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Package leaflet: Information for the user

Naratriptan 2.5mg Film-coated Tablets

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.
- The full name of this product is Naratriptan 2.5mg Film-coated Tablets but within the leaflet it will be referred to as Naratriptan tablets.

What is in this leaflet:

1 What Naratriptan tablets are and what they are used for
2 What you need to know before you take Naratriptan tablets
3 How to take Naratriptan tablets
4 Possible side effects
5 How to store Naratriptan tablets
6 Contents of the pack and other information

1 What Naratriptan tablets are and what they are used for

This medicinal product contains naratriptan which belongs to a group of medicines called triptans (also known as 5 HT_1 receptor agonists).

Naratriptan tablets are used to treat migraine headache with or without aura (a warning sensation that usually involves eyesight distortions, such as seeing light-flashes, zigzag lines, stars, or waves).

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 relieve the headache and 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 tablets

Do not take Naratriptan tablets if you

- are **allergic** to naratriptan or any of the other ingredients of this medicine (listed in section 6).
- have or have ever had **heart problems**, including a heart attack (myocardial infarction), narrowing of arteries (ischaemic heart disease), chest pain which happens while resting (Prinzmetal's angina) or have experienced heart-related symptoms such as shortness of breath or chest pressure.
- have **problems with the blood circulation to your hands and feet** (peripheral vascular disease).
- have ever had a **stroke or a mini-stroke (**also called a transient ischaemic attack).
- have **high blood pressure** which has been diagnosed as moderate or severe or have high blood pressure which is mild and not being treated.
- have **serious kidney or serious liver problems.**
- are taking **other migraine medicines**, including those which contain **ergotamine** or with similar medicines such as **methysergide**, or with any **other triptan or 5-HT_1 receptor agonists.**

Warnings and precautions

Talk to your doctor or pharmacist before taking Naratriptan tablets if you
- are at a **higher risk of heart disease**. This applies if you are a
  - **heavy smoker** or are using nicotine replacement therapy.
  - **woman past the menopause.**
  - **man over 40 years** of age.

Tell your doctor so that your heart function can be checked before Naratriptan tablets are prescribed to you. In very rare cases, people have developed serious heart conditions after taking Naratriptan tablets, even though they had no signs of heart disease before. Contact your doctor for advice if you have any concerns.
- **feel pain or tightness in your chest**. This can be quite intensive and may radiate towards your throat. If the symptoms do not disappear or if they become severe, your doctor may recommend you to stop taking Naratriptan tablets.
- are **allergic to antibiotics called sulfonamides.** If so, you may also be allergic to Naratriptan tablets.
- are **taking medicines for treating your depression or other mental disorders** such as selective serotonin re-uptake inhibitors (SSRIs)/serotonin nor-epinephrine reuptake inhibitors (SNRIs).

Naratriptan tablets must only be used if a diagnosis of migraine has been clearly established in your case. Certain types of migraines cannot be treated with Naratriptan tablets. You should not take more than the usual dose of Naratriptan tablets. Taking Naratriptan tablets or any other pain killer too often for a long time may make your headache worse. Tell your doctor if you experience frequent or daily headaches even though you are regularly using medicines to treat your headache. Your doctor may recommend you to stop taking Naratriptan tablets.

Children and adolescents

Naratriptan tablets are not recommended for use in children and adolescents.

Other medicines and Naratriptan tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
In particular, tell your doctor or pharmacist if you are taking
- **medicines for the treatment of migraine** such as any other **triptan/5-HT_1 receptor agonists** or **ergotamine** containing preparations. These medicines must not be taken at the same time as Naratriptan tablets. Stop taking these medicines at least 24 hours before taking Naratriptan tablets. Do not take Naratriptan tablets at least 24 hours before taking other migraine medicines.
- **medicines for the treatment of depression** (antidepressants including **SSRIs** and **SNRIs**). Taking Naratriptan tablets with these medicines may cause a condition called serotonin syndrome. The symptoms of this condition includes confusion, restlessness, fever, sweating, uncoordinated movements of the limbs or eyes, uncontrollable muscle twitches or diarrhoea.
- **herbal products containing St John's Wort**. Side effects are more likely to occur while taking Naratriptan tablets with these herbal medicines.

Naratriptan tablets with food and drink

Naratriptan tablets can be taken with or without food.

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.

Pregnancy

Before starting treatment, you must tell your doctor if you are pregnant or if you intend to become pregnant. There are no studies on the use of Naratriptan tablets in pregnant women and it is not known if Naratriptan tablets may harm your unborn baby. Your doctor may recommend that you do not take Naratriptan tablets while you are pregnant.

Breast-feeding

Mothers who wish to breast-feed should discuss with their doctor. It is not known if naratriptan passes into the mother's milk. You are advised not to breastfeed for 24 hours after taking Naratriptan tablets. Do not feed your child with milk produced during this period.

Driving and using machines

There is currently no information available about the effect of Naratriptan tablets on the ability to drive and use machines. However, this medicine might cause drowsiness in some people (see section 4). Do not drive or operate machinery if you are affected.

Naratriptan tablets contain 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.

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

3 How to take Naratriptan tablets
Dosage
Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Your doctor will prescribe the dose of Naratriptan tablets that is right for you. Do not change your dose of Naratriptan tablets without talking to your doctor. Naratriptan tablets should be taken as soon as you feel a migraine coming on, although it can be taken at any time during an attack. You must not use Naratriptan tablets to prevent a migraine attack.

The recommended dose is:
Adults (18 to 65 years of age)
The usual dose for adults is one Naratriptan 2.5mg tablet.
If the first tablet relieves your migraine but your symptoms start to come back, you can take a second Naratriptan 2.5mg tablet 4 hours after your first dose.
The total daily dose should not exceed more than two Naratriptan 2.5mg tablets.
If the first tablet has no effect on your migraine, do not take the second tablet for the same migraine attack. Ask your doctor or pharmacist for advice.

Patients with kidney problems
In patients with mild or moderate kidney problems, the daily dose of Naratriptan tablets should not exceed one Naratriptan 2.5mg tablet. Do not take Naratriptan tablets if you have severe kidney problems.

Patients with liver problems
In patients with mild or moderate liver problems, the daily dose of Naratriptan tablets should not exceed one Naratriptan 2.5mg tablet. Do not take Naratriptan tablets if you have severe liver problems.

Elderly (over 65 years of age)
Naratriptan tablets are not recommended for use in elderly patients.

Use in children and adolescents
Naratriptan tablets are not recommended for use in children and adolescents.

Method of administration
Naratriptan tablets should be swallowed **whole with water**.

Duration of treatment
Your doctor will advise you on how long your treatment should last. The duration of treatment will depend on how severe your condition is and how well you are responding to the treatment.

If you take more Naratriptan tablets than you should
If you take too many tablets, or if a child takes a tablet or someone you know has received too much medicine, please tell your doctor or nurse immediately or contact the nearest hospital emergency department.
The following symptoms have been seen when very high doses of Naratriptan tablets have been swallowed: high blood pressure, dizziness, tension in the neck, tiredness and loss of coordination.
There is no specific treatment for Naratriptan tablets overdose. The treatment would be based on the symptoms.

If you stop taking Naratriptan tablets
You must take your medicine exactly as directed. **Do not stop** your therapy on your own for any reason because your condition could worsen. Do not change your dosage schedule without talking to your doctor.
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.

You should stop taking Naratriptan tablets and see your doctor immediately if the following symptoms occur:
- a sudden allergic reaction, includes shortness of breath, rash, wheezing, swelling of eyelids, face, lips or throat and complete collapse.

These side effects are rare (may affect up to 1 in 1,000 people).

The following side effects have also been reported:

Common side effects (may affect up to 1 in 10 people) include:
- tingling sensation (this is usually of short duration, which may be severe and may affect any part of the body including the chest or throat)
- dizziness
- drowsiness
- feeling sick
- being sick
- hot flushes
- tiredness
- generally feeling unwell.

Uncommon side effects (may affect up to 1 in 100 people) include:
- visual disturbances
- slow or fast heartbeat
- irregular heartbeat
- heaviness, pressure, tightness or pain in the chest, throat or other parts of the body
- slight increase in blood pressure which may last for up to 12 hours after taking Naratriptan tablets.

Rare side effects (may affect up to 1 in 1,000 people) include:
- pain in the lower left side of the stomach and bloody diarrhoea
- rash
- hives
- itching
- swelling of the face.

Very rare side effects (may affect up to 1 in 10,000 people) include:
- narrowing of the artery that supplies blood to the heart
- chest pain
- heart attack
- poor blood circulation to the arms and legs, causing pain and discomfort.

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 Naratriptan tablets
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 blister and carton after "EXP". The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.
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 tablets contain
- The active substance is naratriptan. Each film-coated tablet contains 2.78mg of naratriptan hydrochloride equivalent to 2.5mg of naratriptan.
- The other ingredients are:

Tablet core: cellulose microcrystalline, lactose, croscarmellose sodium, magnesium stearate.
Film-coating: hypromellose 6cp (E464), titanium dioxide (E171), triacetin, iron oxide yellow (E172) and FD&C blue #2/ indigo carmine aluminium lake (E132).

What Naratriptan tablets look like and contents of the pack
Green coloured, capsule shaped, film-coated tablets debossed with "N" on one side and plain on the other side.

The film-coated tablets are available in:
PVC/PVdC/Aluminium blisters or Aluminium/Aluminium blisters.
Pack sizes: 6 or 12 film-coated tablets.

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