Patient Information Leaflet

SCHEDULING STATUS:

S4

NARAMIG tablet

Naratriptan 2,5 mg per tablet

Read all this leaflet carefully before you start taking NARAMIG.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, your pharmacist, nurse or other health care provider.
- NARAMIG has been prescribed for you personally and you should not share your medicines with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

1. What NARAMIG is and what it is used for:

NARAMIG is used to treat migraines.

2. What you need to know before you use NARAMIG:

Do not take NARAMIG:

- if you are allergic (hypersensitive) to naratriptan or any of the other ingredients included in NARAMIG, see Section 6
- if you have a heart problem such as heart failure or chest pains (angina), or have already had a heart attack
- if you have circulation problems in your legs that cause cramp-like pains when you walk (peripheral vascular disease)
- if you have had a stroke or a mini-stroke (also called a transient ischaemic attack or TIA)
- if you have high blood pressure
- if you have kidney or liver disease**,** check with your doctor. If your kidney or liver problems are severe then NARAMIG may not be suitable for you
- if you are taking other medicines to treat your migraine which contain any triptans (e.g. sumatriptan) or ergotamine preparations (e.g methysergide and dihydroergotamine).

If you think any of these apply to you, **don't take NARAMIG** until you have checked with your doctor.

Warnings and precautions:

Take special care with NARAMIG;

Your doctor needs to know before you take NARAMIG:

- if you have **extra risk factors for heart disease**:

- if you are a man over 40
- if you are a woman who has been through the menopause
- if you smoke or are overweight
- if you have diabetes or high cholesterol
- if you have a strong family history of heart disease.

If any of the points in the list applies to you, it could mean you have a greater risk of developing heart disease – so please tell your doctor so that your heart function can be checked before NARAMIG is prescribed for you.

In some cases, people have developed serious heart conditions after taking NARAMIG, even though they had no signs of heart disease before.

- if you are allergic to antibiotics called sulphonamides, you may also be allergic to NARAMIG
- If you are taking any antidepressants classed as selective serotonin re-uptake inhibitors (SSRIs) or serotonin noradrenaline re-uptake inhibitors (SNRIs), then you should speak to your doctor before you start taking NARAMIG
- if you are over 65 years old or under the age of 18 years.

If you take NARAMIG frequently: Taking NARAMIG too often may make your headaches worse. Tell your doctor if this applies to you**.** You may need to stop taking NARAMIG.

Other medicines and NARAMIG:

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

Some medicines must not be taken with NARAMIG. These include:

- other medicines used to treat migraines, e.g. ergotamine and methysergide

- triptans (e.g. sumatriptan), used to treat migraines.

Some medicines may cause adverse effects if they are taken with NARAMIG. These include:

- SSRIs *(Selective Serotonin Re-uptake Inhibitors)* or SNRIs (*serotonin-noradrenaline re-uptake inhibitors*) used to treat depression. Using NARAMIG with these medicines can cause confusion, weakness and/or lack of co-ordination (*serotonin syndrome*). Contact your doctor immediately if you get any of these symptoms.

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 healthcare provider for advice before taking this medicine.

The ingredients in NARAMIG can pass into breast milk. Don't breastfeed your baby after taking NARAMIG**.**

Driving and using machines:

The symptoms of migraine and NARAMIG can make you drowsy. Do not drive or operate machinery, unless you are feeling well.

NARAMIG contains lactose:

- Patients with the rare hereditary conditions of lactose/fructose or galactose tolerance should not take NARAMIG.
- May have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to use NARAMIG:

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

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

The usual dose for adults aged 18 to 65, is a single 2,5 mg tablet.

Swallow the tablet whole with some water.

Take NARAMIG as soon as your migraine begins, but you may take a tablet anytime during the attack.

Do not take NARAMIG to try to prevent an attack.

If your symptoms start to come back, **you may take a second NARAMIG tablet** after **four hours.** You should not take more than 2 tablets in a 24 hour period.

If the first tablet has no effect, don't take a second tablet. If NARAMIG doesn't give you any relief, ask your doctor or pharmacist for advice.

If you take more NARAMIG than you should:

Taking too much NARAMIG could make you ill. If you take more than the recommended dose, contact your doctor or pharmacist as soon as possible for advice. If possible, show them the NARAMIG pack

4. Possible side effects:

NARAMIG can have side effects.

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

Allergic reactions:

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

- raised and itchy rash *(hives)*
- swelling sometimes of the face or mouth *(angioedema)* causing difficulty in breathing
- collapse.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to NARAMIG. You may need urgent medical attention or hospitalisation. Do not take any more NARAMIG tablets.

Frequent side effects include:

- tingling
- feeling sick (nausea) or being sick (vomiting), although this may be due to the migraine itself
- pain, heaviness or pressure in any part of the body including the chest and throat
- heat sensations.

Other side effects include:

- allergic reaction
- feeling drowsy
- heart problems where your heartbeat may go faster *(tachycardia)*, slower *(bradycardia)* or change rhythm *(cardiac arrhythmias)* or heart attack
- Poor blood circulation to arms and legs
- pain in the lower left side of the stomach and bloody diarrhoea *(ischaemic colitis).*

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 NARAMIG.

5. How to store NARAMIG:

Store all medicines out of reach of children.

Store at or below 30 ºC.

Do not use after the expiry date 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 NARAMIG contains:

The active substance is naratriptan.

Each tablet contains 2,5 mg naratriptan as naratriptan hydrochloride.

Contains sugar (as anhydrous lactose 94,07 mg/tablet).

The other ingredients are microcrystalline cellulose, croscarmellose sodium, magnesium stearate and the film-coat contains methylhydroxypropylcellulose, titanium dioxide (E171), triacetin, Iron oxide yellow (E172), indigo carmine aluminium lake (E132).

What NARAMIG looks like and contents of the pack:

NARAMIG tablets are green film-coated, D shaped, biconvex, with ‘GX CE5’ engraved on the one face.

NARAMIG tablets are packed in double foil blister packs or child-resistant foil blister packs of 2, 4, 6 and 12 tablets.

Holder of certificate of registration and manufacturer:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

Registration number:

32/7.3/0463

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