

## PATIENT INFORMATION LEAFLET FOR PRASEN 100, 300 & 400

### SCHEDULING STATUS

S3

### PRASEN 100, PRASEN 300, PRASEN 400 (Capsules)

#### Gabapentin

Contains sugar: 10,80 mg / 32,40 mg / 43,20 mg mannitol

### Read all of this leaflet carefully before you start taking PRASEN

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

#### 1. What PRASEN is and what it is used for

PRASEN belongs to a group of medicines used in controlling epilepsy.

The active substance in PRASEN is gabapentin.

PRASEN is used to treat various forms of epilepsy (seizures that are initially limited to certain

parts of the brain, whether the seizure spreads to other parts of the brain or not) in adults and children over 12 years of age. It is also used as additional treatment to the main treatment to help achieve sufficient seizure control with other antiepileptic medicine, when used alone or in combination with these medicine.

## **2. What you need to know before you take PRASEN**

### **Do not take/give PRASEN:**

- If you are allergic (hypersensitive) to gabapentin or any of the other ingredients of PRASEN (listed in section 6).
- If your child is under the age of 12 years.
- If you are pregnant or breastfeeding your baby.
- If you have a severe kidney disease.

### **Warnings and precautions**

Special care should be taken with PRASEN:

- If you suffer from kidney problems your doctor may prescribe a different dosing schedule.
- If you are on haemodialysis (to remove waste products because of kidney failure), tell your doctor if you develop muscle pain and/or weakness.
- If you develop signs such as persistent stomach pain, feeling sick and being sick contact your doctor immediately as these may be symptoms of acute pancreatitis (an inflamed pancreas).
- If you have nervous system disorders, respiratory/breathing disorders, or you are more than 65 years old, your doctor may prescribe you a different dosing regimen.
- If you get an allergic reaction or serious skin reaction, which may develop into more serious problems if they are not treated. You need to know the symptoms to look out for while you are taking PRASEN.
- Cases of abuse and dependence have been reported for PRASEN. Talk to your doctor if

you have a history of abuse or dependence.

- If you have had thoughts of harming or killing yourself, immediately contact your doctor. Pay attention to any changes, especially sudden changes, in mood, behaviours, thoughts, or feelings.
- If you are pregnant or plan to become pregnant. It is not known if PRASEN can harm your unborn baby.
- If you are breastfeeding or plan to breastfeed. PRASEN can pass into breast milk. You and your healthcare provider should decide how you will feed your baby while you are taking PRASEN.
- Unexpected muscle pain, weakness or tenderness and if at the same time you feel unwell or have a high temperature/fever it may be caused by an abnormal muscle breakdown which can be life-threatening and lead to kidney problems.

### **Children under the age of 12 years**

Do not give PRASEN to children under the age of 12 years.

### **Other medicines and PRASEN**

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

PRASEN could interact with other medicines and the dosages of the medicines might have to be changed by your doctor as the amounts of PRASEN or other medicines in your blood may be affected.

Tell your doctor or pharmacist:

- If you are taking any medicines containing opioids (such as morphine), as opioids may increase the effect of **PRASEN**. In addition, combination of **PRASEN** with opioids may cause symptoms like sleepiness and/or decrease in breathing.

- If you are taking antacids for indigestion. **PRASEN** and antacids containing aluminium and magnesium when taken at the same time, the absorption of **PRASEN** from the stomach may be reduced. It is therefore recommended that **PRASEN** is taken at the earliest two hours after taking an antacid.
- If you require a urine test, tell your doctor or hospital what you are taking as **PRASEN** may interfere with some laboratory tests,
- Do not take other medicines that make you sleepy or drowsy while taking **PRASEN** without first talking with your healthcare provider. Taking **PRASEN** with medicines that cause sleepiness or drowsiness may make your sleepiness or drowsiness worse.

**PRASEN** is also not expected interact with other antiepileptic medicines or the contraceptive pill.

### **Pregnancy and breastfeeding**

**PRASEN** should not be used during pregnancy or breastfeeding as safety and efficacy has not been established. 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 **PRASEN**.

### **Driving and using machines**

**PRASEN** may cause dizziness, drowsiness and tiredness. You should not drive, operate heavy machinery, or do other dangerous activities until you know how **PRASEN** affects you.

### **3. How to take PRASEN**

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

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

Adults and children over 12 years:

Take the number of capsules as instructed. Your doctor will usually build up your dose gradually. Usual effective dose is 900 – 1800 mg/day in three divided doses with not more than 12 hours between doses.

Therapy is started at a low dose. Thereafter, the dose may be increased to a maximum dose of 1 800 mg/day in 3 separate doses, i.e. once in the morning, once in the afternoon and once in the evening.

PRASEN can be taken with or without food.

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

#### **If you take more PRASEN than you should**

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

Take along any capsules that you have not taken, together with the container and the leaflet so that the hospital can easily tell what medicine you have taken. You may experience an increase in side effects caused by PRASEN such as double vision, slurred speech, drowsiness, lethargy, loss of consciousness and diarrhoea.

#### **If you forget to take use PRASEN**

If you forget to take a capsule, take the missed dose right away, unless it is almost time for your next dose. Do not take a double dose to make up for forgotten individual doses.

#### **If you stop taking using PRASEN**

Do not stop taking PRASEN or decrease the dose without checking with your doctor. If your

treatment is stopped it should be done gradually over a minimum of 1 week. If you stop taking PRASEN suddenly or before your doctor tells you, there is an increased risk of seizures/fits.

#### **4. Possible side effects**

PRASEN can have side effects.

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

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

- PRASEN may cause a serious or life-threatening allergic reaction that may affect your skin or other parts of your body such as your liver or blood cells. You may or may not have rash when you get this type of reaction. Call your doctor right away if you have any of the following symptoms:
  - skin rash,
  - hives,
  - fever,
  - swollen glands that do not go away,
  - swelling of your lip and tongue,
  - yellowing of your skin or of the whites of the eyes,
  - unusual bruising or bleeding,
  - severe weakness or tiredness,
  - unexpected pain in your muscles,
  - frequent infections.
- stomach pain with feeling sick and being sick as these may be symptoms of acute

pancreatitis (an inflamed pancreas),

- breathing problems, which if severe you may need emergency care to continue breathing normally,
- if you are on haemodialysis, tell your doctor if you feel muscle pain and/or weakness.

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

Tell your doctor if you notice any of the following:

*Frequent side effects:*

- Viral infection, respiratory/chest infections, urinary tract/bladder infections, inflammation of the ear or other infections,
- feeling drowsy, dizziness, lack of coordination,
- feeling tired, fever,
- eating problems (anorexia), increased appetite
- anger towards others, confusion, mood changes, depression, anxiety, nervousness, difficulty with thinking,
- seizures/fits, jerky movements, difficulty with speaking, loss of memory, tremor or shaking, difficulty sleeping, headache, sensitive skin, decreased sensation (numbness), difficulty with coordination, unusual eye movement, increased, decreased or absent reflexes,
- blurred vision, double vision,
- vertigo or dizziness,
- high blood pressure,
- difficulty breathing, bronchitis, sore throat, cough, dry nose,
- vomiting (being sick), nausea (feeling sick), problems with teeth, swollen gums, diarrhoea, stomach pain, indigestion or heartburn, constipation, dry mouth or throat, flatulence or passing wind,
- swelling of the face, bruises, rash, itchiness, acne,

- joint pain, muscle pain, back pain, twitching,
- difficulties with erection (impotence),
- swelling in the legs and arms, difficulty with walking, weakness, pain, feeling unwell, flu-like symptoms,
- increase in weight,
- accidental injury, falling.

*Less frequent side effects:*

- Agitation (feeling restless),
- racing heartbeat,
- difficulty swallowing,
- abnormal blood test results suggesting problems with the liver,
- Increase or decrease in the sugar levels in your blood,
- loss of consciousness, mental problems,
- trouble breathing, shallow breaths (respiratory depression)

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 PRASEN.

### **5. How to store PRASEN**

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original container.

Do not store in a bathroom.

Do not use PRASEN after the expiry date.

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 PRASEN 100, 300 & 400 contains:**

- Active substance is gabapentin.
- Other ingredients are: Corn (Maize) Starch, magnesium stearate, mannitol, talc.

Capsule shell for PRASEN 100: Gelatine, purified water, titanium dioxide (E171).

Capsule shell for PRASEN 300: Gelatine, iron oxide yellow (E172), purified water, titanium dioxide (E171).

Capsule shell for PRASEN 400: FD&C Blue #1 (E133), FD&C Yellow #6 (E110), gelatine, purified water, titanium dioxide (E171).

Printing ink for PRASEN 100, 300 & 400:

The imprinting ink Green Tek SB 4027 contains shellac, iron oxide yellow (E172) & FD&C Blue #1 Aluminium Lake (E133).

The imprinting ink Blue Tek SB 6018 contains shellac and FD&C Blue #2 Aluminium Lake (E132).

### **What PRASEN looks like and contents of the pack**

#### **PRASEN 100**

Opaque white cap and opaque white body imprinted with 'S617/100 mg' on cap with edible blue ink and “S” on body with edible green ink. Filled with a white to off white powder.

PRASEN is packed in a child resistant HDPE container containing 100 or 500 capsules.

**PRASEN 300**

Opaque yellow cap and opaque yellow body imprinted with 'S618/300 mg' on cap with edible blue ink and “S” on body with edible green ink. Filled with a white to off white powder. PRASEN is packed in a child resistant HDPE container containing 100 or 500 capsules.

**PRASEN 400**

Opaque orange cap and opaque orange body imprinted with 'S619/400 mg' on cap with edible blue ink and “S” on body with edible green ink. Filled with a white to off white powder. PRASEN is packed in a child resistant HDPE container containing 100 or 500 capsules.

Not all pack sizes may be marketed.

**Holder of Certificate of Registration**

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**Access to the corresponding Professional Information**