

PROZAC[®] CAPSULE

Fluoxetine (20mg)

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What Prozac is used for

Depression: Prozac is indicated for the treatment of the symptoms of depressive illness, with or without associated anxiety symptoms.

Obsessive-compulsive disorder, which is anxiety disorder characterised by recurrent, unwanted thoughts (obsessions) and/or repetitive behaviours (compulsion).

Pre-menstrual Dysphoric Disorder (PMDD), a severe form of premenstrual syndrome that affects a woman's daily activities and relationship with others before menstruation.

How Prozac works

Prozac 20 mg hard capsules contains the active substance fluoxetine, which is one of a group of medicines called selective serotonin re-uptake inhibitors (SSRI) antidepressants. It is not fully understood how Prozac and other SSRIs work, but they may help by increasing the level of serotonin in the brain which are involved in controlling mood.

Before you use Prozac

- When you must not use it

Do not take Prozac if you are:

- allergic to fluoxetine or any of the other ingredients of this medicine (see **Product description**).

- taking other medicines known as monoamine oxidase inhibitors (MAOIs), since serious or fatal reaction (e.g. serotonin syndrome, see **Side effect**) can occur. Examples of MAOIs include medicines used to treat:
 - depression (such as nialamide, iproniazide and moclobemide),
 - infections (such as linezolid)
 - a blood disorder called methaemoglobinaemia (high levels of altered forms of haemoglobin in the blood) (such as methylene blue).

Treatment with Prozac should only be started at least 2 weeks after discontinuation of MAOI or reversible MAOI (RIMA).

Do not take any MAOIs or RIMAs 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.

- Before you start to use it

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- Greater severity of depression
- thoughts of death
- a history of seizures
- mania in the past; if you have a manic episode (feeling elated or over-excited, which causes unusual behaviour), contact your doctor immediately
- liver problems (your doctor may need to adjust your dosage);
- diabetes
- glaucoma (increase pressure in the eye);
- history of bleeding disorders or appearance of bruises or unusual bleeding, or if you are pregnant (see 'Pregnancy')

Pregnancy, breast-feeding and fertility

Pregnancy

Do not take this medicine whilst pregnant or plan to become pregnant until you and your doctor have discussed the risks and benefits involved.

If you take Prozac 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 Prozac so they can advise you.

Breast-feeding

Fluoxetine is excreted in breast milk and may cause side effects in babies. Do not take this medicine whilst breast-feeding until you and your doctor have discussed the risks and benefits involved.

Fertility

It is not known how Prozac impacts fertility.

- Taking other medicines

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 **MAOIs** (see also When you must not use it)
- **lithium, tryptophan**; there is an increased risk of serotonin syndrome (see **Side effects**) 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

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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)
- **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.
- **warfarin**, or medicines known to affect platelet function (including clozapine [used to treat certain mental disorders,] aspirin and NSAIDs); 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.

Ask your doctor or pharmacist if you are not sure if you have been taking one of these medicines above.

Do not start taking any other medicines for depression without first checking with your doctor. Do this even if you have already stopped taking Prozac.

How to use Prozac

- How much to use

Depression, with or without associated anxiety symptoms - adults and the elderly: A dose of 20 mg/day is recommended as the initial dose.

Obsessive-compulsive disorder – adults and the elderly: 20 mg/day to

60 mg/day. A dose of 20 mg/day is recommended as the initial dose. Although there may be an increased potential for side-effects at higher doses, a dose increase may be considered after several weeks if there is no response.

Pre-menstrual Dysphoric Disorder (PMDD): a dose of 20 mg per day is recommended. Initial treatment should be limited to 6 months, after which patients should be reassessed regarding the benefit of continued therapy.

The use of Prozac in children and adolescents (under the age of 18) is not recommended (see under Things to be careful of).

- When to use it

Use as directed by your doctor or pharmacist.

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.

- How long to use it

Continue taking Prozac for as long as your doctor recommends.

- If you forget to use it

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 use too much (overdose)

- If you take too many capsules, go to your nearest hospital emergency department (or 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.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Prozac.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- 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.

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If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- *Things to be careful of*

Talk to your doctor or pharmacist while 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;
- history of bleeding disorders or appearance of bruises or unusual bleeding, or if you are pregnant (see '*Pregnancy, breast feeding and fertility*'), diabetes (your doctor may need to adjust your dose of insulin or other antidiabetic treatment);
- heart problems;
- ongoing ECT (electro-convulsive therapy);
- appearance of bruises or unusual bleeding;
- ongoing treatment with medicines that thin the blood (see *Taking other medicines*);
- 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 (see under **Side effect**). Contact your doctor immediately as Prozac may 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 behavior 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 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 behavior 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.

Prozac may slow growth or possibly delay sexual maturity.

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 18 are taking Prozac.

Sexual dysfunction

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

Driving and using machines

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

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 also *Things to be careful of*)
- 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.

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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.

Common (may affect up to 1 in 10 people)

- Not feeling hungry and weight loss.
 - Nervousness and anxiety.
 - Restlessness and 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 and vomiting.
 - Dry mouth.
 - Rash, urticaria, and itching.
 - Excessive sweating.
 - Joint pain.
 - Passing urine more frequently.
 - Unexplained vaginal bleeding.
- Feeling shaky or chills.
- Some patients have had;(uncommon -may affect up to 1 in 100 people):
- a combination of symptoms (known as “**serotonin syndrome**”) including unexplained fever with faster breathing or heart rate, sweating, muscle stiffness or tremor or sleepiness (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.

- Feeling detached from yourself
 - Strange thinking
 - Abnormally high mood
 - Sexual problems, including orgasm problems, occasionally persisting after treatment discontinuation
 - 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
- Not known** (cannot be estimated from the available data)
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see “Pregnancy, breast-feeding and lactation” for more information.

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

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Prozac

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required, these measures will help to protect the environment.

Product Description

- What it looks like

Prozac is a hard capsule. The capsules are yellow and green, and marked ‘Lilly 3105’. The capsules are available in PVC/aluminium blister packs of 28.

- Ingredients

- Active ingredient

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The active substance is fluoxetine hydrochloride. Each capsule contains 20 milligram (mg) of fluoxetine (as fluoxetine hydrochloride)

- Inactive ingredients

Maize starch flowable and dimethicone.

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, black iron oxide (E172), propylene glycol and may contain ammonium hydroxide and potassium hydroxide.

- MAL number:

MAL07031127ACSZ

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Product Registration Holder

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