

Package leaflet: Information for the user

PROZAC® 20mg hard capsules

fluoxetine (as hydrochloride)

The name of your product is Prozac 20mg hard capsules, but it will be referred to as Prozac throughout this leaflet.

EIGHT IMPORTANT THINGS YOU NEED TO KNOW ABOUT PROZAC

Prozac 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.

Prozac is not for use in children and adolescents under 18. See section 2, *Use in children and adolescents aged 8 to 18 years*.

Prozac 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 Prozac hard capsules*.

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

Taking some other medicines with Prozac 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 and breast-feeding*.

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

1. What Prozac is and what it is used for

Prozac contains fluoxetine which is one of a group of medicines called selective serotonin reuptake inhibitor (SSRI) antidepressants.

This medicine is used to treat the following conditions:

Adults:

- Major depressive episodes
- Obsessive-compulsive disorder
- Bulimia nervosa: Prozac 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. Prozac should be offered to a child or young person with moderate to severe major depressive disorder **only** in combination with psychological therapy.

How Prozac 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 Prozac 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 Prozac

Do not take Prozac 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.**
- taking other medicines, known as nonselective 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, toloxatone and also linezolid (an antibiotic) and methylthionium chloride also called methylene blue (used to treat medicinal or chemical induced methaemoglobinemia).

Treatment with Prozac 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, methylthionium chloride (methylene blue)).

Do not take any MAOIs for at least 5 weeks after you stop taking Prozac. If Prozac has been prescribed for a long period and/or at a high dose, a longer interval needs to be considered by your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Prozac 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; Prozac might need to be discontinued;
- mania now or in the past; if you have a manic episode, contact your doctor immediately because Prozac 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 or appearance of bruises or unusual bleeding;
- ongoing treatment with medicines that thin the blood (see '*Other medicines and Prozac*');
- ongoing treatment with tamoxifen (used to treat breast cancer) (see '*Other medicines and Prozac*');
- starting to feel restless and cannot sit or stand still (akathisia). Increasing your dose of Prozac 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 Prozac 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.

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. Prozac 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 Prozac 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 Prozac 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 Prozac 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 Prozac.

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

Other medicines and Prozac

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

Prozac 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 Prozac as serious or even fatal reactions (serotonin syndrome) can occur (see section '*Do not take Prozac*'). Treatment with Prozac 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, methylthionium chloride (methylene blue)). Some MAOIs type B (selegeline) can be used with Prozac provided that your doctor monitors you closely.
- **lithium, tryptophan**; there is an increased risk of serotonin syndrome when these drugs are taken with Prozac. Your doctor will carry out more frequent check-ups.
- **phenytoin** (for epilepsy); because Prozac 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 Prozac.
- **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), antimalaria 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 Prozac may possibly change the blood levels of these medicines, your doctor may need to lower their dose when administered with Prozac.
- **tamoxifen** (used to treat breast cancer), because Prozac 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); Prozac may alter the effect of these medicines on the blood. If Prozac 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 Prozac since this may result in an increase in side effects. If you are already taking St John's wort when you start on Prozac, stop taking St John's wort and tell your doctor at your next visit.

Prozac with food, drink and alcohol

- You can take Prozac with or without food, whatever you prefer.
- You should avoid alcohol while you are taking this medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Talk to your doctor as soon as possible if you're pregnant, if you might be pregnant, or if you're planning to become pregnant.

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

When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like fluoxetine may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately. Caution should be exercised when used during pregnancy, especially during late pregnancy or just before giving birth since the following effects have been reported in new born children: irritability, tremor, muscle weakness, persistent crying, and difficulty in sucking or in sleeping.

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

Prozac may affect your judgment or co-ordination. Do not drive or use machinery without advice from your doctor or pharmacist.

3. How to take Prozac

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

Swallow the capsules with a drink of water. Do not chew the capsules.

Adults:

The recommended dose is:

- **Depression:** The recommended dose is 1 capsule (20mg) daily. Your doctor will review and adjust your dosage if necessary within 3 to 4 weeks of the start of treatment. If required, the dosage can be gradually increased up to a maximum of 3 capsules (60mg) daily. The dose should be increased carefully to ensure that you receive the lowest effective dose. You may not feel better immediately when you first start taking your medicine for depression. This is usual because an improvement in depressive symptoms may not occur until after the first few weeks. Patients with depression should be treated for at least 6 months.
- **Bulimia nervosa:** The recommended dose is 3 capsules (60mg) daily.
- **Obsessive-compulsive disorder:** The recommended dose is 1 capsule (20mg) daily. Your doctor will review and adjust your dosage if necessary after 2 weeks of treatment. If required, the dosage can be gradually increased up to a maximum of 3 capsules (60mg) 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 10mg/day (given as 2.5ml of Prozac oral liquid). After 1 to 2 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. 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 2 capsules (40mg). The maximum dose is 3 capsules (60mg) daily.

Liver impairment:

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

If you take more Prozac than you should

- If you take too many capsules, go to your nearest hospital emergency department (or casualty) or tell your doctor straight away.
- Take the pack of Prozac 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 Prozac

- 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 Prozac

- **Do not** stop taking Prozac 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 capsules.

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

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
- lung problems
- sensitivity to sunlight
- muscle pain
- problems urinating
- producing breast milk

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 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 HPRA 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

Keep out of the sight and reach of children.

Do not take Prozac after the expiry date which is stated on the pack.

Do not store your capsules above 30°C.

If you have any other questions please talk to your doctor or pharmacist.

If your doctor decides to stop treatment, return any left-over capsules to a pharmacist. Only keep them if your doctor tells you to.

Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

6. Contents of the pack and other information

What Prozac contains

The **active substance** is fluoxetine hydrochloride. Each capsule of Prozac contains 20mg fluoxetine (as hydrochloride). **Other ingredients** inside the capsule are: maize starch flowable and dimeticone. The capsule shell is made of gelatin, patent blue V (E131), yellow iron oxide (E172), titanium dioxide (E171) and black edible printing ink which contains shellac and black iron oxide (E172).

What Prozac looks like and contents of the pack

Prozac is a hard capsule. The capsules are yellow and green, marked with 'Lilly 3105'. They are available in PVC/aluminium blister packs of 30 capsules.

Manufactured by: Patheon France, 40, boulevard de Champaret, 38300 Bourgoin-Jallieu, France.

Procured from within the EU and repackaged by PPA Holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 ONU, UK.

PROZAC® 20mg hard capsules, PPA No: 1328/32/1

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