PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed according to a physician's prescription only

Naramig Tablets 2.5 mg

Each film-coated tablet contains: naratriptan (as hydrochloride) 2.5 mg.

Inactive and allergenic ingredients in the preparation see in section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the physician or the pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

Naramig Tablets 2.5 mg, called in this leaflet "Naramig".

Naramig is not recommended for children under the age of 18 or for adults over 65.

1. What is the medicine intended for?

Naramig is used to treat migraine.

Migraine symptoms may be caused by the temporary widening of blood vessels in the head. Naramig reduces the widening of these blood vessels. This in turn helps to take away the headache and relieve other symptoms of a migraine attack, such as nausea or vomiting and sensitivity to light and sound.

Therapeutic group
Naramig contains naratriptan (as hydrochloride), which belongs to a group of medicines called triptans (also called selective serotonin agonists ($5\text{-}HT_1$)).

2. Before using the medicine

Do not use the medicine:

- **If you are sensitive (allergic)** to naratriptan or to any of the additional ingredients contained in the medicine (for the list of inactive ingredients refer to section 6).
- **If you have a heart problem** such as heart failure or chest pains (*angina*), or have 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** (you may be able to take Naramig if your high blood pressure is mild and is being treated).
- **If you have kidney or liver disease.**
- **With other migraine medicines,** including those which contain

ergotamine, or with similar medicines such as methysergide, or with other 5-HT_1 receptor agonists, such as sumatriptan.

If any of these apply to you:

→ Tell your physician, and do not take Naramig.

Special warnings regarding the use of the medicine

Refer to your physician or pharmacist before taking Naramig.

If you have any extra risk factors

- **If you are a heavy smoker** or are using **nicotine replacement therapy**, and especially
- **If you are a man over 40 years old**, or
- **If you are a woman who has been through the menopause.**

In very rare cases, people have developed serious heart conditions after taking Naramig, even though they had no signs of heart disease before using the medicine.

If any of the points in the list apply to you, you may have a greater risk of developing heart disease – so:

→ **Tell your physician so that your heart function can be checked** before Naramig is prescribed for you.

If you are allergic to antibiotics called sulphonamides

If so, you may also be allergic to Naramig. If you know you are allergic to an antibiotic but you are not sure whether it is a sulphonamide:

→ **Tell your physician or pharmacist before taking Naramig.**

If you take Naramig frequently

Taking Naramig too often may make your headaches worse.

→ **Tell your physician if this applies to you.** Your physician may recommend you stop taking Naramig.

If you feel pain or tightness in your chest after you take Naramig

These effects may be intense but they usually pass quickly. If they do not pass quickly, or they become severe:

→ **Get medical help immediately.** Section 4 of this leaflet has more information about these possible side effects.

Reports of transient or permanent blindness or significant partial vision loss have been reported with the use of serotonin selective agonists (5-HT_1). A causal relationship between these events and the use of serotonin selective agonists (5-HT_1) has not been clearly established since visual disorders may be part of a migraine attack.

Drug interactions

Some medicines must not be taken with Naramig and others may cause adverse effects if they are taken with Naramig.

If you are taking, or have recently taken, other medicines including non-prescription medicines and food supplements, tell the physician or the pharmacist. Especially if you are taking:

- any medicines for your **migraine** which contain any **triptan/5-HT_1 agonist** (such as sumatriptan or zolmitriptan). Do not take Naramig at the same time as these medicines. Stop taking these medicines at least 24 hours before taking Naramig.
- **ergotamine** also used to treat **migraine** or similar medicines such as methysergide. Do not take Naramig at the same time as these medicines. Stop taking these medicines at least 24 hours before taking Naramig.
- any **antidepressants** classed as selective serotonin reuptake inhibitors (SSRIs), such as citalopram, fluoxetine or paroxetine, or serotonin norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine. If you are not sure, talk to your physician or pharmacist.
- **Hypericum** (St. John's Wort) for treatment of depression. Using herbal remedies that contain *Hypericum* while you are taking Naramig may make side effects more likely.

Pregnancy and breast-feeding
- **If you are pregnant, think you may be pregnant or are planning to become pregnant,** consult the physician before taking this medicine. There is only limited information about the safety of Naramig for pregnant women, though until now there is no evidence of any increased risk of birth defects. Your physician may recommend that you do not take Naramig while you are pregnant.
- **Do not breast-feed your baby for 24 hours** after taking Naramig. If you express any breast milk during this time, discard the milk and do not give it to your baby.

Driving and using machines
- Either the symptoms of migraine or your medicine may make you drowsy. **If you are affected, do not drive or operate machinery.**

Important information about some of the ingredients of the medicine
Naramig contains lactose
Naramig contains a small amount of a sugar called lactose. If you have been told by your physician that you have an intolerance to certain sugars:
→ **Refer to your physician before** taking Naramig.

Naramig contains less than 1 mmol sodium (23 mg) in each tablet; **it can therefore be said that it is essentially 'sodium-free'.**

3. How should you use the medicine?

Only take Naramig after your migraine headache begins.
Do not take Naramig to try to prevent an attack.

Always use according to the physician's instructions. Check with the physician or the pharmacist if you are unsure.

How much to take
The dosage and treatment will be determined only by the physician. The usual dosage is:
- **The usual dose for adults aged 18 to 65** is one tablet of Naramig.

Method of administration
Take the tablet whole with water.
Do not crush/halve/chew the tablet.

Naramig is not recommended for children under the age of 18 or for adults over 65.

Do not exceed the recommended dose.

When to take Naramig
- **It is best to take Naramig as soon as you feel a migraine coming on,** although it can be taken at any time during an attack.

If migraine symptoms come back
- You can take a second Naramig tablet after 4 hours, unless you have kidney or liver damage.
- **If you have kidney or liver damage,** do not take more than one tablet in 24 hours.
- **Do not take more than two tablets in 24 hours.**

If the first tablet has no effect
- **Do not take a second tablet for the same attack.**

If Naramig does not give you any relief:
→ **Ask your physician or pharmacist for advice.**

If you accidentally have taken a higher dosage
- **Do not take more than two tablets of Naramig in 24 hours.**

Taking too much Naramig could make you ill. If you have taken more than two tablets in 24 hours:
→ **Talk to your physician.**

If you have taken too much Naramig or if a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

4. Side effects

As with any medicine, use of Naramig may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Tell your physician straight away if you notice any of the following serious side effects – you may need urgent medical treatment:
- **Heartbeat may go faster,** slower or change rhythm (affects up to **1 in 100** people).
- **Pain in the lower left side of the stomach** and bloody diarrhoea (*ischaemic colitis* – affects up to **1 in 1,000** people).

- **Allergic reaction** (affects up to **1 in 1,000** people). **The signs of allergy include rash; hives (itchy lumps); itching; wheezing; swollen eyelids, face or lips; collapse.**

If you get any of these symptoms soon after taking Naramig:
→ **Do not take any more. Contact a physician straight away.**
- **Heaviness, pressure or pain in the chest,** throat or other parts of the body (affects up to **1 in 100** people). These effects may be intense but generally pass quickly.

If these effects continue or become severe (especially the chest pain):
→ **Get medical help urgently.** In a very small number of people these symptoms can be caused by a heart attack.

Additional side effects

Common side effects – effects that occur in up to 1 in 10 people:
- **Nausea** or vomiting, although this may be due to the migraine itself.
- **Tiredness,** drowsiness or sleepiness, or generally feeling unwell.
- **Dizziness,** tingling feelings or getting hot flushes.

If you get any of these effects:
→ **Tell your physician or pharmacist.**

Uncommon side effects – effects that occur in up to 1 in 100 people:
- **Visual disturbances** (although these may be due to the migraine attack itself).
- **Slight increase in blood pressure** which may occur up to 12 hours after taking Naramig.

If you get any of these effects:
→ **Tell your physician or pharmacist.**

Very rare side effects – effects that occur in up to 1 in 10,000 people:
- **Heart problems,** including chest pains (*angina*) and heart attack.
- **Poor blood circulation to the arms and legs,** causing pain and discomfort.

If you get these symptoms:
→ **Tell your physician or pharmacist.**

If a side effect has appeared, if any of the side effects get worse or when you suffer from a side effect that has not been mentioned in the leaflet, you should consult the physician.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of reach and sight of children and/or infants in order to

avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store below 30°C.

6. Additional information

- **In addition to the active ingredient the medicine also contains –**
  The tablet core:
  Microcrystalline cellulose, anhydrous lactose, croscarmellose sodium, magnesium stearate.

  The tablet coating:
  Methylhydroxypropylcellulose, titanium dioxide (E171), triacetin, iron oxide yellow (E172), indigo carmine aluminium lake (E132).
- **What does the medicine look like and what is the content of the package –**
  Naramig tablets are green, film-coated, D-shaped, engraved with GX CE5 on one side. They are available in blister packs of 2 or 4 tablets.
  Not all pack sizes may be marketed.
- **License Holder:** GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- **Manufacturer:** GlaxoSmithKline Pharmaceuticals S.A., Poznan, Poland.
- Revised in January 2021 according to MoH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 113-42-29550-01.

Nar PT v5A