1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

MITIL TABLETS 5 mg

prochlorperazine as a maleate salt

Contains sugar: Lactose 63,7 mg

Read all of this leaflet carefully before you start taking MITIL TABLETS

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

What is in this leaflet

1. What MITIL TABLETS are and what they are used for
2. What you need to know before you take MITIL TABLETS
3. How to take MITIL TABLETS
4. Possible side effects
5. How to store MITIL TABLETS
6. Contents of the pack and other information

1. What MITIL TABLETS are and what are they used for

MITIL TABLETS belong to a group of medicines called phenothiazine antipsychotics.

MITIL TABLETS are used to control mild and moderate mental and emotional disturbances, characterised by anxiety, tension and agitation.

These tablets are used in the treatment of Ménière's syndrome, labyrinthitis, vertigo and migraine. They are also particularly effective for the prevention and treatment of nausea and vomiting.

2. What you need to know before you take MITIL TABLETS

Do not take MITIL TABLETS:

- if you are hypersensitive (allergic) to prochlorperazine maleate or any of the other ingredients of MITIL TABLETS (listed in section 6).
- if you have fatigue, slowed pulse and breathing, weakness (central nervous system depression) or you are in a coma.
- if you have a shortage of blood cells causing fatigue, shortness of breath, fever (bone marrow suppression).
- if you have a tumour of the adrenal gland (phaeochromocytoma).
- if you are a child weighing less than 10 kg.
- if you are pregnant or breastfeeding because safety has not been established.
- if you are taking medicines that cause central nervous system depression, for example alcohol, general anaesthetics, sedatives or pain-relieving medicines called opioids (see Warnings and precautions and Other medicines and MITIL TABLETS).

- if you overdose on other medicines or have a gastrointestinal blockage, this medicine may mask the symptoms of overdose or blockage (see Other medicines and MITIL TABLETS).

Warnings and precautions

Take special care with MITIL TABLETS:

- Hypersensitivity (allergic) reactions may occur with MITIL TABLETS. If you experience any of the following symptoms, you need to stop taking MITIL TABLETS and tell your doctor or go to the casualty department at your nearest hospital: difficulty breathing, swelling of the mouth and a very itchy rash.
- MITIL TABLETS may cause sleepiness and difficulty in concentration which is made worse if you consume alcohol or take medicines that cause central nervous system depression (see Do not take MITIL TABLETS, Other medicines and MITIL TABLETS and Driving and using machines).
- If you are epileptic and receiving treatment or if you have a history of seizures as you may be more prone to seizures (fits).
- Uncontrolled muscle movements may occur (dystonic reactions), especially in children and adolescents.
- If you experience an unexplained fever, pale skin, dizziness, muscle stiffness, heart rhythm problems, difficulty controlling bladder and bowel and not feeling like yourself, you need to stop taking MITIL TABLETS as these may be signs of neuroleptic malignant syndrome (a potentially life-threatening condition that can be caused by certain medicines).
- If you stop taking MITIL TABLETS abruptly, you may get withdrawal symptoms (nausea, vomiting, inability to sleep and relapse of your condition) and uncontrolled

muscle movements, shaking (extrapyramidal symptoms). Therefore, your doctor will advise you on how to taper your MITIL TABLETS if and when he/she wants you to stop treatment.

- MITIL TABLETS should be avoided if you have liver or kidney problems, Parkinson's disease (a movement disorder of the nervous system), hypothyroidism (underactive thyroid), cardiac failure (heart failure), myasthenia gravis (an auto-immune condition that causes muscle weakness and difficulty with movements), prostatic hypertrophy (enlarged prostate), a history of or active closed angle glaucoma (increased pressure in the eye) and agranulocytosis (reduced white blood cells).
- MITIL TABLETS should be used with caution if you have reduced heart, brain or lung function or diabetes.
- If you are elderly, abnormally thin or if you are in a very weak state, your doctor will prescribe a lower starting dose of MITIL TABLETS to you and gradually increase the dose as needed.
- If you are elderly or in a very weak state, you may be more prone to side effects of MITIL TABLETS. Your doctor will advise you to have regular eye examinations and blood tests.
- If you suffer from an irregular heartbeat (QT interval prolongation), MITIL TABLETS may worsen this, which could be fatal. Your doctor will decide if you should take MITIL TABLETS. You may be required to have some medical and laboratory tests beforehand to rule out possible risk factors e.g. heart disease, family history of QT prolongation, low potassium, low calcium, low magnesium, starvation, alcohol abuse and the use of other medicines that prolong the QT interval (see Other medicines and MITIL TABLETS and Possible side effects).

- If you suffer from depression, your doctor may not prescribe MITIL TABLETS alone. Antidepressants may also be prescribed to you. If you have a mental condition that affects how you think, feel and behave (schizophrenia), it may take longer for MITIL TABLETS to start working.
- MITIL TABLETS may make you more sensitive to the sun. Avoid direct sunlight or wear protective sunscreen.
- If you handle MITIL TABLETS frequently, you may develop skin sensitivity to the tablets. Take care when handling the tablets to avoid tablet contact with your skin.
- There is a possibility that you could develop a blood clot in your calf muscle (painful, red, swollen calf muscle) when taking MITIL TABLETS. Your doctor will decide if you are at high risk for blood clots.
- If you have diabetes or are at risk of developing diabetes, you should monitor your blood sugar. High blood sugar has been reported in patients taking this type of medicine.
- If you are elderly, MITIL TABLETS should be used with caution, especially in very hot or very cold weather as you may be at risk of high or low body temperature (hyperthermia or hypothermia, respectively). You may also be at risk of low blood pressure upon rising (postural hypotension). Your doctor may start you on a lower dose of MITIL TABLETS initially because the elderly are more sensitive to medicines acting on the central nervous system. You may be prone to drug-induced Parkinsonism (tremor, muscle stiffness, slowed movements caused by the medicine) when taking MITIL TABLETS for a long time. You should let your doctor know if you have been diagnosed with dementia or if you are at risk of stroke because MITIL TABLETS may increase your risk of stroke or death.

Children

MITIL TABLETS should be used with extreme caution in children. You may take MITIL TABLETS only if you weigh more than 10 kg (see Do not take MITIL TABLETS). MITIL TABLETS have been associated with involuntary muscle contractions (dystonic reactions).

Other medicines and MITIL TABLETS

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

Tell your doctor if you are taking any of the following:

- Central nervous system depressants e.g. alcohol, general anaesthetics, sedatives and pain-relieving medicines called opioids may result in weakness, fatigue and dizziness and these effects may be increased by MITIL TABLETS.
- Overdose of other medicines may be masked by MITIL TABLETS which reduce vomiting and bowel movements.
- Adrenaline, used to treat an overdose, should not be used if you have taken more MITIL TABLETS than prescribed.
- Blood pressure lowering medicines e.g. doxazosin, guanethidine, carvedilol, may result in severely low blood pressure.
- Anticholinergics e.g. ipratropium, used to treat asthma, may reduce the antipsychotic effects of MITIL TABLETS and may enhance the anticholinergic effects of MITIL TABLETS leading to constipation and heat stroke.

- Levodopa, used to treat Parkinson's disease, does not treat the extrapyramidal side effects (movement disorders) of MITIL TABLETS. Your doctor may prescribe a different treatment instead.
- Metoclopramide, used to treat nausea, may increase the risk of extrapyramidal side effects (movement disorders) of MITIL TABLETS.
- Antacids, anti-Parkinson medicines and lithium (used to treat stomach acid, Parkinson's disease and mood disorders respectively) interfere with the absorption of MITIL TABLETS.
- Lithium, used to treat mood disorders, when used with MITIL TABLETS may result in neurotoxicity. Symptoms of neurotoxicity include fatigue, depression, headaches.
- Blood sugar lowering medicines e.g. metformin, used to treat high blood sugar, may require a dosage increase because high doses of MITIL TABLETS reduce their action.
- QT-prolonging medicines (certain anti-dysrhythmics, antidepressants and other antipsychotics) (i.e. medicines that result in the heart's electrical system taking longer to recharge between beats) e.g. sotalol, citalopram and quetiapine, and medicines causing electrolyte imbalance e.g. diuretics (medicines that help the body get rid of excess fluids) e.g. hydrochlorothiazide; may increase the risk of irregular heartbeat.
- Desferrioxamine, a medicine used to remove excess iron or aluminium from your body, may cause a change in how your brain works resulting in a loss of consciousness (transient metabolic encephalopathy).
- Medicines that result in the suppression of bone marrow e.g. carbamazepine (used to treat epilepsy), because there is an increased risk of reduced white blood cell count.
- Amitriptyline or amitriptylinoxide, medicines used to treat depression, because MITIL TABLETS may cause an increase in levels of amitriptyline or amitriptylinoxide in the blood.

- Amphetamine (a stimulant used to treat sleep disorder) and clonidine (used to treat high blood pressure) action may be opposed by MITIL TABLETS.
- Propranolol (used to treat high blood pressure) and phenobarbital (used to control seizures) may have an increase or a decrease in activity.

MITIL TABLETS with food, drink and alcohol

Do not take MITIL TABLETS with alcohol (see Do not take MITIL TABLETS). Usage of MITIL TABLETS with alcohol may lead to sleepiness and difficulty in concentrating (see Warnings and precautions, Driving and using machines and Other medicines and MITIL TABLETS).

Pregnancy, breastfeeding and fertility

You should not take MITIL TABLETS if you are pregnant or breastfeeding your baby.

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 healthcare provider for advice before taking this medicine.

Driving and using machines

MITIL TABLETS are expected to influence your ability to drive.

It is not always possible to predict to what extent MITIL TABLETS may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which MITIL TABLETS affects you (see Possible side effects).

MITIL TABLETS contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking MITIL TABLETS.

3. How to take MITIL TABLETS

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

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

The usual dose of MITIL TABLETS is:

Adults:

PREVENTION OF NAUSEA AND VOMITING:

5 mg to 10 mg (1 to 2 tablets) of MITIL TABLETS two or three times a day.

TREATMENT OF NAUSEA AND VOMITING:

20 mg (4 tablets) of MITIL TABLETS given orally; further doses may be given as required.

TREATMENT OF MIGRAINE:

20 mg (4 tablets) of MITIL TABLETS at once followed, if required, by 10 mg (2 tablets) of MITIL TABLETS two hours later. In an established attack if you are unable to retain tablets, treatment may be administered in a different form (25 mg of prochlorperazine maleate suppository).

TREATMENT OF VERTIGO AS WELL AS THAT ASSOCIATED WITH MÉNIÈRE'S DISEASE:

15 mg to 30 mg (3 to 6 tablets) of MITIL TABLETS in divided doses; after several weeks the dose may gradually be reduced to 5 mg to 10 mg (1 to 2 tablets) of MITIL TABLETS daily.

TREATMENT OF PSYCHOSES:

12,5 mg (2½ tablets) of MITIL TABLETS twice a day for seven days adjusted gradually to 75 mg to 100 mg (15 to 20 tablets) of MITIL TABLETS daily according to the response. Some patients may be maintained on doses of 25 mg to 50 mg (5 to 10 tablets) of MITIL TABLETS daily.

TREATMENT OF NON-PSYCHOTIC ANXIETY DISORDERS:

5 mg to 10 mg (1 to 2 tablets) of MITIL TABLETS up to 3 to 4 times daily.

Your doctor will tell you how long your treatment with MITIL TABLETS will last. Do not stop treatment early because your doctor may want you to take MITIL TABLETS for a specified period of time. If you have the impression that the effect of MITIL TABLETS is too strong or too weak, tell your doctor or pharmacist.

If you take more MITIL 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.

Symptoms of overdose:

Drowsiness, loss of consciousness, low blood pressure, increased heart rate, electrocardiogram (ECG) changes, irregular heartbeat and reduced body temperature, involuntary and uncontrolled muscle movements, altered mental state, cool, clammy skin.

If you forget to take MITIL TABLETS

Do not take a double dose to make up for forgotten individual doses.

If you have missed a dose of MITIL TABLETS, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take several doses, contact your doctor without delay.

If you stop taking MITIL TABLETS

Abrupt cessation may lead to withdrawal symptoms (nausea, vomiting, inability to sleep, relapse, restlessness, muscle contractions, involuntary muscle movements and Parkinsonism).

4. Possible side effects

MITIL TABLETS can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,

- rash or itching,
- fainting,
- rash with red, raised patches (erythema multiforme).

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

- Fatigue, paleness (haemolytic anaemia), frequent infections, bruising easily, fatigue, paleness (aplastic anaemia), pinpoint red and purple spots on the skin, nose bleeds, bruising easily (thrombocytopenic purpura), infections, fever, chills, mouth sores within 4 to 10 weeks of starting treatment (agranulocytosis) and fatigue, fever, mouth sores (leukopenia),
- fatigue, joint pain, butterfly-shaped rash on your face (systemic-lupus-erythematosus-like syndrome),
- milky discharge from the breasts, irregular or absent menstrual periods (hyperprolactinaemia), reduced body temperature (hypothermia),
- mild fatigue and nausea, seizures, coma (syndrome of inappropriate antidiuretic hormone secretion),
- disorientation, difficulty focusing, sleep and emotional disturbances (delirium),
- fits (convulsions), muscle spasms, difficulty speaking or swallowing (dystonia), involuntary muscle movements (extrapyramidal dysfunction) that may result in akathisia (restlessness), tardive dyskinesia (involuntary, purposeless movements) or oculogyric crisis (involuntary deviation of the eye upwards),

- rapid heartbeat (ventricular tachycardia), electrocardiographic (ECG) changes (including QT prolongation) (longer time for the heart's electrical system to recharge between beats), life-threatening irregular heartbeat (ventricular fibrillation), heart attack (cardiac arrest), sudden death,
- blood clots in the veins (venous thromboembolism) which may include pulmonary embolism (blood clot in an artery in the lungs),
- slow or shallow breathing (respiratory depression),
- a rare, life-threatening reaction that can take place after taking certain medicines (neuroleptic malignant syndrome) (symptoms include altered consciousness, increase body temperature, body stiffness).

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:

- Reduced blood pressure (usually upon standing) (postural hypotension).

Side effects with an unknown frequency:

- Redness, scaling and peeling of the skin (exfoliative dermatitis), rash after skin contact with something (contact sensitivity),
- hormonal issues which may result in: spontaneous production of milk from the breasts (galactorrhoea), development of breast tissue in men (gynaecomastia), inability of a man to achieve an erection (impotence), elevated or irregular body temperature (impaired body temperature regulation),

- weight gain, increased blood sugar levels (hyperglycaemia or altered glucose tolerance), nausea, vomiting, loss of energy (hyponatraemia),
- speech, behaviour and movement disturbances (catatonic-like state), feeling restless or irritated (agitation), feeling sad or down (depression),
- difficulty sleeping (insomnia), electroencephalogram (EEG) changes, extrapyramidal dysfunction (involuntary muscle movements) resulting in slow muscle movements and body stiffness (Parkinsonism-like syndrome) and perioral tremor (involuntary movements of the muscles around the mouth),
- enlarged pupils of the eyes (mydriasis), small pupils of the eyes (miosis), pigment in the eyes, blurred vision,
- ECG abnormalities (ST depression, U-wave and T-wave changes), irregular heartbeat (dysrhythmia, A-V block),
- blocked nose (nasal congestion),
- dry mouth, difficulty passing stools (constipation),
- yellowing of the whites of eyes and skin (jaundice and neuroleptic jaundice),
- skin reaction to the sun (photosensitivity), skin reaction when touching the tablets (contact skin sensitisations), pigmentation of the skin, skin rashes,
- loss of male sexual ability (impotence), prolonged and painful erection (priapism), inhibition of ejaculation, difficulty passing urine,
- withdrawal symptoms in the newborn baby, which include shaking, difficulty breathing and difficulty in feeding,
- minor abnormalities in liver function tests.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of MITIL TABLETS.

5. How to store MITIL TABLETS

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 MITIL TABLETS contain

The active substance is 5 mg of prochlorperazine as a maleate salt.

The other ingredients are lactose, magnesium stearate, microcrystalline cellulose, powdered vegetable stearin, starch maize.

Contains sugar: lactose 63,7 mg

What MITIL TABLETS look like and contents of the pack

MITIL TABLETS are plain white, biconvex tablets.

25 or 250 tablets are packed in a white polypropylene container and sealed with a white linear low density polyethylene snap-on cap with a tamper-proof tear-off seal together with a white foam insert and a leaflet.

25 or 250 tablets are packed in a round amber polyvinylchloride container and sealed with a white linear low density polyethylene snap-on cap with a tamper-proof tear-off seal and a leaflet.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912/+27 (0)11 239-6200

This leaflet was last revised in

18 August 2025

Registration number

J/2.6/184

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Botswana: B9322530 S2

Namibia: NS3 90/2.6/001059