

Scheduling Status:

S5

MODIPRAN 20 CAPSULES

Fluoxetine hydrochloride

Sugar free.

Read all of this leaflet carefully before you start taking MODIPRAN 20 CAPSULES.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MODIPRAN 20 CAPSULES 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 MODIPRAN 20 CAPSULES is and what it is used for
2. What you need to know before you take MODIPRAN 20 CAPSULES
3. How to take MODIPRAN 20 CAPSULES
4. Possible side effects
5. How to store MODIPRAN 20 CAPSULES
6. Contents of the pack and other information.

1. What MODIPRAN 20 CAPSULES is and what it is used for:

MODIPRAN 20 CAPSULES contains fluoxetine, which belongs to a group of medicines called antidepressants.

MODIPRAN 20 CAPSULES is used for the treatment of:

- Major depressive disorders.
- Obsessive-compulsive disorder.
- An eating disorder called bulimia nervosa.

2. What you need to know before you take MODIPRAN 20 CAPSULES:

Do not take MODIPRAN 20 CAPSULES:

- If you are hypersensitive (allergic) to fluoxetine or any of the other ingredients of MODIPRAN 20 CAPSULES (listed in section 6).
- If you suffer from severe kidney failure.
- If you are on antidepressant medicine called monoamine oxidase inhibitors (MAOIs), e.g. phenelzine, tranylcypromine and selegiline, since serious or even fatal reactions may occur. Treatment with MODIPRAN 20 CAPSULES should only be started at least 2 weeks after stopping the MAOI. Do not take any MAOIs for at least 5 weeks after you stop taking MODIPRAN 20 CAPSULES. If MODIPRAN 20 CAPSULES 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 linezolid (an antibiotic used to treat bacterial infections).
- 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 or your child is younger than 18 years of age.

Warnings and precautions:

Take special care with MODIPRAN 20 CAPSULES:

- Stop taking MODIPRAN 20 CAPSULES if you experience a combination of the following symptoms: muscle spasms, muscle stiffness, irritability, agitation, sweating, diarrhoea, confusion, disorientation, unusually increased reflexes, tremor, rigidity, incoordination and fever. These symptoms could be indicative of a potentially life-threatening condition called serotonin syndrome.
- Treatment with MODIPRAN 20 CAPSULES should be discontinued if you develop a rash or allergic reaction (characterised by itching, swollen lips or face or shortness of breath).
- If you experience worsening of your depression and/or the emergence of suicidal ideation and behaviour, immediately inform your doctor.
- 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 younger than 25 years with psychiatric conditions who were treated with an antidepressant (see "Thoughts of suicide and worsening of your depression or anxiety disorder").
- If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away (see "Thoughts of suicide and worsening of your depression or anxiety disorder").
- If you suffer from any heart dysfunction.
- Do not stop taking your medicine without consulting your doctor. The frequency of taking MODIPRAN 20 CAPSULES should be decreased slowly.

Inform your doctor of any of the following:

- If you suffer from epilepsy or fits. Treatment with MODIPRAN 20 CAPSULES should be stopped if seizures occur for the first time, or if there is an increase in the seizure frequency (if you have a previous

diagnosis of epilepsy). You should not take MODIPRAN 20 CAPSULES if you have unstable epilepsy. If your epilepsy is controlled, your doctor should monitor you carefully.

- If you are receiving electroconvulsive therapy (ECT).
- If you suffer from any liver or kidney disease.
- If you are underweight.
- If you suffer from high blood sugar. MODIPRAN 20 CAPSULES may alter your blood sugar levels. Your doctor may need to adjust your dose of insulin or other antidiabetic medicine.
- If you have a history of bleeding disorders or you develop unusual bruising and purple or red-brown spots (pin-point bleeds) visible through the skin or bleeding from any other part of the body, or if you are pregnant (see “Pregnancy and breastfeeding”).
- If you are taking any medicine that thins your blood (see “Other medicines and MODIPRAN 20 CAPSULES”).
- If you are starting to feel restless and cannot sit or stand still (akathisia). Increasing your dose of MODIPRAN 20 CAPSULES may make this worse.
- If you suffer from Parkinson’s disease.
- If you suffer from glaucoma (increased pressure in your eye).
- If you have a history of mental illness known as mania or hypomania. Treatment with MODIPRAN 20 CAPSULES should be stopped if you enter a manic phase (characterised by unusual and rapid changing ideas or inappropriate happiness and excessive physical activity).
- If you are taking tamoxifen (a medicine used to treat breast cancer).

MODIPRAN 20 CAPSULES 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 you first start taking antidepressants. These medicines usually take about two weeks or sometimes longer to work. In that time, you may be more likely to think like this. 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.

Other medicines and MODIPRAN 20 CAPSULES

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

Do not take MODIPRAN 20 CAPSULES with:

- MAOIs e.g. phenelzine, tranylcypromine and selegiline (used to treat depression). MODIPRAN 20 CAPSULES should only be started at least 2 weeks after stopping an irreversible, non-selective MAOI. Do not take any irreversible non-selective MAOIs for at least 5 weeks after you stopped taking MODIPRAN 20 CAPSULES.
- Metoprolol (a medicine used to treat high blood pressure, heart failure and angina).

Tell your doctor if you are taking:

- Tamoxifen or vinblastine (used to treat breast cancer).
- Mequitazine, cyproheptadine (antihistamines used for allergies).
- Medicines with serotonergic activity (e.g. SNRIs and other SSRIs, such as lithium (used for mental illness), tramadol (used for pain relief), triptans (used for migraine or cluster headaches), tryptophan (an amino acid), selegiline (used for Parkinson's disease) or the St John's wort (*Hypericum perforatum*) (a complementary medicines used to treat depression).
- Antiepileptic medicine (phenytoin, carbamazepine, oxcarbazepine), medicine used to treat anxiety disorders (diazepam, alprazolam), medicine used to treat psychiatric disorders (haloperidol, clozapine) and antidepressants (imipramine and desipramine).
- Buprenorphine and opioids (used for pain management).
- Medicines that may affect the rhythm of your heart, e.g. class IA and III antiarrhythmic medicines, antipsychotic medicines (e.g. phenothiazine derivatives, pimozide), tricyclic antidepressants (TCAs), certain antimicrobial medicines (e.g. sparfloxacin, moxifloxacin, intravenous erythromycin, pentamidine, used to treat bacterial infections), antimalaria treatment (particularly halofantrine, used to treat malaria) or certain antihistamines (astemizole, mizolastine, used to treat allergies).
- Digoxin (heart medicine used to treat heart failure).
- Medicines that have a blood thinning effect e.g. warfarin, nonsteroidal anti-inflammatory drugs (NSAIDs, e.g. ibuprofen) or aspirin.
- Diuretics (used to treat high blood pressure and reduce water retention in your body).
- Desmopressin (used to reduce the amount of urine produced by your kidneys).
- Mefloquine, chloroquine (used to prevent or treat malaria).
- Bupropion (used to assist smoking cessation).

- A group of medicines known as butyrophenones, e.g. benperidol (used to treat psychiatric disorders).
- Propafenone, flecainide, encainide (used to treat heart problems).
- Nebivolol (used to treat high blood pressure).
- Atomoxetine (used to treat attention deficit hyperactivity disorder (ADHD)).
- Risperidone (used to treat mental disorders).

MODIPRAN 20 CAPSULES with food, drink and alcohol

See section 3. Avoid the use of alcohol while taking MODIPRAN 20 CAPSULES.

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 MODIPRAN 20 CAPSULES.

The safe use of MODIPRAN 20 CAPSULES during pregnancy and breastfeeding has not been established.

MODIPRAN 20 CAPSULES is excreted into human breast milk and can cause side effects in babies.

MODIPRAN 20 CAPSULES may affect the quality of your sperm if you are male. This could affect fertility but the impact on human fertility has not been observed so far.

Driving and using machines

MODIPRAN 20 CAPSULES may impair your ability to perform activities requiring mental alertness or physical coordination such as operating machines or driving a vehicle. Caution is advised while taking MODIPRAN 20 CAPSULES. You should not drive or operate machines until you are aware of the measure to which MODIPRAN 20 CAPSULES affects you.

3. How to take MODIPRAN 20 CAPSULES

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

Always take MODIPRAN 20 CAPSULES exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Major depressive disorders:

Adults and elderly patients: 20 mg daily, preferably in the morning.

Obsessive-compulsive disorder:

Adults: 20 mg – 60 mg daily.

Bulimia nervosa (eating disorder):

Adults: 60 mg daily.

Caution is advised in elderly: dosages above 20 mg daily are not recommended.

Hepatic/concurrent diseases:

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

Your doctor will tell you how long your treatment with MODIPRAN 20 CAPSULES will last. If you have the impression that the effect of MODIPRAN 20 CAPSULES is too strong or too weak, tell your doctor or pharmacist.

Your doctor will help you when you need to change your dose. The dose should be increased/decreased 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.

If you take more MODIPRAN 20 CAPSULES than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms of overdose include heart problems (such as an irregular heartbeat and heart attack), lung problems, drowsiness, tremor, rapid, uncontrollable movements of the eyes, nausea, vomiting, agitation, restlessness, seizures and signs of altered central nervous system status ranging from excitation to coma.

If you forget to take MODIPRAN 20 CAPSULES

Do not take a double dose to make up for the forgotten individual doses. Continue to take the next dose at the usual time. If you have trouble remembering when to take MODIPRAN 20 CAPSULES, ask your pharmacist for some hints.

DO NOT STOP TAKING MODIPRAN 20 CAPSULES WITHOUT CONSULTING YOUR DOCTOR.

If you stop taking MODIPRAN 20 CAPSULES

Do not stop taking MODIPRAN 20 CAPSULES without asking your doctor first, even when you start to feel better. It is important that you keep taking MODIPRAN 20 CAPSULES. Make sure you do not run out of capsules.

You may notice the following effects (withdrawal symptoms) when you stop taking MODIPRAN 20 CAPSULES: Dizziness; tingling feelings like pins and needles; headache; sleep disturbances (intense dreams, inability to sleep); unusual tiredness or weakness; tremor (shakiness); feeling confused; feeling agitated; feeling anxious; nausea/vomiting (feeling sick or being sick).

When stopping MODIPRAN 20 CAPSULES, your doctor will help you to reduce your dose slowly over one or two weeks – this should help reduce the chance of withdrawal effects. Most people find that any symptoms on stopping MODIPRAN 20 CAPSULES are mild and disappear within a few weeks.

4. Possible side effects:

MODIPRAN 20 CAPSULES can have side effects.

Not all side effects reported for MODIPRAN 20 CAPSULES are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MODIPRAN 20 CAPSULES, please consult your health care provider for advice.

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

- Swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to MODIPRAN 20 CAPSULES. 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:

- Suicidal behaviour (thoughts of suicide or harming yourself) (see section 2).
- A reaction to the medicine causing increased levels of serotonin in your body known as serotonin syndrome (including unexplained fever with faster breathing or heart rate, sweating, muscle stiffness or tremor, confusion, extreme agitation or sleepiness (see section 2)).
- Unexplained bleeding or bruising more easily than normal.
- Frequent infections, such as fever, severe chills, sore throat or mouth ulcers.
- Stroke. Symptoms can include collapse, numbness or weakness of the arms or legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech and loss of speech.
- Inappropriate antidiuretic hormone secretion (a condition where your body retains too much water, resulting in weakness, drowsiness, nausea and vomiting, cramps or tremors, confusion or coma).
- Fits (seizures).
- Changes in the way your heart beats, for example, if you notice it beating faster than normal or skipping beats.

- Lung problems, including inflammation of your lungs and fibrosis (scarring or thickening of lung tissue) characterised by troubled breathing, shortness of breath, a dry cough, fatigue, unexplained weight loss, aching muscles and joints.
- Bleeding inside of your stomach or intestines (including bleeding gums, vomiting blood, blood in your stool or the passage of black, tarry stools).
- Hepatitis (inflammation of your liver characterised by yellowing of your skin or whites of the eyes, tiredness and pain in your stomach area).
- Irregular or prolonged vaginal bleeding.
- Heavy vaginal bleeding shortly after giving birth (postpartum haemorrhage) (see section 2, “Pregnancy, breastfeeding and fertility”).
- Persistent, painful erection.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Not feeling hungry, weight loss.
- Trouble sleeping, abnormal dreams (including nightmares), having difficulty falling asleep.
- Feeling nervous, anxious or tense.
- Decreased or loss of sex drive (libido).
- Headache.
- Poor concentration.
- Dizziness.
- Change in taste.
- Feeling tired or sleepy.
- Shaking or tremors.
- Blurred vision.
- Flushing (blushing/redness of your skin).
- Increased yawning.
- Diarrhoea, nausea (feeling sick), vomiting (being sick), indigestion, dry mouth.

- Excessive sweating.
- Joint pain.
- Frequent, abnormal urination.
- Sexual problems (including difficulty in maintaining an erection for sexual activity), orgasm problems.
- Feeling shaky or having chills.

Less frequent side effects:

- Low sodium levels in your blood, characterised by muscle weakness, spasms or cramps.
- Feeling detached from yourself, abnormal thinking, elevated mood, hallucinations (seeing, feeling or hearing things that are not real), feeling agitated, panic attacks, feeling confused, stuttering, feeling aggressive.
- Grinding or clenching your teeth.
- Feeling restless or having difficulty sitting still, uncontrollable twitching, jerking or writhing movements, problems with balance or coordination.
- Memory loss or memory problems.
- Enlarged (dilated) pupils.
- Buzzing, hissing, whistling, ringing or other persistent noise in the ears.
- Low blood pressure.
- Inflammation of your blood vessels (characterised by redness, swelling of the affected area, general aches and pains).
- Widening of your blood vessels usually near the surface of your skin, leading to increased blood flow with flushing or warmth.
- Nosebleeds.
- Sore throat (pharyngitis).
- Difficulty swallowing, pain in the tube connecting your mouth and your stomach (oesophageal pain).
- Unusual hair loss or thinning.
- Cold sweat, feeling hot or cold.
- Sensitivity to sunlight.
- Muscle pain, muscle tenderness or weakness, not caused by exercise.

- Inability to urinate, passing urine more frequently, painful urination.
- High prolactin levels in your blood and unusual secretion of breast milk.
- Feeling abnormal, generally unwell or overall weak.
- Abnormal liver function test results.

Side effects with unknown frequency:

- An underactive thyroid gland, causing a decrease in metabolism. Symptoms include feeling tired and lethargic, muscle weakness, cramps, feeling cold, a slow heart rate, dry and flaky skin, hair loss, a deep and husky voice and weight gain.
- Visual disturbances.
- Bone fractures.
- Abdominal pain.

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 doctor, pharmacist or nurse. 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>.

By reporting side effects, you can help provide more information on the safety of MODIPRAN 20 CAPSULES.

5. How to store MODIPRAN 20 CAPSULES

- Store at or below 25 °C in the original container. Protect from light.
- Keep the blister strips in the carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date stated on the container/carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What MODIPRAN 20 CAPSULES contains

The active ingredient is fluoxetine as the hydrochloride.

MODIPRAN 20 CAPSULES: Each capsule contains 20 mg fluoxetine as the hydrochloride.

The other ingredients are dimeticone 350, maize starch pregelatinized, hard gelatine capsule consisting of gelatine, patent blue V (E131), titanium dioxide (E171) and yellow ferric oxide (E172).

What MODIPRAN 20 CAPSULES looks like and contents of the pack

Hard gelatine capsules, size 3, cap and body opaque light green, filled with a homogenous white powder.

MODIPRAN 20 CAPSULES is supplied in:

- White opaque PP securitainers.
- PP/aluminium blister strips in a carton.

Pack sizes: 30 or 100 capsules.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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