

Naramig® 2.5 mg film-coated tablets

3186
29.12.22[5]

(natriptan hydrochloride)

PATIENT INFORMATION LEAFLET

Your medicine is available by using the above name but will be referred to as Naramig throughout the leaflet

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Naramig is and what it is used for
2. What you need to know before you take Naramig
3. How to take 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 tablets contain natriptan (hydrochloride), which belongs to a group of medicines called triptans (*also known as 5-HT₁ receptor agonists*).

Naramig tablets are used to treat migraine.

Migraine symptoms may be caused by the temporary widening of blood vessels in the head. Naramig tablets are believed to reduce 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 feeling or being sick (nausea or vomiting) and sensitivity to light and sound.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NARAMIG

Do not take Naramig:

- **If you are allergic** to natriptan, or any of the other ingredients of this medicine (listed in 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.** 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-HT₁ receptor agonists, such as sumatriptan.

If any of these apply to you:

→ **Tell your doctor, and don't take Naramig.**

Warnings and precautions

Talk to your doctor 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**, 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. If any of the points in the list applies to you, it could mean you have a greater risk of developing heart disease - so:

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

If you take Naramig frequently

Taking Naramig too often may make your headaches worse.

→ **Tell your doctor if this applies to you.** He or she 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 don't pass quickly, or they become severe:

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

Not for older people or children under 18

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

Other medicines and Naramig

Tell your doctor if you're taking, have recently taken or might take any other medicines.

Some medicines must not be taken with Naramig and others may cause adverse effects if they're taken with Naramig. **You must tell your doctor if you are taking:**

- any medicines for your **migraine** which contain any **triptan/5-HT₁ agonist** (such as sumatriptan or zolmitriptan). Don't 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. Don't 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 noradrenaline reuptake inhibitors (SNRIs) such as venlafaxine. If you are not sure, talk to your doctor or pharmacist.
- **St John's Wort** (*Hypericum perforatum*). Using herbal remedies that contain St John's Wort 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 have a baby ask your doctor** for advice before taking this medicine. There is only limited information about the safety of Naramig for pregnant women, though up till now there is no evidence of any increased risk of birth defects. Your doctor may recommend that you do not take Naramig while you are pregnant.
- **Don't breast-feed your baby for 24 hours after taking Naramig.** If you express any breast milk during this time, discard the milk and don't 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, don't drive or operate machinery.**

Naramig contains lactose

Naramig tablets contain a small amount of a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars:

→ **Contact your doctor before taking Naramig.**

Naramig contains less than 1 mmol sodium (23 mg) per tablet, **that is to say essentially 'sodium-free'.**

3. HOW TO TAKE NARAMIG

Only take Naramig after your migraine headache begins.

Don't take Naramig to try to prevent an attack.

Always take this medicine exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

How much to take

- **The usual dose for adults aged 18 to 65** is one Naramig 2.5 mg tablet, swallowed whole with water.

Naramig is not recommended for children under 18 and adults over 65.

When to take Naramig

- **It's 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 your symptoms start to 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** don't take more than one tablet in 24 hours.
- **No one should take more than two tablets in 24 hours.**

If the first tablet has no effect

- **Don't take a second tablet for the same attack.**

If Naramig doesn't give you any relief:

→ **Ask your doctor or pharmacist for advice.**

If you take more Naramig than you should · Don't take more than two Naramig tablets in 24 hours.

Taking too much Naramig could make you ill. If you have taken more than two tablets in 24 hours:

→ **Contact your doctor for advice.**

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor 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; itching; wheezing; swollen eyelids, face or lips; complete collapse.**

If you get any of these symptoms soon after taking Naramig:

→ **Don't take any more. Contact a doctor straight away.**

- **Heaviness, pressure, tightness 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.

Common:

may affect up to 1 in 10 people

- **Feeling sick** (nausea) or being sick (vomiting), although this may be due to the migraine itself.
- **Tiredness**, drowsiness or sleepiness (somnolence), or generally feeling unwell.
- **Dizziness**, tingling feelings or getting hot flushes.

If you get any of these effects:

→ **Tell your doctor or pharmacist.**

Uncommon:

may affect 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 doctor or pharmacist.**

Very rare:

may affect 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 doctor or pharmacist.**

If you get side effects

If you notice any unwanted effects, even ones not listed in this leaflet, or if any of the side effects becomes troublesome:

→ **Tell your doctor or pharmacist.**

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE NARAMIG

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

If the tablets become discoloured or show signs of any deterioration, you should seek the advice of your pharmacist who will advise you what to do.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Naramig contains

Each tablet contains 2.78 mg naratriptan hydrochloride equivalent to 2.5 mg naratriptan.

The other ingredients in the tablet core are microcrystalline cellulose, lactose, croscarmellose sodium and magnesium stearate. Other ingredients in the tablet coating are hypromellose, titanium dioxide (E171), triacetin, yellow iron oxide (E172), indigo carmine aluminium lake (E132).

What Naramig looks like and contents of the pack

Naramig tablets are green, film-coated, D-shaped tablets engraved 'GX CE5' on one side and plain on other side.

They are available in blister packs of 6 or 12 tablets.

Not all pack sizes may be marketed.

Product Licence Holder and Manufacturer

Manufactured by

Delpharm Poznan Spolka Akcyjna, ul. Grunwaldzka 189, 60-322 Poznan, Poland.

Procured from within the EU by Product Licence holder:

Star Pharmaceuticals Ltd., 5 Sandridge Close, Harrow, Middlesex HA1 1XD.

Repackaged by Servipharm Ltd.

POM

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Naramig is a trademark of Glaxo Group Ltd.

Additional information

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist who have the information you need, and will advise you.

Blind or partially sighted?

Is this leaflet hard to see or read?

Call 020 8423 2111 to obtain the leaflet in a format suitable for you.

Naratriptan 2.5 mg film-coated tablets

(naratriptan hydrochloride)

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If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others.

It may harm them, even if their signs of illness are the same as yours.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you take Naratriptan
3. How to take Naratriptan
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6. Contents of the pack and other information

1. WHAT NARATRIPTAN IS AND WHAT IT IS USED FOR

The tablets contain active substance naratriptan (hydrochloride), which belongs to a group of medicines called triptans (*also known as 5-HT₁ receptor agonists*).

Naratriptan tablets are used to treat migraine.

Migraine symptoms may be caused by the temporary widening of blood vessels in the head. Naratriptan tablets are believed to reduce 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 feeling or being sick (nausea or vomiting) and sensitivity to light and sound.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NARATRIPTAN

Do not take Naratriptan:

- **If you are allergic** to naratriptan, or any of the other ingredients of this medicine (listed in 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.** You may be able to take Naratriptan 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-HT₁ receptor agonists, such as sumatriptan.

If any of these apply to you:

→ **Tell your doctor, and don't take Naratriptan.**

Warnings and precautions

Talk to your doctor or pharmacist before taking Naratriptan.

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**, or
- **If you are a woman who has been through the menopause.**

In very rare cases, people have developed serious heart conditions after taking Naratriptan, even though they had no signs of heart disease before. If any of the points in the list applies to you, it could mean you have a greater risk of developing heart disease - so:

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

If you are allergic to antibiotics called sulphonamides

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

→ **Tell your doctor or pharmacist before taking Naratriptan.**

If you take Naratriptan frequently

Taking Naratriptan too often may make your headaches worse.

→ **Tell your doctor if this applies to you.** He or she may recommend you stop taking Naratriptan.

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

These effects may be intense but they usually pass quickly. If they don't pass quickly, or they become severe:

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

Not for older people or children under 18

Naratriptan is not recommended for people aged over 65 or for children under the age of 18.

Other medicines and Naratriptan

Tell your doctor if you're taking, have recently taken or might take any other medicines.

Some medicines must not be taken with Naratriptan and others may cause adverse effects if they're taken with Naratriptan. **You must tell your doctor if you are taking:**

- any medicines for your **migraine** which contain any **triptan/5-HT₁ agonist** (such as sumatriptan or zolmitriptan). Don't take Naratriptan at the same time as these medicines. Stop taking these medicines at least 24 hours before taking Naratriptan.
- **ergotamine** also used to treat **migraine** or similar medicines such as methysergide. Don't take Naratriptan at the same time as these medicines. Stop taking these medicines at least 24 hours before taking Naratriptan.
- any **antidepressants** classed as selective serotonin reuptake inhibitors (SSRIs), such as citalopram, fluoxetine or paroxetine, or serotonin noradrenaline reuptake inhibitors (SNRIs) such as venlafaxine. If you are not sure, talk to your doctor or pharmacist.
- **St John's Wort** (*Hypericum perforatum*). Using herbal remedies that contain St John's Wort while you are taking Naratriptan may make side effects more likely.

Pregnancy and breast-feeding

- **If you are pregnant, think you may be pregnant or are planning to have a baby ask your doctor** for advice before taking this medicine. There is only limited information about the safety of Naratriptan for pregnant women, though up till now there is no evidence of any increased risk of birth defects. Your doctor may recommend that you do not take Naratriptan while you are pregnant.
- **Don't breast-feed your baby for 24 hours after taking Naratriptan.** If you express any breast milk during this time, discard the milk and don't 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, don't drive or operate machinery.**

Naratriptan contains lactose

Naratriptan tablets contain a small amount of a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars:

→ **Contact your doctor** before taking Naramig.

Naramig contains less than 1 mmol sodium (23 mg) per tablet, **that is to say essentially 'sodium-free'**.

3. HOW TO TAKE NARATRIPTAN

Only take Naratriptan after your migraine headache begins.

Don't take Naratriptan to try to prevent an attack.

Always take this medicine exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

How much to take

- **The usual dose for adults aged 18 to 65** is one Naratriptan 2.5 mg tablet, swallowed whole with water.
- Naratriptan is not recommended for children under 18 and adults over 65.

When to take Naratriptan

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

If your symptoms start to come back

- You can take a second Naratriptan tablet after 4 hours, unless you have kidney or liver damage.
- **If you have kidney or liver damage** don't take more than one tablet in 24 hours.
- **No one should take more than two tablets in 24 hours.**

If the first tablet has no effect

- **Don't take a second tablet for the same attack.**

If Naratriptan doesn't give you any relief:

→ **Ask your doctor or pharmacist for advice.**

If you take more Naratriptan than you should - Don't take more than two Naratriptan tablets in 24 hours.

Taking too much Naratriptan could make you ill. If you have taken more than two tablets in 24 hours:

→ Contact your doctor for advice.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor 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; itching; wheezing; swollen eyelids, face or lips; complete collapse.**

If you get any of these symptoms soon after taking Naratriptan:

→ **Don't take any more. Contact a doctor straight away.**

- **Heaviness, pressure, tightness 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.

Common:

may affect up to 1 in 10 people

- **Feeling sick** (nausea) or being sick (vomiting), although this may be due to the migraine itself.
- **Tiredness**, drowsiness or sleepiness (somnolence), or generally feeling unwell.
- **Dizziness**, tingling feelings or getting hot flushes.

If you get any of these effects:

→ **Tell your doctor or pharmacist.**

Uncommon:

may affect 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 Naratriptan.

If you get any of these effects:

→ **Tell your doctor or pharmacist.**

Very rare:

may affect 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 doctor or pharmacist.**

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If you notice any unwanted effects, even ones not listed in this leaflet, or if any of the side effects becomes troublesome:

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Reporting of side effects

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5. HOW TO STORE NARATRIPTAN

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Naratriptan contains

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Manufactured by

Delpharm Poznan Spolka Akcyjna, ul. Grunwaldzka 189, 60-322 Poznan, Poland.

Procured from within the EU by Product Licence holder:

Star Pharmaceuticals Ltd., 5 Sandridge Close, Harrow, Middlesex HA1 1XD.

Repackaged by Servipharm Ltd.

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