

Naramig(R) tablets

(Naratriptan hydrochloride)

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you start taking Naramig tablets.

This leaflet answers some common questions about Naramig tablets. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you taking Naramig tablets against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What are Naramig tablets used for?

Naramig tablets contain the active ingredient naratriptan hydrochloride. This medicine belongs to a group of drugs called serotonin agonists.

Naramig tablets are used to relieve a migraine attack. They should not be used to prevent migraine attacks from occurring. Naramig tablets may be used for migraine headaches with or without what is known as 'aura'.

It is thought that migraine headache is due to inflammation and widening of certain blood vessels in the head. Naramig tablets work by making those vessels normal again and ease

the symptoms of migraine.

Your Naramig tablets do not work in other types of headache which are not a migraine.

Naramig tablets are not addictive.

Before you take Naramig tablets

Do not take if:

You must not take Naramig tablets if:

- * **you have ever had an allergic reaction to naratriptan hydrochloride or any of the ingredients listed toward the end of this leaflet. (See "Ingredients").**
- * **you have or have had:**
 - heart disease or heart attack.
 - Prinzmetal's angina (an uncommon form of angina where pain is experienced at rest rather than during activity).
 - angina.
 - shortness of breath, pain or tightness in the chest, jaw or upper arm.
 - stroke, or any other blood circulation problem that affects the brain.
 - blood vessel problems that cause poor circulation in the arm and/or legs.
 - high blood pressure.
 - kidney disease.
 - liver disease.

- * **you have just taken another serotonin agonist (eg Imigran, Zomig).**
- * **you have taken ergotamine (eg Cafergot), dihydroergotamine (eg Dihydergot) or methysergide (eg Deseril) in the last 24 hours.**
- * **you are taking any antidepressants called selective serotonin reuptake inhibitors (SSRIs) or serotonin noradrenaline reuptake inhibitors (SNRIs).**
- * **the expiry date (EXP) printed on the pack has passed.**
- * **the packaging is torn or shows signs of tampering**

Tell your doctor if:

You must tell your doctor if:

- * **you are allergic to foods, dyes, preservatives or any other medicines, including any that contain sulphur (eg sulphonamide antibiotics).**
- * **you are allergic to lactose.**
- * **you are taking or have taken any other medicines in the last few days, including medicines you buy without a prescription, particularly herbal preparations containing St John's Wort.**
- * **you are breastfeeding, pregnant or trying to become pregnant.**
- * **you have or have had any of the following medical conditions:**
 - migraine known as "hemiplegic", "basilar" or "ophthalmoplegic" migraine.
 - high blood cholesterol or lipid ("fat") levels.

- a family history of heart problems.

How do I take Naramig tablets?

Take your medicine as your doctor has told you. The label on the pack will tell you how many tablets to take and how often you should take them. If you do not understand what you should do, ask your doctor or pharmacist.

How much to take

The recommended dose for adults is one 2.5 mg tablet.

If the first Naramig tablet helps your migraine, but the migraine comes back later, you may take another tablet four hours after taking the first.

Do not take more than two Naramig tablets in any twenty-four hours.

How to take it

Your Naramig tablet should be swallowed whole with a drink of water. Do not crush or chew the tablet as it has a bitter taste.

When to take it

It is best to take your Naramig tablet as early as possible in the migraine attack but it will work if you take your tablet later during the attack.

Do not take more Naramig tablets if the first dose has not provided any relief from your symptoms. You may take your usual headache relief medication provided it does not contain ergotamine or methysergide. If you are not sure what to do, ask your doctor or pharmacist.

If your migraine is not relieved by Naramig, you may use Naramig tablets on another occasion to treat another migraine attack.

Provided there are no side effects, at least three separate migraine attacks can be treated with Naramig tablets before you and your doctor decide this medicine is ineffective for you.

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too many Naramig tablets, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking Naramig tablets

Things you must do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it is not working and change your treatment unnecessarily.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

As with many other medicines, Naramig tablets may cause drowsiness in some people.

Be careful driving or operating machinery until you know how Naramig tablets affect you.

If you use Naramig tablets too often, it may make your headache worse. If this happens, your doctor may tell you to stop taking Naramig tablets.

What are the side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking Naramig tablets, even if the problem is not listed below.

Like other medicines, Naramig tablets can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

It is likely that some side-effects may be due to the migraine itself.

Tell your doctor if you experience any of the following after taking Naramig tablets:

- * pain, numbness, tingling, heat or flushing in any part of the body.
- * feeling of sleepiness, drowsiness, dizziness or tiredness.
- * nausea (feeling sick) or vomiting.
- * feeling of faintness.
- * muscle pain, stiffness, tightness or rigidity.
- * reduced ability to produce saliva (dry mouth).

Tell your doctor immediately and do not take any more Naramig tablets if you:

- * feel heaviness, pressure or tightness in any part of the body, including the chest or throat.
- * feel irregular heart beats.
- * have wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction.
- * start to experience severe abdominal pain and pass blood in your stools.
- * have persistent purple discolouration and/or pain in the fingers, toes, ears, nose or jaw in response to cold.

These side effects are likely to be serious. Stop taking Naramig tablets and seek medical attention straight

away.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

How do I store Naramig tablets?

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Keep Naramig tablets in the blister pack in a cool, dry place where it stays below 30 degrees C.

Do not leave them in a car, on a window sill or in a bathroom.

Keep Naramig tablets in the blister pack until time to take.

Return any unused or expired medicine to your pharmacist.

Product description

What Naramig tablets look like

Naramig 2.5 mg tablets are green, D-shaped and engraved with "GX CE5" on one side. A box contains 2 or 4 tablets in foil blisters.

The tablets have a film coating to protect the tablet and give the distinctive colour.

Ingredients

Each Naramig tablet contains the active ingredient called naratriptan hydrochloride.

Naramig tablets also contain lactose, microcrystalline cellulose (460), croscarmellose sodium, magnesium stearate (572) and Opadry Green OY-S-21027.

Naramig tablets contain lactose.

Supplier

Your Naramig tablets are supplied by:

GlaxoSmithKline Australia Pty Ltd
1061 Mountain Highway
Boronia
Victoria, 3155
Australia.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

This leaflet was prepared on 22 June 2007.

The information provided applies only to: Naramig(R).

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