

**NARATRIPTAN 2.5 MG FILM-COATED TABLETS**

[Naratriptan (as naratriptan hydrochloride)]

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist (chemist).
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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**1. What Naratriptan is and what it is used for**

Naratriptan contains naratriptan (hydrochloride), which belongs to a group of medicines called triptans (*also known as 5-HT<sub>1</sub> receptor agonists*).

Naratriptan tablets are used to treat migraine with or without aura.

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. Before you take Naratriptan****Not for the elderly or children under 18**

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

**Do not take Naratriptan:**

- If you are allergic (*hypersensitive*) to naratriptan, or any of the other ingredients (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-HT<sub>1</sub> receptor agonists, such as sumatriptan.

If any of these apply to you:

- Tell your doctor, and do not take Naratriptan.

**Take special care with Naratriptan**

Your doctor needs to know certain information before you 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, 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 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.

**Taking other medicines and Naratriptan**

Please tell your doctor if you are taking or have recently taken any other medicines. This includes any herbal products or medicines obtained without a prescription.

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 or 5HT<sub>1</sub> receptor agonist (such as sumatriptan or zolmitriptan). Do not 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.
- 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 or could be pregnant, ask your doctor or pharmacist (chemist) for advice before taking any medicine. Talk to your doctor before you take Naratriptan. 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.
- 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 use any tools or machines.

**Important information about some of the ingredients of Naratriptan**

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 Naratriptan.

### 3. How to take Naratriptan

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

Always take Naratriptan exactly as your doctor has told you.  
You should check with your doctor or pharmacist if you are not sure.

#### How much to take

##### Adults

The usual dose for adults aged 18 to 65 is one Naratriptan tablet swallowed whole with water.

##### Children and the elderly

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

##### 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, 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 as it is unlikely to be of any benefit.
- However Naratriptan may be used for subsequent migraine attacks.

If Naratriptan doesn't give you any relief:

- Ask your doctor or pharmacist for advice.

##### If you take more Naratriptan than you should

- Do not 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 product, ask your doctor or pharmacist.

### 4. Possible side effects

Like all medicines, Naratriptan can cause side effects, but not everybody gets them.

#### Allergic reaction: get a doctor's help straight away

(affects up to 1 in 1000 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 Naratriptan:

- Do not take any more. Contact a doctor straight away.

#### Common side effects

(affects 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 side effects

(affects 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).
- Heartbeat may go faster, slower or change rhythm.
- Slight increase in blood pressure which may last for up to 12 hours after taking Naratriptan.

If you get any of these effects:

- Tell your doctor or pharmacist.

#### Rare side effects

(affects 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 side effects

(affects 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please:

- Tell your doctor or pharmacist.

### 5. How to store Naratriptan

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Do not use Naratriptan after the expiry date which is stated on the blister and on the outer carton. The expiry date refers to the last day of that month.

If you have any unwanted Naratriptan, do not dispose of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

### 6. Further information

#### What Naratriptan contains

The active substance is naratriptan.

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

The other ingredients are:

Tablet core: microcrystalline cellulose, lactose anhydrous, croscarmellose sodium and magnesium stearate.  
Film-coating: polyethylene glycol / macrogol, titanium dioxide (E171), polyvinyl alcohol, iron oxide yellow (E172), FD&C Blue #2 / indigo carmine aluminum lake (E132) and talc.

#### What Naratriptan looks like and contents of the pack

Naratriptan 2.5 mg film-coated tablets are green, oblong shaped, film-coated tablets. They are available in blister packs of 2, 3, 4, 6, 12 or 18 tablets.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder and manufacturer is: Channele Medical, Loughrea, Co. Galway, Ireland.

The distributor is: Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK

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

Belgium:	Naratriptan Channele Medical 2,5 mg filmomhulde tabletten
France:	Naratriptan 2,5 mg comprimé pelliculé
Germany:	Naratriptan Channele Medical 2,5 mg Filmtabletten
Netherlands:	Naratriptan Channele Medical 2,5 mg filmomhulde tabletten
Portugal:	Naratriptano Channele
Spain:	Naratriptan 2,5 mg comprimidos recubiertos con película EFG
United Kingdom:	Naratriptan 2.5 mg film-coated tablets

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