major depressive episodes (feeling sad, severe enough to affect your daily life or make you consider harming yourself)
- Obsessive-compulsive disorder (OCD). OCD is an anxiety disorder.
- Bulimia nervosa (an eating disorder). Prozamel Capsules are used as an additional treatment besides 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. Prozamel should be offered to a child or young person with moderate to severe major depressive disorder **only** in combination with psychological therapy.

2. What you need to know before you take Prozamel Capsules

Do Not take Prozamel Capsules

- 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 capsules straight away and contact your doctor immediately.**
- if you are taking other medicines, 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 such MAOIs include medicines used to treat depression such as nialamide, iproniazide, moclobemide, phenelzine, tranylcypromine, isocarboxazid, tolloxatone and also linezolid (an antibiotic) and methylthioninium chloride also called methylene blue (used to treat medicinal or chemical induced methaemoglobinemia).

Treatment with Prozamel Capsules should only be started at least 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, linezolid, methylthioninium chloride (methylene blue)). Do not take any MAOIs for at least 5 weeks after you stop taking Prozamel Capsules. If Prozamel 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 (a medicine used in heart failure). The side effects of metoprolol may be increased including slowing your heartbeat excessively.

Warnings and precautions

Talk to your doctor or pharmacist before taking Prozamel Capsules if any of the following applies to you:

- epilepsy or fits. If you have a fit (seizures) or experience an increase in seizure frequency, contact your doctor immediately; Prozamel might need to be discontinued;
- mania now or in the past; if you have a manic episode, contact your doctor immediately because Prozamel might need to be discontinued;
- 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);
- heart problems;
- 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);
- glaucoma (increased pressure in the eye);
- ongoing treatment with diuretics (water tablets), especially if you are elderly;
- ongoing ECT (electro-convulsive therapy);
- history of bleeding disorders. appearance of bruises, unusual bleeding, or if you are pregnant (see ‘Pregnancy, breast-feeding and fertility’)
- ongoing treatment with medicines that thin the blood (see ‘*Other medicines and Prozamel Capsules*’);
- ongoing treatment with tamoxifen (used to treat breast cancer) (see ‘*Other medicines and Prozamel Capsules*’);
- starting to feel restless and cannot sit or stand still (akathisia). Increasing your dose of Prozamel 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; contact your doctor immediately, since Prozamel might need to be discontinued.

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.

Use in children and adolescents under 18 years of age

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. Prozamel 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 Prozamel 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 Prozamel 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 Prozamel 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 Prozamel.

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

Medicines like Prozamel (so called SSRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Other medicines and Prozamel Capsules

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

Prozamel may affect the way some other medicines work (interaction), especially the following:

- Certain **monoamine oxidase inhibitors (MAOIs)**, some used to treat depression. Non-selective MAOIs and MAOIs type A must not be used with Prozamel as serious or even fatal reactions (serotonin syndrome) can occur (see section “*Do not take Prozamel*”). Treatment with Prozamel should only be started at least 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, linezolid, methylthioninium chloride (methylene blue)). Some MAOIs type B (selegiline) can be used with Prozamel provided that your doctor monitors you closely.
- **lithium, tryptophan, opioids (e.g. buprenorphine, tramadol)**; there is an increased risk of serotonin syndrome when these drugs are taken with Prozamel. Your doctor will carry out more frequent check-ups.
- **phenytoin** (for epilepsy); because Prozamel 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 Prozamel.
- **tramadol** (a painkiller) or **triptans** (for migraine); there is an increased risk of hypertension (raised blood pressure).
- medicines that may affect the heart’s rhythm, e.g. **Class IA and III antiarrhythmics, antipsychotics** (e.g. fentiazine derivatives, pimozide, haloperidol), **tricyclic antidepressants**, certain **antimicrobial agents** (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine), anti-malaria treatment particularly halofantrine, certain **antihistamines** (astemizole, mizolastine).
- **flecainide** or **encainide** (for heart problems), **carbamazepine** (for epilepsy), tricyclic antidepressants (for example **imipramine, desipramine** and **amitriptyline**); because Prozamel may possibly change the blood levels of these medicines, your doctor may need to lower their dose when administered with Prozamel.
- **tamoxifen** (used to treat breast cancer), because Prozamel 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.
- **warfarin, NSAID** or other medicines which can thin the blood (including clozapine, used to treat certain mental disorders, and aspirin); Prozamel may alter the effect of these medicines on the blood. If Prozamel treatment is started or stopped when you are taking warfarin, your doctor will need to perform certain tests.

- You should not start to take the herbal remedy **St John's wort** while you are being treated with Prozamel since this may result in an increase in side effects. If you are already taking St John's wort when you start on Prozamel, stop taking St John's wort and tell your doctor at your next visit.

Prozamel Capsules with food and drink

- You can take Prozamel Capsules with or without food, whatever you prefer.
- You should not drink alcohol whilst taking Prozamel Capsules.

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 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 Prozamel while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking Prozamel.

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 newborn children: irritability, tremor, muscle weakness, persistent crying, and difficulty in sucking or in sleeping. If you take Prozamel 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 Prozamel 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

You should avoid driving a car or operating hazardous machinery until you are reasonably certain your performance is not affected. Prozamel Capsules may - as any other psychoactive drug - impair the judgement or skills you require for performing these activities.

Prozamel Capsules contain lactose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Prozamel Capsules

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

You should take Prozamel Capsules with a glass of water. You can take the capsules during or between meals. If you have to take more than one capsule a day, take them all together, in a single dose.

Adults:

Recommended dose

Treatment of major depressive episodes

Adults and the elderly take 20 mg/day to 60 mg/day. A dose of 20 mg/day is recommended as the initial dose. More undesirable effects (see section 4. "Possible side effects") may occur if you take higher doses. However, your doctor may increase the dose after three weeks if you do not respond to the treatment.

Treatment for depression should be continued for at least 6 months.

Treatment of obsessive-compulsive disorder

Adults and the elderly take 20 mg/day to 60 mg/day. A dose of 20 mg/day is recommended as the initial dose. More undesirable effects (see section 4. "Possible side effects") may occur if you take higher doses. However, your doctor may increase the dose after two weeks if you do not respond to treatment.

If your condition does not improve within 10 weeks, your doctor will reconsider whether to continue the treatment with fluoxetine. If you show a good response, your doctor may continue your treatment beyond 10 weeks. Your dose will be adjusted individually so that you receive the lowest effective dose. Periodically your doctor will assess if you need to continue treatment.

Treatment of bulimia nervosa

For adults and the elderly a dose of 60 mg/day is recommended.

For treatment of all the above conditions:

The recommended dose may be increased or decreased. The safety and efficacy of treatment at doses above 80 mg/day has not been thoroughly investigated. High doses will therefore only be prescribed when your doctor considers that the benefits outweigh the risks.

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/day (given as 2.5ml of oral liquid). After one to two weeks, your doctor may increase the dose to 20mg/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 should review the need for continuing treatment beyond 6 months. If you have not improved, your treatment should be reassessed.

Elderly people:

Caution is recommended when increasing the dose and the daily dose should not exceed 40 mg. The maximum recommended dose is 60 mg/day.

Hepatic impairment or patients with other medication which may cause interactions (your doctor will know about these):

Your doctor may prescribe you a lower or less frequent dose.

Renal impairment:

Your doctor may prescribe you a lower or less frequent dose.

If you take more Prozamel Capsules than you should

If you take an overdose of fluoxetine alone, the symptoms are usually mild. Symptoms of overdose include nausea (feeling sick); vomiting; seizures (fits); heart problems, ranging from irregular heartbeat with no symptoms, to a heart attack (cardiac arrest); lungs not working properly (pulmonary dysfunction), which may cause difficulty breathing; central nervous system (CNS) alterations, such as excitation and an altered level of consciousness or loss of consciousness.

Contact your doctor or go to your nearest emergency department if you take more Prozamel Capsules than you should. Your heart and breathing will be monitored and your symptoms will be treated. Fatal overdose is extremely rare when fluoxetine is taken on its own

If you forget to take Prozamel

- 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 Prozamel Capsules

Do not stop taking Prozamel Capsules unless your doctor told you to do so. When stopping treatment, your dose of Prozamel Capsules should be gradually reduced over several weeks or months in order to reduce withdrawal reactions.

You may notice the following effects when you stop taking Prozamel: 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 Prozamel are mild and disappear within a few weeks. If you experience symptoms when you stop treatment, contact your doctor.

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 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 capsules straight away and tell your doctor immediately.**
- If you feel restless and cannot sit or stand still, you may have akathisia; increasing your dose of Prozamel 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 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 Prozamel:

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 heartbeat 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 function 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
- untypical wild behaviour
- hallucinations
- agitation
- panic attacks
- confusion
- stuttering
- 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 (inflammation of the liver)
- lung problems
- sensitivity to sunlight
- muscle pain
- problems urinating
- producing breast milk

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

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

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

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, Prozac 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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Prozac Capsules

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.
- Do not store above 25°C. Store in the original package.
- 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 Prozac contains

The active substance is **fluoxetine** as fluoxetine hydrochloride. Each capsule contains 20 mg fluoxetine.

The other ingredients are

Lactose monohydrate, microcrystalline cellulose, magnesium stearate, colloidal anhydrous silica, gelatin, titanium dioxide (E171), yellow iron oxide (E172), quinoline yellow (E104), indigo carmine (E132).

What Prozamel looks like and contents of the pack

Prozamel 20 mg hard capsules are green in colour and contain a white powder.

Pack sizes: 10, 30 & 100 capsules

Not all pack sizes may be marketed.

Marketing authorisation holder and Manufacturer

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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