

Package leaflet: Information for the user

Naraverg 2.5 mg Film-coated Tablets naratriptan

Read all of this leaflet carefully before you start using 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 Naraverg is and what it is used for
2. What you need to know before you take Naraverg
3. How to take Naraverg
4. Possible side effects
5. How to store Naraverg
6. Contents of the pack and other information

1. What Naraverg is and what it is used for

Your medicine contains naratriptan (hydrochloride), which belongs to a group of medicines called triptans (also known as 5-HT₁ receptor agonists).

It is used to treat migraine headache.

Migraine symptoms may be caused by the temporary widening of blood vessels in the head. Naratriptan is 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 Naraverg

Do not take Naraverg

- **If you're allergic** to naratriptan, or any of the other ingredients of this medicine (listed in section 6).
- **If you have a heart problem** such as narrowing of the arteries (*ischaemic heart disease*) 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 Naraverg if your high blood pressure is mild and is being treated.
- **If you have serious kidney or serious liver disease.**
- **With other migraine medicines,** including those which contain ergotamine, or with similar medicines such as methysergide, or with any triptan or 5-HT₁ receptor agonists.

If any of these apply to you, tell your doctor, and don't take Naraverg

Warnings and precautions

Talk to your doctor or pharmacist before taking Naraverg

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 Naraverg, 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 Naraverg is prescribed for you.

If you are allergic to antibiotics called sulphonamides

If so, you may also be allergic to Naraverg. 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 Naraverg.**

If you take Naraverg frequently

Taking Naraverg too often may make your headaches worse. **Tell your doctor if this applies to you.** He or she may recommend you stop taking Naraverg.

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

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 taking antidepressants called SSRIs (*Selective Serotonin Reuptake Inhibitors*) or SNRIs (*Serotonin Noradrenaline Reuptake Inhibitors*), tell your doctor or pharmacist before taking Naraverg.

Other medicines and Naraverg

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

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

- any triptan or 5-HT₁ receptor agonist used to treat **migraine**. Don't take Naraverg at the same time as these medicines. Don't take them again for at least 24 hours after taking Naraverg.
- **ergotamine** also used to treat **migraine**, or similar medicines such as methysergide. Don't take Naraverg at the same time as these medicines. Stop taking these medicines at least 24 hours before taking Naraverg. Don't take them again for at least 24 hours after taking Naraverg
- **SSRIs (*Selective Serotonin Reuptake Inhibitors*)** or **SNRIs (*Serotonin Noradrenaline Reuptake Inhibitors*)** used to treat **depression**. Taking Naraverg with these medicines can cause confusion, weakness and/or lack of co-ordination. Tell your doctor immediately 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 Naraverg may make side effects more likely.

Pregnancy and, breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby,, ask your doctor or pharmacist 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 Naraverg. 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.**

Naraverg contains lactose,

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

Naraverg contains sodium

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

3. How to take Naraverg

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

**Only take Naraverg after your migraine headache begins.
Don't take Naraverg to try to prevent an attack.**

How much to take

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

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

When to take Naraverg

- **It's best to take Naraverg as soon as you feel a migraine headache 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 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 Naraverg doesn't give you any relief:

Ask your doctor or pharmacist for advice.

If you take more Naraverg than you should

- **Don't take more than two Naraverg tablets in 24 hours.**

Taking too much Naraverg 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 reaction: get a doctor's help straight away

(may affect up to 1 in 1,000 people)

- **The signs of allergy include rash; wheezing; swollen eyelids, face or lips; complete collapse.**

If you get any of these symptoms soon after taking Naraverg, don't take any more. Contact a doctor straight away.

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 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)

- Heaviness, pressure, tightness or pain in the chest, throat or other parts of the body. 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.

Other uncommon side effects include:

- 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 last for up to 12 hours after taking Naraverg.

If you get any of these effects, **tell your doctor or pharmacist.**

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

- Pain in the lower left side of the stomach and bloody diarrhoea (ischaemic colitis).

If you get these symptoms, **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.**

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Naraverg

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 or blister. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not use this medicine if you notice any visible signs of deterioration.

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 Naraverg contains

- The active substance is naratriptan. Each film-coated tablet contains 2.5 mg naratriptan (as naratriptan hydrochloride).
- The other ingredients in the tablet core are lactose, microcrystalline cellulose, colloidal anhydrous silica, croscarmellose sodium and magnesium stearate.
- The other ingredients in the coating are hypromellose (E464), titanium dioxide (E171), lactose monohydrate, macrogol 3350, triacetin, quinoline yellow aluminium lake (E104), indigo carmine aluminium lake (E132) and yellow iron oxide (E172).

What Naraverg looks like and contents of the pack

Green, biconvex, round, film-coated tablets debossed “NT 2.5” on one side and plain on the other. Naraverg is available in blisters of 2, 4, 6, 12 film-coated tablets and hospital packs of 18 or 50 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva Pharma B.V.
Swensweg 5
2031GA Haarlem
The Netherlands

Manufacturers

TEVA UK Ltd
Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG, England

Pharmachemie B.V.
Swensweg 5, 2031 GA Haarlem, The Netherlands

TEVA Santé SA
Rue Bellocier, 89107 Sens
France

TEVA Pharmaceutical Works Private Limited Company
Pallagi út 13, 4042 Debrecen, Hungary

Merckle GmbH
Ludwig-Merckle-Str. 3
89143 Blaubeuren

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany:	Naratriptan-ratiopharm 2.5 mg Filmtabletten
Denmark:	Naratriptan Teva
France:	Naratriptan Teva 2.5 mg, comprimé pelliculé
Ireland:	Naraverg 2.5 mg Film-coated Tablets
Netherlands:	Naratriptan HCL 2,5 mg Teva, filmomhulde tabletten
United Kingdom:	Naratriptan 2.5 mg Film-coated Tablets

This leaflet was last revised in August 2020.