

Package leaflet: Information for the user

Naratriptan 2.5 mg Film-coated Tablets

Naratriptan

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 Naratriptan is and what it is used for
2. What you need to know before you take Naratriptan
3. How to take Naratriptan
4. Possible side effects
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1. What Naratriptan is and what it is used for

Naratriptan Film-coated Tablets contain naratriptan (as hydrochloride), which belongs to a group of medicines called triptans (*also known as 5-HT₁ receptor agonists*).

Naratriptan Film-coated Tablets are used in acute treatment of the headache phase of migraine attacks with or without aura in adults (aged 18-65 years).

Migraine symptoms may be caused by the temporary widening of blood vessels in the head. Naratriptan Film-coated Tablets are believed to reduce the widening of these blood vessels. This 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 heart problems** such as a narrowing of the arteries in your heart (*ischemic heart disease*) or chest pains (*angina*), or if you 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 severe kidney or liver disease.**
- **with other migraine medicines**, including those which contain ergotamine, or with similar medicines such as methysergide, or with other triptans or 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 your headache is accompanied by the following symptoms;

weakness of one side of the body, speaking difficulties, dizziness, ringing in ears, double vision, clumsy or uncoordinated movements, impaired consciousness, seizure-like movements or rash.

If any of these apply to you:

→ **Tell your doctor, and don't take 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 years of age**, 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, therefore,

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

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.

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 are taking antidepressants called SSRIs (*Selective Serotonin Reuptake Inhibitors*) or SNRIs (*Serotonin Noradrenaline Reuptake Inhibitors*)

→ **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.

Other medicines and Naratriptan

Tell your doctor if you're taking, have recently taken or might take any other medicines. This includes herbal or non-prescription medicines.

Some medicines must not be taken with Naratriptan and others may cause side effects if they're taken with Naratriptan.

You must tell your doctor if you are taking:

- any triptan or 5-HT₁ receptor agonist used to treat **migraine** (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. Do not take Naratriptan at the same time as these medicines. Stop taking these medicines at least 24 hours before taking Naratriptan.
- **SSRIs** (selective serotonin reuptake inhibitors) or **SNRIs** (serotonin norepinephrine reuptake inhibitors) used to treat **depression**. Taking these medicines at the same time as Naratriptan may

cause confusion, weakness and/or decreased coordination. Tell your doctor right away if you are affected in this way.

- **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, although there is no evidence of any increased risk of birth defects to date. Your doctor may recommend that you do not take Naratriptan while you are pregnant.
- **Do not breast-feed your baby for 24 hours after taking Naratriptan.** 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.**

Naratriptan contains lactose

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

Naratriptan 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 years** is one Naratriptan 2.5 mg Film-coated Tablet, swallowed whole with water.

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

When to take Naratriptan

- **It is 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 Film-coated 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

- **Do not 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.**

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Allergic reactions: see a doctor straight away (may affect up to 1 in 1,000 people)

- **Signs of allergy include: rash, wheezing, swollen eyelids, face or lips, circulatory collapse.**

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

→ **Stop taking Naratriptan. See a doctor immediately.**

Common side effects (may affect up to 1 in 10 people)

- Feeling sick (nausea) or being sick (vomiting), which may also be triggered by the migraine attack itself
- tiredness, drowsiness or generally feeling unwell
- dizziness, feeling of pins and needles, flushing.

If you notice any of these symptoms:

→ **Tell your doctor or pharmacist.**

Uncommon side effects (may affect up to 1 in 100 people)

- Feeling of heaviness, feeling of pressure, tightness or pain in the chest, throat or other parts of the body. These symptoms may be intense but they usually pass quickly.

If these symptoms persist or get worse (particularly the chest pain):

→ **See a doctor immediately.** In very few patients, these symptoms may be caused by a heart attack.

Other uncommon side effects (may affect up to 1 in 100 people)

- **Visual disturbances** (although these may be due to the migraine attack itself).
- **Heart beat may go faster, slower or change rhythm**
- **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.**

Rare side effects (may affect up to 1 in 1,000 people)

- excessive sleepiness (somnolence)
- Pain in the lower left side of your stomach region and bloody diarrhoea (*ischaemic colitis*)

If you notice any of these symptoms:

→ **Tell your doctor or pharmacist.**

Very rare side effects (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.**

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 national reporting system listed in [Appendix V](#).

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Naratriptan

Keep this medicine out of the sight and reach of children.

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

Do not store above 30°C.

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 Naratriptan Film-coated Tablets contains

- The active substance is naratriptan (each film-coated tablet contains 2.5 mg naratriptan, as the hydrochloride salt).
- The other ingredients in the tablet core are microcrystalline cellulose, anhydrous lactose, croscarmellose sodium and magnesium stearate. Other ingredients in the tablet coating are hypromellose (E 464), titanium dioxide (E 171), iron oxide yellow (E 172), polyethylene glycol (E 1521).

What Naratriptan Film-coated Tablets looks like and contents of the pack

Naratriptan Film-coated Tablets are 12 × 6 mm, caplet-shaped, light yellow, film-coated tablets, having 'NH' on one side and plain on other side.

Naratriptan Film-coated Tablets are available in Aluminium blister packs containing 6, 12, 14, 18, 20, 28, 30, 50, 60 or 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Renata Pharmaceuticals (Ireland) Limited
12 Crowe Street,
Dundalk,
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A91 NN29.

Manufacturer

Alterno Labs d.o.o.,
Brnčičeva ulica 29,
Ljubljana-Črnuče, 1231,
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This medicine is authorised in the Member States of the European Economic Area under the following names:

Ireland	Naratriptan 2.5 mg Film-coated Tablets
Malta	Naratriptan 2.5 mg Film-coated Tablets

This leaflet was last revised in <{MM/YYYY}><{month YYYY}>.