PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S5

BETAPAM 5 mg Tablet

Diazepam

Contains sugar (lactose monohydrate): 145,7 mg per tablet

Contains: TARTRAZINE

Read all of this leaflet carefully before you start taking BETAPAM

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

1. **What BETAPAM is and what it is used for**

Diazepam belongs to a group of medicines called benzodiazepines. Diazepam helps in the treatment of anxiety and muscle spasm (cramps) such as those caused by cerebral spasticity.

2. What you need to know before you take BETAPAM

Do not take BETAPAM:

- if you are hypersensitive (allergic) to diazepam or any of the other ingredients of BETAPAM) listed in section 6
- if you have an allergy to BETAPAM or any other benzodiazepine medicine (e.g. clonazepam, flurazepam and temazepam)
- if you have breathing or lung problems
- if you have severe liver problems.
- if you have a condition called “sleep apnoea syndrome” (where your breathing stops when you are asleep)
- if you have a condition called “myasthenia gravis” (where your muscles are weak and get tired easily)
- if you have problems with phobias (strong fears) or obsessions (troublesome, unwanted and repeated thoughts, ideas or feelings).

Warnings and precautions

Take special care with BETAPAM :

- if you regularly drink alcohol and/or CNS depressants, or take recreational drugs.
- if you have had problems with alcohol or drug abuse in the past.
- if you are driving a car and/or operating machinery.
- if you have been told that you cannot tolerate or digest some sugars.
- if you have liver, kidney, lung or heart problems.
- if you are being treated for depression.
- if you are to give BETAPAM to a child younger than 6 months of age. BETAPAM is not recommended for use in this age group unless there are no other treatment options
- if you are elderly or weak, your doctor will decide whether to prescribe a lower dose of BETAPAM for you.

Other medicines and BETAPAM

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

BETAPAM can affect the way some medicines work. Also some medicines can affect the way BETAPAM works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines to treat mental health problems such as antidepressants.
- Other medicines to relieve anxiety such as other benzodiazepine medicines (clonazepam,
- flurazepam and temazepam).
- Medicines to help you sleep.
- Medicines to treat convulsions or epilepsy such as phenytoin.
- Strong pain killers, such as morphine.
- Medicines for allergies, which make you sleepy.
- Medicines to treat stomach problems and heartburn, such as cimetidine, or omeprazole.
- Medicines to treat fungal skin infections, such as ketoconazole.

Anaesthetics: If you are going to have an anaesthetic for an operation or dental treatment, it is important to tell your doctor or dentist that you are taking BETAPAM.

BETAPAM with food, drink and alcohol

Drinking alcohol: Do not drink alcohol while you are taking BETAPAM, because BETAPAM can make you sleepy. You are more likely to have problems with your concentration and to fall more deeply asleep which may cause serious problems with your breathing or heartbeat.

Pregnancy, breast-feeding 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 professional for advice before taking BETAPAM.

Driving and using machines

Talk to your doctor before about driving or using tools or machines, while you are taking BETAPAM. This is because BETAPAM can make you sleepy, making it difficult to concentrate and slow down your reactions. You should also read the section on “Drinking alcohol”. If you are in any doubt about whether you can do a particular activity, talk to your doctor.

BETAPAM contains lactose monohydrate:

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

BETAPAM contains TARTRAZINE

It may cause allergic reactions.

3. How to take BETAPAM

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

Always take BETAPAM exactly as your doctor has told you. Check with your doctor or pharmacist if you are unsure.

You should be treated for as short as possible. Treatment should not be longer than 2 -3 months, including the time that you are coming off your tablets. You should consult your healthcare professional regularly to see if you need to continue your treatment, especially if you are symptom free.

- You will be started with a low dose of BETAPAM. Your doctor will slowly increase it until you are taking the right dose for you. Your doctor will always give the lowest possible dose that works for you.
- Your doctor will want you to take BETAPAM for the shortest possible time.
- The usual adult dose is 5 - 10 mg initially. Depending on the severity of your symptoms, your doctor may prescribe a dose of 5 - 20 mg daily.
- If you are elderly or very ill, or weak, or have problems with your liver or kidneys, your doctor may give you a lower dose.

- Children's dose: Your doctor will prescribe the correct dose for your child, according to your child's weight and severity of his/her illness.

If you have the impression that the effect of BETAPAM is too strong or too weak, tell your doctor or pharmacist.

If you take more BETAPAM than you should

If you take more BETAPAM than you should, or if someone else takes your BETAPAM tablets by mistake, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.
If you take too many tablets you may feel sleepy, have difficulty controlling your movements (lack of co-ordination), or have slow or slurred speech or jerky eye movements.

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

If you forget to take BETAPAM

- If you forget to take a dose, miss the skipped dose. Then take the next dose when it is due.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking BETAPAM

- Do not stop taking BETAPAM without talking to your doctor.
- When you stop taking BETAPAM, your anxiety may return and you may experience sleeping problems, and you may get withdrawal symptoms, especially if you stop too quickly. For the symptoms you may have, see "Withdrawal symptoms" under "Possible side effects".
- When it is time to lower your dose or stop taking BETAPAM, it must be done slowly. This lowers the chance of you having withdrawal symptoms. Your doctor will tell you how to do this.

4. Possible side effects

BETAPAM can have side effects.

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

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

- Chest pain which may spread to your neck and shoulders and down your left arm. This may be a sign of a heart attack.
- Breathing problems (respiratory depression). Early signs include sudden noisy, difficult and uneven breathing. Your skin may become blue.
- A feeling of fullness in your bladder and urge to pass water, but then difficulty emptying your bladder.
- Being restless, aggressive, angry, irritable or agitated.
- Nightmares and seeing or hearing things that re not really there (hallucinations).
- Mental problems such as delusions (believing in things that are not real) or losing contact with reality.
- A change in your behaviour that is out of character.

These are very serious side effects. If you have them, you may have had a serious reaction to BETAPAM. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Feeling tired
- Weak muscles

Less frequent side effects:

Mind and nervous system

- Poor co-ordination, including feeling unsteady when you walk
- Slow or slurring of speech
- Headache
- Feeling dizzy
- Uncontrollable movements, for example of your hands (tremor)
- Anterograde amnesia (difficulty remembering new things)
- Confusion
- Depression
- Being less alert

Heart and circulation

- Low blood pressure. The signs include feeling dizzy or light-headed
- Uneven heartbeat

Stomach and gut

- Feeling sick (nausea)
- Constipation
- Dry mouth
- More saliva in your mouth than usual

Sexual

- A higher or lower interest in sex.

Eyes and ears

- Problems with your eye-sight, including double or blurred vision.
- Vertigo. The signs include feeling dizzy or a spinning sensation.

Skin

- Skin rashes

Liver and kidneys

- Changes in how well your liver is working (shown by blood tests).
- Loss of bladder control (wetting yourself).

Injury

When you take BETAPAM you are at risk of falling and breaking your bones. This risk is increased if you are elderly or are taking other sedatives (including alcohol).

Withdrawal symptoms:

You can become dependent on benzodiazepine medicines like BETAPAM. This means that if you stop treatment suddenly, or lower the dose too quickly, you may get withdrawal symptoms. The symptoms

can include:

Frequent withdrawal symptoms include:

- Headache
- Muscle pain and feeling restless
- Feeling very worried, tense, confused or bad tempered.

Less frequent withdrawal symptoms include:

- Feeling sensitive to light, noise and touch
- Seeing or hearing things that are not really there (hallucinations)
- Tingling and numb in your arms and legs
- Feeling lost or losing contact with reality
- Fits (seizures)

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 BETAPAM.

5. How to store BETAPAM

Store all medicines out of reach of children.

Store at or below 25 °C in a cool, dry place.

Protect from light and moisture.

Store in the original package.

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 BETAPAM contains

- The active ingredient is diazepam.
- The other ingredients are certolake tartrazine (C.I. 19140), lactose monohydrate, magnesium stearate, microcrystalline cellulose, starch maize.

What BETAPAM looks like and contents of the pack

BETAPAM: Yellow, biconvex, scored tablets.

Contents of the pack:

Amber PVC containers of 30,100, 500, and 1000 tablets.

Polypropylene containers of 100 and 500 tablets.

H.D.P.E. Bucket of 5000 tablets.

Patient ready packs of different pack sizes.

Holder of Certificate of Registration

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