

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

MARPREM 5 mg TABLETS (Tablet)

MARPREM 10 mg TABLETS (Tablet)

MARPREM 20 mg TABLETS (Tablet)

Escitalopram oxalate

Read all of this leaflet carefully before you start taking MARPREM TABLETS.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

MARPREM TABLETS have 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.

1. WHAT MARPREM TABLETS CONTAIN

The active substance is escitalopram oxalate.

MARPREM 5 mg TABLETS:

Each film-coated tablet contains escitalopram oxalate equivalent to 5 mg escitalopram.

MARPREM 10 mg TABLETS:

Each film-coated tablet contains escitalopram oxalate equivalent to 10 mg escitalopram.

MARPREM 20 mg TABLETS:

Each film-coated tablet contains escitalopram oxalate equivalent to 20 mg escitalopram.

The other ingredients of **MARPREM TABLETS** are butylhydroxyanisole, butylhydroxytoluene, cellulose microcrystalline, croscarmellose sodium, hypromellose, macrogol 400, magnesium stearate, silica colloidal anhydrous, silicified microcrystalline cellulose, talc and titanium dioxide (C.I. No. 77891).

Sugar free.

2. WHAT MARPREM TABLETS ARE USED FOR

MARPREM TABLETS belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRIs).

MARPREM TABLETS are used to treat depression (major depressive episodes).

3. BEFORE YOU TAKE MARPREM TABLETS

Do not take **MARPREM TABLETS**:

- If you are hypersensitive (allergic) to escitalopram, or any of the other ingredients of **MARPREM TABLETS**.
- If you are under 18 years of age – Because the safety and effectiveness of **MARPREM TABLETS** have not been determined in children.
- If you take other medicines which belongs to a group called MAO (monoamine oxidase) inhibitors. If you have taken any of these medicines you will need to wait 14 days before you start taking **MARPREM TABLETS**. After stopping **MARPREM TABLETS**, you must allow 7 days before taking any of these medicines

Take special care with **MARPREM TABLETS**:

Before taking **MARPREM TABLETS**, tell your doctor:

- If you have or have had mania. Some patients with a history of mania/hypomania may enter a manic phase. If you experience this, contact your doctor.
- If you have epilepsy. Treatment with **MARPREM TABLETS** should be stopped if seizures occur or if there is an increase in seizure frequency.
- If you have diabetes. Insulin and/or oral medication dosage may need to be adjusted.
- If you are receiving electroconvulsive treatment.
- If you have liver disease. Your doctor may need to adjust your dosage.
- If you have kidney disease.
- If you have or have ever had bleeding problems.
- If you are an elderly patient.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away. If you are depressed you can sometimes have thoughts of harming or killing yourself. Since **MARPREM TABLETS** may take time to work, an improvement may not occur during the first few weeks or more of treatment.

- Some patients with panic disorder may experience increased anxiety symptoms when they start to take **MARPREM TABLETS**. These anxiety symptoms usually decrease within two weeks of continued treatment.

Taking MARPREM TABLETS with food and drink:

MARPREM TABLETS can be taken with or without food.

Pregnancy and Breastfeeding:

- The safe use of **MARPREM TABLETS** during pregnancy and breastfeeding has not been determined.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **MARPREM TABLETS**.

Driving and using machinery:

Do not drive a car or operate machinery until you know how **MARPREM TABLETS** affects you.

Taking other medicines with MARPREM TABLETS:

Before taking **MARPREM TABLETS**, tell your doctor if you are using any of the following medicines:

- Monoamine oxidase inhibitors (MAOIs) e.g. moclobemide, tranylcypromine, phenelzine. **MARPREM TABLETS** should not be used together with a monoamine oxidase inhibitor (MAOI). If you have taken any of these medicines you will need to wait 14 days before you start taking **MARPREM TABLETS**. After stopping **MARPREM TABLETS**, you must allow 7 days before taking any of these medicines.
- Other medicines that increase serotonin e.g. sumatriptan (used to treat migraine), tramadol (used against severe pain), lithium (used in the treatment of manic-depressive disorder) and tryptophan (an amino acid found in dietary supplements that may be used for depression and insomnia).
- Cimetidine (used to treat stomach ulcers). These may cause increased blood levels of **MARPREM TABLETS**.
- Desipramine (used to treat depression).
- Metoprolol (used in heart diseases).
- Other antidepressants (used to treat depression).
- Selegiline (used to treat Parkinson's disease, depression and senile dementia)
- Aspirin and non-steroidal anti-inflammatory drugs (medicines used for pain relief or to thin the blood).
- Warfarin (medicine used to thin the blood).

If you are using any of the above medicines, you may not be able to take **MARPREM TABLETS**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side effects.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

4. HOW TO TAKE MARPREM TABLETS

Always take **MARPREM TABLETS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **MARPREM TABLETS** is too strong or too weak, talk to your doctor or pharmacist.

Adults:

Depression:

- The normal recommended dose of **MARPREM TABLETS** is 10 mg taken as one daily dose.
- The dose may be increased by your doctor to a maximum of 20 mg per day.
- It may take 2 to 4 weeks before you start to feel better. Continue to take **MARPREM TABLETS** even if it takes some time before you feel an improvement in your condition.

Elderly patients (above 65 years of age):

- Your doctor may consider a lower starting dose and maximum dose.

Patients with kidney disease:

- It is usually not necessary to adjust the dosage in mild or moderate kidney impairment.

Patients with liver disease:

- Your doctor should consider a lower dosage.

If you stop taking MARPREM TABLETS:

- When you have completed your course of treatment, it is generally advised that the dose of **MARPREM TABLETS** should be gradually reduced.

If you take more MARPREM TABLETS 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.

If you forget to take MARPREM TABLETS:

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at your next regularly scheduled time. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

MARPREM TABLETS can have side effects.

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

- hives; difficulty breathing; swelling of your face, lips, tongue, or throat, sudden swelling of skin or mucosa (angioedema).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **MARPREM TABLETS**. 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:

- **MARPREM TABLETS** may cause a very serious condition called serotonin syndrome. Symptoms of serotonin syndrome include: Confusion, mania, agitation, hyperactivity (excessively increased activity), shivering, high fever, tremor (shake), eye movements, twitchy muscles, loss of coordination.
- Seizures (fits) or convulsions.
- Hallucinations (seeing things or hearing voices that do not exist) or mania (unusual excitement).
- Difficulties urinating.

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

Tell your doctor if you notice any of the following:

Increase in the amount of urine excreted; low level of sodium in the blood; sexual disturbances (ejaculation problems, loss of male sexual ability, decreased sexual drive and women may experience difficulties achieving orgasm); confusion; agitation; anxiety; panic attacks; nervousness; dizziness; inability to sleep; sleepiness; tremor (shake); movement disorders (involuntary movements of the muscles); problems with vision; dizziness when you stand up due to low blood pressure (postural hypotension); blocked or runny nose (sinusitis); yawning; taste disturbances; diarrhoea (frequent or loose watery stools); constipation; dry mouth; nausea; vomiting; lack of appetite; abnormal liver function tests (increased amounts of liver enzymes in the blood); increased sweating; bruise, bleeding into the skin; itching; joint pain; muscle pain; flow of milk in women that are not nursing; fatigue; inability to sleep; dizziness; drowsiness; fever.

Tell your doctor if any of the above side effects are severe, bothersome, do not go away or about any concerns you have while taking **MARPREM TABLETS**.

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

6. STORING AND DISPOSING OF MARPREM TABLETS

Store at or below 25 °C (room temperature).

The containers must be tightly closed.

Do not remove blisters from carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF MARPREM TABLETS

MARPREM 5 mg TABLETS / MARPREM 10 mg TABLETS / MARPREM 20 mg TABLETS:

1) Blister Pack:

Tablets are packed in clear PVC film and printed aluminium foil. Each blister contains 10 tablets.

Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.

2) HDPE Container Pack:

Tablets are packed in 40 ml HDPE containers with polypropylene closures with induction sealing wad. Each container contains 30 tablets.

Pack size: 30's - One HDPE container contains 30 tablets.

8. IDENTIFICATION OF MARPREM TABLETS

MARPREM 5 mg TABLETS:

White to off-white colored, round shaped, film-coated, biconvex tablets debossed with 'F' on one side and '53' on the other side.

MARPREM 10 mg TABLETS:

White to off-white colored, oval shaped, film-coated, biconvex tablets debossed with 'F' on one side and '54' on the other side with a deep scoreline between '5' and '4'.

MARPREM 20 mg TABLETS:

White to off-white colored, oval shaped, film-coated, biconvex tablets debossed with 'F' on one side and '56' on the other side with a deep scoreline between '5' and '6'.

9. REGISTRATION NUMBER/REFERENCE NUMBER

MARPREM 5 mg TABLETS: 44/1.2/0954

MARPREM 10 mg TABLETS: 44/1.2/0955

MARPREM 20 mg TABLETS: 44/1.2/0956

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Novagen Pharma (Pty) Ltd

Office 2, 100 Sovereign Drive

Route 21 Corporate Park

Nellmapius Drive

Irene – Pretoria

South Africa

Tel.: +27 (12) 345 3175

11. DATE OF PUBLICATION

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