

Eli Lilly (SA) (Pty) Ltd
Product name: PROZAC 20
Dosage form; Strength: Capsule; Fluoxetine 20 mg

Date: 17 January 2022
Reference: PU3105_ZA_PIL_v01_MTC

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

PROZAC 20 (20 mg capsules)

Fluoxetine

Sugar free

Read all of this leaflet carefully before you start taking PROZAC 20

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PROZAC 20 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What PROZAC 20 is and what it is used for
2. What you need to know before you take PROZAC 20
3. How to take PROZAC 20
4. Possible side effects
5. How to store PROZAC 20
6. Contents of the pack and other information

1. What PROZAC 20 is and what it is used for

PROZAC 20 capsules contain the active substance fluoxetine which is one of a group of medicines called selective serotonin re-uptake inhibitors (SSRI) antidepressants.

PROZAC 20 is used for the treatment of:

- Major depressive disorder
- Bulimia nervosa
- Obsessive-compulsive disorder

2. What you need to know before you take PROZAC 20

Do not take PROZAC 20:

- If you are hypersensitive (allergic) to fluoxetine or any of the other ingredients of PROZAC 20 (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 suffer from severe kidney failure.
- If you are taking linezolid, an antibiotic.
- If you are taking metoprolol (a medicine used in heart failure)
- If you are taking pimozide (a medicine used in Tourette's syndrome).
- If you are taking other medicines known as monoamine oxidase inhibitors (MAOI) since serious or even fatal reactions can occur. Treatment with PROZAC 20 should only be started at least 2 weeks after stopping the MAOI.

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Do not take any MAOIs for at least 5 weeks after you stop taking PROZAC 20. If PROZAC 20 has been prescribed for a long period and/or at a high dose, a longer interval needs to be considered by your doctor.

Usage in the elderly: If you are elderly and have other illnesses or you are receiving other medicines for other illnesses then PROZAC 20 must be used with caution.

Dosages over 20 mg per day are not recommended.

Warnings and precautions

Take special care with PROZAC 20:

- If you have 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. In that time 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.

- If you start feeling restless and cannot sit or stand still (akathisia), contact your doctor or pharmacist.
- If you develop 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”. Although this syndrome occurs rarely, it may result in potentially life-threatening conditions. Contact your doctor immediately if this occurs, as your treatment with PROZAC 20 will need to be stopped.
- 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 suffer from epilepsy or fits. If you have a fit (seizures) or experience an increase in seizure frequency, contact your doctor immediately; PROZAC 20 might need to be stopped.
- Tell your doctor if you suffer from kidney disease, liver disease or heart disease as your dose of PROZAC 20 may need adjustment.
- Tell your doctor if you have diabetes as your doctor may need to adjust your dose of insulin or other anti-diabetic treatment.
- PROZAC 20 may cause weight loss, which could be undesirable in underweight depressed patients.
- Tell your doctor if you have a history of bleeding disorders or appearance of bruises or unusual bleeding.
- Tell your doctor if you are at risk of glaucoma (increased pressure in the eye).

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- Tell your doctor if you are taking any medicine that thins the blood.
- Tell your doctor if you are having ECT (electro-convulsive therapy).
- Tell your doctor if you are having treatment with tamoxifen used to treat breast cancer.
- Tell your doctor if you have mania now or in the past; if you have a manic episode, contact your doctor immediately because PROZAC 20 may need to be discontinued.

Sexual dysfunction

Medicines like PROZAC 20 (so called SSRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Children and adolescents

Safety and efficacy of PROZAC 20 in children below 18 years of age have not been established.

Other medicines and PROZAC 20

Always tell your health care provider if you are taking any other medicines (this includes complementary or traditional medicines).

Do not take PROZAC 20 with:

- Certain monoamine oxidase inhibitors (MAOIs), some used to treat depression. If used with PROZAC 20 may cause serious or even fatal reactions (serotonin syndrome) can occur. Treatment with PROZAC 20 should only be started at least 2 weeks after you stop taking a MAOI.

Do not take any irreversible, non-selective MAOIs for at least 5 weeks after you stop taking PROZAC 20. If PROZAC 20 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 heartbeat becoming too slow.

PROZAC 20 may affect the way some other medicines work (interaction), especially with the following:

- Lithium, there is an increased risk of serotonin syndrome when lithium is taken with PROZAC 20.
- Use of other medicines with serotonergic activity (e.g. Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs), other Selective Serotonin Reuptake Inhibitors (SSRIs), such as triptans, tryptophane, selegiline, St. John's Wort or tramadol) may result in serotonin syndrome.
- When taking other medicines such as phenytoin, carbamazepine, haloperidol, clozapine, diazepam, alprazolam, imipramine and desipramine changes in blood levels have been observed.
- If you are taking tryptophan, you may experience agitation, restlessness and stomach distress.
- Anti-coagulants (such as warfarin), Non-Steroidal Anti-inflammatory, NSAID (such as ibuprofen, diclofenac), aspirin and other medicines which can thin the blood. PROZAC 20 may alter the effect of these medicines on the blood. If PROZAC 20 treatment is started or stopped

when you are taking warfarin, your doctor will need to perform certain tests, adjust your dose and check on you more frequently.

- Tamoxifen (used to treat breast cancer); because PROZAC 20 may change the blood levels of this medicine, resulting in the possibility of a reduction in the effect of tamoxifen, your doctor may need to consider prescribing a different antidepressant treatment.
- Medicines that may affect the heart's rhythm, e.g. Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial medicines (e.g. moxifloxacin, erythromycin IV, pentamidine), anti-malaria treatment particularly halofantrine or certain antihistamines (astemizole, mizolastine), because taking one or more of these medicines with PROZAC 20 may increase the risk of changes in the electrical activity of the heart.
- Cyproheptadine (for allergies); because it may reduce the effect of PROZAC 20.
- Medicines that lower sodium levels in the blood (including, drug that causes increase in urination, desmopressin, carbamazepine and oxcarbazepine); because these medicines may increase the risk of sodium levels in the blood becoming too low when taken with PROZAC 20.
- Anti-depressants such as tricyclic anti-depressants, other selective serotonin reuptake inhibitors (SSRIs) or bupropion, mefloquine or chloroquine (used to treat malaria), tramadol (used to treat severe pain) or anti-psychotics such as phenothiazines or butyrophenones; because PROZAC 20 may increase the risk of seizures when taken with these medicines.

PROZAC 20 with food, drink and alcohol:

- You can take PROZAC 20 with or without food.
- You should avoid alcohol while you are taking PROZAC 20.

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Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy

Safety in pregnancy has not been established.

PROZAC 20 use should be considered during pregnancy only if the potential benefit justifies the potential risk to the foetus, taking into account the risks of untreated depression.

If you take PROZAC 20 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 20 so they can advise you.

In babies whose mothers took fluoxetine, as in PROZAC 20, during the first few months of pregnancy, there have been some studies describing an increased risk of birth defects affecting the heart.

When taken during pregnancy, particularly in the last 3 months of pregnancy, PROZAC 20 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.

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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.

Breastfeeding

The safety of PROZAC 20 has not been established in breastfeeding women.

PROZAC 20 is excreted in human breast milk and can cause side effects in babies. You should only breastfeed if it is clearly necessary. If breastfeeding is continued, your doctor may prescribe a lower dose of PROZAC 20.

Fertility

Fluoxetine, as in PROZAC 20, 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 machinery

- PROZAC 20 may affect your judgment and/or co-ordination.
- Do not drive or use machinery if you experience any side effects that may affect your ability to do so.

It is not always possible to predict to what extent PROZAC 20 may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PROZAC 20 affects them.

3. How to take PROZAC 20

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Do not share medicines prescribed for you with any other person.

Always take PROZAC 20 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

PROZAC 20 is for oral use in adults only.

- **Major depressive disorder:** Adults and elderly: A dose of 20 mg/day is recommended, preferably in the morning.
- **Bulimia nervosa:** A dose of 60 mg/day is recommended.
- **Obsessive-compulsive disorder:** A dose of 20 to 60 mg/day is recommended.

Your doctor will tell you how much PROZAC 20 you need and how long your treatment will last.

Your doctor may increase or decrease your dose.

If you have the impression that the effect of PROZAC 20 is too strong or too weak, tell your doctor or pharmacist.

PROZAC 20 capsules are not suitable for increasing or decreasing your dose by titration in small dose quantities.

Concurrent disease: A lower or less frequent dose will be given to you if you suffer from liver disease or other diseases.

If you take more PROZAC 20 than you should

- In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take the pack of PROZAC 20 with you.

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

If you forget to use PROZAC 20

- If you miss a dose, take your next dose the next day at the usual time.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking PROZAC 20

- Do not stop taking PROZAC 20 without asking your doctor first, even when you start to feel better. It is important that you keep taking PROZAC 20.
- Stopping your treatment with PROZAC 20 may lead to the following effects (withdrawal symptoms), such as dizziness, paraesthesia (an unusual or unexplained tingling, pricking, or burning sensation on the skin), headache, inability to sleep, tremor, confusion, sensory disturbances, unusual tiredness or weakness, agitation, anxiety and nausea.
- When stopping PROZAC 20, 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

PROZAC 20 can have side effects.

Not all side effects reported for PROZAC 20 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PROZAC 20, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking PROZAC 20 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- If you have thoughts of harming or killing yourself at any time.
- If you get a rash or allergic reaction such as itching, swollen lips/tongue or wheezing/shortness of breath.

These are all very serious side effects. If you have them, you may have had a serious reaction to PROZAC 20. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- If you feel restless and cannot sit or stand still, you may have akathisia; increasing your dose of PROZAC 20 may make you feel worse.
- If your skin starts to turn red or you develop a skin reaction, or your skin starts to blister or peel.
- 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;
- Feelings of weakness, drowsiness or confusion mostly in elderly people;
- 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;

These are all serious side effects. You may need urgent medical attention.

The following side effects have also been reported in patients taking PROZAC 20:

Frequent side effects:

- Insomnia
- Memory impairment
- Headache
- Diarrhoea, feeling sick (nausea)
- Fatigue
- 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

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- Rash, urticaria, itching
- Excessive sweating
- Joint pain
- Passing urine more frequently
- Unexplained vaginal bleeding
- Feeling shaky or chills
- Ear pain
- Weight gain

Less frequent side effects:

- 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
- Enlarged (dilated) pupils
- Ringing in the ears
- Low blood pressure
- Shortness of breath
- Nose bleeds
- Difficulty swallowing
- Hair loss

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- Increased tendency to bruising
- Unexplained bruising or bleeding
- Cold sweat
- Difficulty passing urine
- Feeling hot or cold
- Liver disease, abnormal liver function test results
- 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
- Fits (seizures)
- 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

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- Producing breast milk

Frequency unknown side effects:

- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see “*Pregnancy*”, in section 2 for more information.
- Bone fracture

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. Alternatively, report suspected adverse events to the company at ade_za@lilly.com. By reporting side effects, you can help provide more information on the safety of PROZAC 20.

5. How to store PROZAC 20

Store all medicines out of reach of children.

Store at or below 30 °C in blister packs. Protect from light.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PROZAC 20 contains

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

The other ingredients are starch flowable powder and dimeticone.

The capsule shell is made of gelatin, patent blue V, yellow iron oxide, titanium dioxide.

What PROZAC 20 looks like and contents of the pack

- PROZAC 20 capsule is a size 3 capsule with an opaque green cap and an opaque off white body imprinted with Lilly and 3105.
- PROZAC 20 capsules are supplied in blister packs of 30.

Holder of Certificate of Registration

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