SCHEDULING STATUS: **S5**

AREM®, 5 mg, tablets

Nitrazepam

Contains sugar (lactose monohydrate 357,7 mg)

Read all of this leaflet carefully before you start taking AREM

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

Nitrazepam as contained in AREM belongs to a group of medicines called benzodiazepines, which are tranquillisers (medicines that have a calming effect).

AREM tablets are used for the short term treatment of sleeplessness (also known as insomnia) when it is severe.

2. What you need to know before you take AREM

Do not take AREM if:

- you are hypersensitive (allergic) to nitrazepam or any of the other ingredients of AREM (listed in section 6),
- you have a mental disorder characterised by a disconnection from reality,

- you have breathing or lung problems,
- you are pregnant or breastfeeding your infant,
- you have depression or self-harm tendencies,
- you have porphyria (an inherited condition causing skin blisters, abdominal pain and brain or nervous system disorders),
- you have a condition called “sleep apnoea syndrome” (where your breathing stops when you are asleep).

Warnings and precautions

Take special care with AREM:

- you are elderly or weak
- you have problems with your heart and lungs, kidneys or liver
- have low blood levels of a protein called albumin
- you are taking medicine for epilepsy (e.g., phenobarbital) or other CNS medicines
- you have abused alcohol or drugs
- you suffer from myasthenia gravis (a condition in which the muscles become weak and tire easily)
- you have a poor blood supply to the brain (arteriosclerosis)
- you have sudden increased pressure to the eye (acute narrow-angle glaucoma)
- you suffer from gout
- you are taking opioids for pain management (see below “AREM and other medicines”)
- you are awoken during the period of maximum medicine activity, memory may be impaired.

Dependence

When taking this medicine there is a risk of dependence, which increases with the dose and duration of treatment and also in patients with a history of alcoholism and drug abuse. Therefore, you should take AREM tablets for as short a period of time as possible.

Tolerance

If after a few weeks you notice that the tablets are not working as well as they did when first starting treatment, you should speak to your doctor.

Withdrawal

Treatment should be gradually withdrawn. Withdrawal symptoms occur with AREM tablets even when normal doses are given for short periods of time. See section 3, ‘If you stop taking AREM

tablets.'

Because AREM tablets relax the muscles, elderly patients should take extra care when they get up at night as there is a risk of falls and consequently of injuries including hip fractures.

Other medicines and AREM

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

- antidepressants, other tranquillisers or sleeping pills, or other such medicines that act on the brain and nerves,
- medicines used to relieve pain or anaesthetics,
- antihistamines (used for treating allergies) that cause drowsiness,
- medicines to treat colds,
- opioids (strong pain killers, medicines for substitution therapy and some cough medicines). Taking these medicines with AREM tablets increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However, if your doctor does prescribe AREM tablets together with opioids the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all opioid medicines you are taking and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms,
- medicines for treating epilepsy (e.g., phenytoin and phenobarbital),
- medicines that affect the liver (e.g., the antibiotic rifampicin),
- moxonidine (to lower high blood pressure), muscle relaxants (e.g. baclofen, tizanidine). Taking these medicines with AREM could make you very sleepy,
- medicine to treat heartburn or too much acid in the stomach (e.g., cimetidine).

AREM with drink and alcohol

Do not drink alcohol while you are taking AREM tablets. Alcohol may increase the sedative effects of AREM tablets and make you very sleepy.

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 AREM.

Do not take AREM if you are pregnant or breastfeeding your baby.
Data on the effect of AREM on fertility is not available.

Driving and using machines
AREM can make you sleepy, making it difficult to concentrate and slow down your reactions.

It is not always possible to predict to what extent AREM may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which AREM affects you.

AREM contains sugar (lactose monohydrate)
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 AREM
Do not share medicines prescribed for you with any other person.
Always take AREM exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Treatment with AREM should be as short as possible. The duration of treatment varies from a few days to two weeks, with a maximum, including tapering off process, of four weeks.

The usual starting dose is 5 mg (one tablet) at night. Sometimes two tablets (10 mg) may be required.

If you are elderly or debilitated your starting dose will not usually be more than 2.5 mg (half a tablet).

Swallow the tablet(s) whole with water or another non-alcoholic drink.

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

If you take more AREM than you should

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

Signs of an overdose include slowing down of the nervous system (ranging from tiredness to coma) such as confusion, drowsiness, lack of co-ordination, reduced muscle tension, low blood pressure, slow heartbeat, breathing difficulties. In rare cases overdose may lead to coma (unrousable unconsciousness) and in very rare cases may lead to death.

If you forget to take AREM

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

If you stop taking AREM

- Do not stop taking AREM without talking to your doctor.
- Do not stop taking AREM tablets abruptly. You may experience withdrawal effects if your treatment is stopped suddenly. This is less likely if your dose is gradually reduced towards the end of your treatment.
- Withdrawal symptoms may include: a recurrence of sleep problems, depression, nervousness, extreme anxiety, tension, restlessness, confusion, mood changes, irritability, sweating, diarrhoea, headaches, muscle weakness.
- In severe cases the following symptoms may occur: changes in behaviour, numbness and tingling of the extremities, fits, over-sensitivity to light, noise and touch, hallucinations.
- If you have taken AREM for a long time, the reduction in your dosage will be over a longer period of time than would normally be required when you stop taking this medicine. You may need additional help. Your doctor will be able to discuss this with you.

4. Possible side effects

AREM can have side effects.

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

If any of the following happens, stop taking AREM 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.

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

- severe form of skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome).
- jaundice (yellowing of your skin or the white of your eyes).
- changes in behaviour may occur such as aggression, excitement, confusion, restlessness, agitation, irritability, rages, hallucinations, nightmares and depression. If these behavioural symptoms occur, you must inform your doctor. He/she may want you to stop taking this medicine.
- breathing problems (respiratory depression). Early signs include sudden noisy, difficult and uneven breathing. Your skin may become blue.

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:

- lightheaded-ness, drowsiness
- headache
- impaired balance or coordination, can be due to damage to brain, nerves or muscles

Less frequent side effects:

- changes in the numbers and types of your blood cells
- sleeplessness, nightmares
- hear, see, smell, taste or feel things that appear to be real but only exist in your mind (hallucinations)
- restless, aggressive, irritable, violent uncontrollable anger

- fixed, false beliefs that conflict with reality
- muscle cramps
- changes in sex drive
- uncontrollable movements, for example of your hands (tremor)
- blurred vision or visual disturbances
- feeling dizzy or a spinning sensation
- low blood pressure
- nausea, upset stomach, changes in salivation
- skin rashes, itchy skin
- difficulty in passing water, difficulty to control urination
- muscle weakness

Side effects with unknown frequency

- dependence, total or partial memory loss, depression
- slurred speech
- your body loses heat faster than it can produce heat, causing a dangerously low body temperature
- tingling and numbness of the hands

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 "**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 AREM.

5. How to store AREM

Store all medicines out of reach of children.
Store at or below 25 °C.
Store in airtight containers, protected from light and moisture.
Keep in original packaging until required for use.
Do not use after the expiry date stated on the label / carton / bottle
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 AREM contains

- The active substance is nitrazepam.
- The other ingredients are lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycollate, starch maize and talc (purified).

What AREM looks like and contents of the pack

White to off-white, flat tablet with bevelled edges, debossed “AREM” on the one side and plain on the other side.

30 or 250 tablets are packed in a white polypropylene securitainer with a white low density polyethylene or propylene cap, together with a foam or rayon insert and a leaflet.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

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