

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

DEMETRIN® 10 mg Tablet

Prazepam

Contains sugar (lactose monohydrate)

Each tablet contains 93,73 mg lactose monohydrate

Read all of this leaflet carefully before you start taking DEMETRIN

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

1. What DEMETRIN is and what it is used for

DEMETRIN belongs to a group of medicines known as benzodiazepines and is used for short-term relief of severe or disabling anxiety or when anxiety is causing extreme stress.

2. What you need to know before you take DEMETRIN

Do not take DEMETRIN:

- if you are hypersensitive (allergic) to prazepam, other medicines of the same type called benzodiazepines, or to any of the ingredients of DEMETRIN (listed in section 6)

- if you have severe breathing difficulties (acute pulmonary insufficiency or severe respiratory insufficiency)
- if you have a disease that causes severe muscle weakness and fatigue (myasthenia gravis)
- if you have severe liver problems (severe liver failure). DEMETRIN causes a worsening of the brain symptoms that may be associated with severe liver problems, such as mental confusion, altered level of consciousness or coma
- if you suffer from episodes of interruption of breathing for several seconds during sleep (sleep apnoea)
- if you are pregnant or are breastfeeding (see Pregnancy and breastfeeding section)

Warnings and precautions

Take special care with DEMETRIN:

The duration of treatment should be as short as possible. Your doctor will assess your condition before and throughout your treatment with DEMETRIN. DEMETRIN is for short-term use only, and generally for not more than 6 to 8 weeks including a tapering-off process.

If you take DEMETRIN for a long period of time, you may need to have periodic blood and liver function tests.

Tell your doctor:

- if instances of rage or feelings of hyperexcitability occur as treatment with DEMETRIN should be discontinued (more common in children and the elderly)
- if you have a metabolic condition called porphyria
- if you are elderly or debilitated, you may be given a lower starting dose
- if you have problems breathing or have ever had problems with your lungs
- if you have problems with your kidneys or liver
- if you suffer from anxiety together with underlying depression
- if you have problems with your eyes
- if you have a condition causing abnormal weakness of certain muscles (myasthenia gravis)
- if you have a history of alcohol or drug abuse

DEMETRIN should not be used as treatment if you suffer from psychotic illness, depression, or anxiety with depression as the risk of suicide may be increased.

Dependency and withdrawal effects

If you take DEMETRIN for a long time, you may become physically or psychologically dependent on it, especially if you have a history of alcohol or drug abuse. In this case, if DEMETRIN is stopped suddenly, withdrawal symptoms may occur. These symptoms may include headaches, tremor, stomach and muscle cramps, extreme anxiety, tension, restlessness, confusion, irritability, vomiting and sweating. More serious reactions may include feeling disconnected from your body, feelings or emotions, numbness and tingling of hands and feet, hypersensitivity to light, noise and touch, hallucinations or epileptic fits. For this reason, DEMETRIN needs to be gradually reduced towards the end of your treatment.

Following repeated use of DEMETRIN for a few weeks, you may notice a decrease in its effectiveness (development of tolerance). DEMETRIN is recommended for short-term treatment.

Children and adolescents

DEMETRIN is not recommended for use in children. The safety and efficacy of DEMETRIN in children have not been established.

Other medicines and DEMETRIN

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

DEMETRIN may affect the way other medicines work, and other medicines may affect the way in which DEMETRIN works. You should therefore inform your doctor if you are taking any of the following medicines:

- Opioids or narcotics (strong pain killers)
- Phenothiazines (which are used to treat schizophrenia and other psychotic illnesses)
- Barbiturates (which include some sleeping tablets, hypnotics, sedatives, anticonvulsants and anaesthetics)
- Other antidepressants including those called monoamine oxidase inhibitors (MAOIs)
- CYP3A4 inhibitors. This group of medicines includes some antibiotics (such as erythromycin), antifungal medicines (such as ketoconazole or itraconazole), and antivirals (such as ritonavir, a medicine to treat HIV/AIDS)

- Oral contraceptives can increase the effects of DEMETRIN
- Clozapine (which is used to treat schizophrenia)

DEMETRIN with food, drink and alcohol

Do not drink alcohol while taking DEMETRIN or other central nervous system depressants.

Grapefruit juice should be avoided as it may affect how DEMETRIN works.

Pregnancy and breastfeeding

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.

If you are a woman who is able to become pregnant you should use appropriate contraception while taking DEMETRIN.

DEMETRIN should not be taken if you are pregnant (it may cause congenital malformations in the foetus), planning to fall pregnant, or are breastfeeding your baby.

Driving and using machines

Particularly at the start of your treatment with DEMETRIN, you should avoid operating dangerous machinery, driving a motor vehicle, climbing dangerous heights or taking part in other dangerous activities. You may be less able to make good decisions when taking DEMETRIN and this could lead to accidents.

It is not always possible to predict to what extent DEMETRIN 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 DEMETRIN affects them.

DEMETRIN contains lactose

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

3. How to take DEMETRIN

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

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

The usual daily dose for adults is 30 mg a day (3 tablets) taken in divided doses. Your doctor will decide what dose is right for you.

For elderly or debilitated patients, treatment should be started at a dose of 10 to 15 mg (1 to 1,5 tablets) per day. The dose needs to be decreased gradually towards the end of your treatment.

Your doctor will tell you how long your treatment with DEMETRIN will last. Do not stop treatment suddenly as you can get rebound effects which might cause mood changes, anxiety and restlessness. If you have the impression that the effect of DEMETRIN is too strong or too weak, tell your doctor or pharmacist.

If you take more DEMETRIN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. The possible signs and symptoms of overdosage include drowsiness, confusion, coma, difficulty breathing and decreased blood pressure.

If you forget to take DEMETRIN

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

If you stop taking DEMETRIN

If your doctor decides treatment with DEMETRIN should be stopped, this will be done by gradually by reducing the dose so that the occurrence of withdrawal symptoms is minimised.

4. Possible side effects

DEMETRIN can have side effects.

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

Tell your doctor if you notice any of the following:

Frequent side effects

- drowsiness
- confusion
- depression
- vivid dreams
- loss of muscle coordination
- dizziness
- headache
- hyperactivity
- light-headedness
- slurred speech
- tremor
- blurred vision
- palpitations
- dry mouth
- problems with the stomach and digestion
- sweating
- skin rash
- joint pains
- tiredness and weakness

Less frequent side effects

- fainting
- itching

- various disorders of the genitals and bladder
- swelling of the feet
- decreased blood pressure
- abnormal liver function tests
- increased weight

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

5. How to store DEMETRIN

Store all medicines out of reach of children.

- Store at or below 25 °C in a cool, dark, dry place.
- Store in the original package.
- Do not use after the expiry date stated on the carton.
- 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 DEMETRIN contains

- The active substance is prazepam.
- The other ingredients are maize starch, lactose monohydrate, magnesium stearate, microcrystalline cellulose and silica colloidal anhydrous.

What DEMETRIN looks like and contents of the pack

A white, slightly rounded tablet with a score line across the middle on one side.

DEMETRIN is available in clear PVC/Aluminium foil blisters of 100 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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