

Relpax®

eletriptan hydrobromide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Relpax. It does not contain all 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 risks of you taking Relpax against the benefits it is expected to have for you.

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

Read this leaflet carefully before you start Relpax and keep it with your medicine.

You may need to read it again.

What Relpax is used for

Relpax is used to treat a migraine attack.

Symptoms of a migraine include headache, nausea (feeling sick), vomiting, sensitivity to light and sensitivity to sound.

Some people with migraine also get an "aura", which is a warning sign of temporary change in eyesight or speech, sometimes associated with vomiting.

Relpax is effective in relieving migraine with or without aura.

Relpax does not work in other types of headache, which are not migraine.

Relpax should be taken as early as possible after the migraine

headache starts, but is also effective if taken at a later stage during the migraine.

It does not work if taken during the aura phase, before the headache starts. It is not effective in preventing migraine attacks.

Relpax contains the active ingredient eletriptan hydrobromide. It belongs to a group of medicines called serotonin agonists. It is thought that these medicines work by reducing the size of swollen blood vessels around the brain that may be involved in migraine.

Your doctor, however, may prescribe Relpax for another purpose.

Ask your doctor if you have any questions about why Relpax has been prescribed for you.

This medicine is only available with a doctor's prescription.

Before you take Relpax

When you must not take it

Do not take Relpax if:

1. you have an allergy to:

- Relpax
- any of the ingredients listed at the end of this leaflet

2. you have a headache different from your usual migraine
Instead, check with your doctor.

If you have a headache different from your usual pattern, it may be related to a serious condition (such as stroke or aneurysm) and taking Relpax may be harmful.

3. you have severe liver problems

4. you have high blood pressure that is difficult to treat

5. you have, or have had, heart or blood vessel disease or signs of these conditions. These may include:

- angina, stroke, heart attack
- dizzy or fainting spells
- pains in the chest
- cold hands or feet
- pain in the calves when walking

6. you have taken, within the last 24 hours:

- medicines similar to Relpax such as sumatriptan

7. you have taken or plan to take, within the next 24 hours:

- ergotamine (a medicine used to treat migraine) or medicines derived from ergotamine like dihydroergotamine or methysergide

8. you have taken, within the last 48 hours:

- either of the following antibiotics: erythromycin or clarithromycin
- either of the following antifungals: ketoconazole or itraconazole
- any of the following protease inhibiting drugs: amprenavir, ritonavir, indinavir, saquinavir, nelfinavir
- an antidepressant called nefazodone

Ask your pharmacist or doctor if you are not sure if you are taking any of these medicines.

Do not take Relpax if the packaging is torn or shows signs of tampering.

Do not take Relpax if the expiry date (EXP) or use by date printed

on the pack has passed, even though the tablets may look alright.

Do not give Relpax to children or adolescents under 17 years of age.

If you are not sure if you should be taking Relpax, talk to your doctor.

Before you start to take it

You must tell your doctor if:

1. you have any allergies to:

- any other medicines
- any other substances such as foods, dyes or preservatives

2. you have ever been told you may have an increased risk of heart or blood vessel disease

Heart and blood vessel disease and high blood pressure sometimes do not cause any symptoms, so some people do not know if they have these problems.

Before deciding whether you should take Relpax, your doctor will check you for risk factors for coronary artery disease (CAD) such as high blood pressure, high cholesterol, smoking, obesity, diabetes, family history of CAD, post menopause in females and age over 40 years in males.

3. you have any other health problems including liver or kidney problems

4. you are pregnant, breast-feeding, or intend to become pregnant or breast-feed

Your doctor will discuss the possible risks and benefits of using Relpax during pregnancy or while breast-feeding. You may be advised to stop breast-feeding for 24 hours after taking Relpax.

If you have not told your doctor or pharmacist about any of these things, tell them before you start taking Relpax.

Taking other medicines

Tell your doctor or your pharmacist if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

In particular, tell your doctor if you are taking:

- other medicines for migraine
- certain antibiotics such as erythromycin and clarithromycin
- certain antifungals such as ketoconazole and itraconazole
- medications which may lead to increased serotonin levels, including anti-depressants, such as Nefazodone
- certain protease inhibiting drugs, used in the treatment of HIV/AIDS, called amprenavir, ritonavir, indinavir, saquinavir and nelfinavir
- St John's Wort (botanical name *Hypericum Perforatum*), a herbal remedy used to treat mood disorders

You may need different amounts of Relpax or you may need to take different medicines. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while taking Relpax.

Ask your doctor or pharmacist if you are not sure if you are taking any of these medicines.

How to take Relpax

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information in this leaflet.

If you do not understand the instructions on the packaging, ask your doctor or pharmacist for help.

How much to take

The usual dose of Relpax is 40 mg.

The dose may be increased to 80 mg.

Do not take more than 2 doses of Relpax in any 24 hour period.

Do not take more than a total of 160 mg in one day.

Taking too much of this type of medicine can lead to constant daily headaches.

If you have problems with your kidneys, your doctor may prescribe a lower dose for you.

How to take it

Swallow the tablets whole with a full glass of water, either with or without food.

When to take it

Take Relpax as soon as possible after the start of the migraine attack.

It will also work if taken later during the attack.

Do not take a second dose of Relpax within 2 hours of taking the first dose.

If, after initial relief, your migraine comes back, take a second tablet. In this case, wait at least 2 hours between the first tablet and the second.

If Relpax does not relieve your migraine, do not take a second dose for the same attack.

A migraine not relieved by the first dose will probably not be relieved by a second dose either.

You may take something else for the pain, but do not take medicine containing ergotamine, dihydroergotamine or methysergide after taking Relpax.

If the initial dose of Relpax does not relieve your migraine, you may use Relpax on another occasion to treat another migraine attack.

Relpax will not prevent a migraine attack. If you take it during the "aura period", which occurs just before you get the headache, it will not be effective.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone in Australia - 13 11 26). for advice or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have taken too much Relpax. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Serious heart problems may occur after an overdose.

Keep telephone numbers of these places handy.

While you are taking Relpax

Things you must do

Check with your doctor if your migraine headaches are worse, or if they are occurring more often than before you started Relpax.

Headaches that are not relieved by Relpax are sometimes caused by conditions that need other treatment.

If you become pregnant while taking Relpax, tell your doctor immediately.

If you are taking other medicines for migraine such as ergotamine, dihydroergotamine or methysergide, wait at least 24 hours after your Relpax dose before taking them.

If you are about to start any new medicines, tell your doctor and pharmacist that you are taking Relpax.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Relpax.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not give Relpax to anyone else, even if they have the same condition as you or their symptoms seem similar.

Do not take Relpax to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Relpax affects you.

A migraine itself, or treatment with Relpax, may make you drowsy or dizzy.

Avoid driving, using machinery (or doing anything that may be dangerous) if you become drowsy during a migraine or after taking Relpax.

Be careful drinking alcohol if you suffer from migraine headaches.

Drinking alcohol can make headaches worse, or may cause new headaches to occur. People who suffer from severe headaches should probably avoid alcoholic drinks, especially during a headache.

Side effects

Check with your doctor as soon as possible if you have any problems while taking Relpax, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

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

Ask your doctor or pharmacist any questions you may have.

Tell your doctor immediately, or go to Accident or Emergency at your nearest hospital if you notice any of the following:

- chest pain or an uncomfortable feeling in the chest, which may spread to the arms or neck
- palpitations, fast heart beat
- headache not relieved by Relpax
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing.

These symptoms may be serious and need urgent medical attention.

Tell your doctor if you notice any of the following and if they worry you:

- numbness and/or tingling, weakness
- stomach pain or cramps, dry mouth, indigestion, tight or sore throat or difficulty in swallowing, nausea (feeling sick), vomiting
- dizziness, drowsiness
- flushing, sweating
- chills, pain
- muscle tightness, a spinning sensation
- weakness, lack of energy
- back pain

These side effects are usually mild. Some of these side effects may be due to the migraine itself.

Other side effects not listed above may occur in some people.

Do not be alarmed by this list of possible side effects.

You may not get any of them.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

After taking Relpax

Storage

Keep your tablets where young children cannot reach them.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Keep Relpax in a cool, dry place where the temperature stays below 30°C. Do not store it, or any other medicine, in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of their packaging, they may not keep well.

Disposal

If your doctor tells you to stop taking Relpax, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

Supplier

Relpax is supplied in Australia by:

Viatris Pty Ltd
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

Australian Registration Numbers

Relpax 40 mg - AUST R 68356

Relpax 80 mg - AUST R 68358

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RELPAK® is a Viatris company trade mark

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Product description

What it looks like

Relpax tablets come in two strengths:

- Relpax 40 mg - orange, round tablets, marked REP40 on one side and Pfizer on the other
- Relpax 80 mg - orange, round tablets, marked REP80 on one side and Pfizer on the other

These are available in blister packs of 4 tablets.

Ingredients

Active ingredient

The active ingredient in Relpax is eletriptan hydrobromide.

- Relpax 40 mg contains 40 mg eletriptan per tablet
- Relpax 80 mg contains 80 mg eletriptan per tablet

Other ingredients

- microcrystalline cellulose
- lactose monohydrate
- croscarmellose sodium
- magnesium stearate
- Opadry Clear YS-2-19114-A
- Opadry Orange OY-LS-23016