

RELPAX[®] MIGRAINE

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking RELPAX MIGRAINE, speak to your pharmacist or doctor.

1. Why am I taking RELPAX MIGRAINE?

RELPAX MIGRAINE contains the active ingredient eletriptan hydrobromide. RELPAX MIGRAINE is used to treat migraine attacks. For more information, see Section [1. Why am I taking RELPAX MIGRAINE?](#) in the full CMI.

2. What should I know before I take RELPAX MIGRAINE?

Do not take if you have ever had an allergic reaction to eletriptan hydrobromide or any of the ingredients listed at the end of the CMI.

Talk to your pharmacist or doctor if you have any other medical conditions, take any other medicines, are pregnant or breastfeeding or plan to become pregnant or breastfeed.

For more information, see Section [2. What should I know before I take RELPAX MIGRAINE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RELPAX MIGRAINE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take RELPAX MIGRAINE?

- Always take as directed by your pharmacist or doctor
- One tablet of RELPAX MIGRAINE should be taken as soon as possible after the start of a migraine attack. It will also provide relief later during the migraine; if required, a second dose may be taken.

More instructions can be found in Section [4. How do I take RELPAX MIGRAINE?](#) in the full CMI.

5. What should I know while taking RELPAX MIGRAINE?

Things you must do	<ul style="list-style-type: none">• Tell any pharmacist, doctor or dentist you visit that you are taking RELPAX MIGRAINE.• Call your doctor straight away if<ul style="list-style-type: none">◦ you become pregnant◦ your migraine headache lasts for longer than 24 hours.◦ your pattern of symptoms has changed.◦ you feel this headache is different or worse than your usual migraine e.g. more frequent, more persistent, more severe, or you don't recover between attacks.
Things you must not do	<ul style="list-style-type: none">• Do not give RELPAX MIGRAINE to anyone else, even if they have the same condition as you or their symptoms seem similar.
Driving or using machines	<ul style="list-style-type: none">• Avoid driving, using machinery (or doing anything that may be dangerous) if you become drowsy during a migraine or after taking RELPAX MIGRAINE.
Drinking alcohol	<ul style="list-style-type: none">• Migraine sufferers should probably avoid alcoholic drinks, especially during a headache.• Alcohol can make headaches worse or may cause new headaches to occur.
Looking after your medicine	<ul style="list-style-type: none">• Store RELPAX MIGRAINE below 30°C.

For more information, see Section [5. What should I know while taking RELPAX MIGRAINE?](#) in the full CMI.

6. Are there any side effects?

RELPAX MIGRAINE may cause dizziness, fatigue, and chest pain.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

RELPA[®] MIGRAINE

Active ingredient(s): *eletriptan hydrobromide*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking RELPA[®] MIGRAINE. **Speak to your pharmacist or doctor if you would like further information or if you have any concerns or questions about taking RELPA[®] MIGRAINE.**

Where to find information in this leaflet:

- [1. Why am I taking RELPA[®] MIGRAINE?](#)
- [2. What should I know before I take RELPA[®] MIGRAINE](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take RELPA[®] MIGRAINE?](#)
- [5. What should I know while taking RELPA[®] MIGRAINE](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking RELPA[®] MIGRAINE?

RELPA[®] MIGRAINE contains the active ingredient **eletriptan hydrobromide**.

RELPA[®] MIGRAINE is a serotonin agonist, that works by reducing the size of swollen blood vessels around the brain that may be involved in migraine.

RELPA[®] MIGRAINE is used to treat a migraine attack.

RELPA[®] MIGRAINE tablets do not work in other types of headaches, that are not a migraine.

RELPA[®] MIGRAINE tablets should not be used to prevent migraine attacks from occurring.

2. What should I know before I take RELPA[®] MIGRAINE?

Warnings

Do not take RELPA[®] MIGRAINE if:

- you have not been previously diagnosed with migraine by a doctor.
- you are allergic to eletriptan hydrobromide, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients under Section 7. Product details to make sure you can take this medicine.
- you have a headache different from your usual migraine as it may be related to a serious condition (such as stroke or aneurysm) and taking RELPA[®] MIGRAINE may be harmful. Check with your pharmacist or doctor.
- you have severe liver problem.
- you have high blood pressure that is difficult to treat.
- you have high blood pressure that is difficult to treat.
- you have, or have had, heart or blood vessel disease or signs of these conditions. These may include:
 - o angina, stroke, heart attack,
 - o dizzy or fainting spells,

- o pains in the chest,
- o cold hands or feet,
- o pain in the calves when walking.
- you have taken, within the last 24 hours, medicines similar to RELPA[®] MIGRAINE such as sumatriptan, zolmitriptan, rizatriptan.
- you have taken or plan to take, within the next 24 hours:
 - o ergotamine (a medicine used to treat migraine) or medicines derived from ergotamine, like dihydroergotamine or methysergide.
- you have taken, within the last 48 hours:
 - o either of the following antibiotics: erythromycin or clarithromycin,
 - o either of the following antifungals: ketoconazole or itraconazole,
 - o any of the following protease inhibiting drugs: amprenavir, ritonavir, indinavir, saquinavir, nelfinavir,
 - o antidepressant called nefazodone,
 - o St John's Wort herbal remedy.
- the packaging is torn or shows signs of tampering, or does not look quite right even if the tablets may look alright.
- the expiry date on the pack has passed or if it is damaged, return it to your pharmacist for disposal.

Check with your pharmacist or doctor if you:

- have any allergies to any other medicines or substances such as foods, dyes or preservatives.
- 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 RELPA[®] MIGRAINE, your pharmacist or doctor will check with 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.

- have any other health problems including liver or kidney problems.
- are taking other medicines for migraine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your pharmacist or doctor if you are pregnant or plan to become pregnant.

Talk to your pharmacist or doctor if you are breastfeeding or plan to breastfeed. You may be advised to stop breastfeeding for 24 hours after taking RELPAX MIGRAINE.

Use in children (under 18 years)

Do not use in children under the age of 18 years.

Use in patients over 65 years

Use with caution as it may affect blood pressure more in older adults than in younger adults. Do not take more than 1 tablet per dose unless advised by your doctor.

3. What if I am taking other medicines?

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

Some medicines may interfere with RELPAX MIGRAINE and affect how it works.

Caution should be exercised if you are taking medicines to treat depression such as:

- SSRIs (Selective Serotonin Reuptake Inhibitors), such as citalopram, escitalopram, sertraline or fluoxetine;
- SNRIs (Serotonin Norepinephrine Reuptake Inhibitors) such as desvenlafaxine, duloxetine, venlafaxine; and
- St John's Wort (botanical name Hypericum Perforatum, a herbal remedy used to treat mood disorders).

These medicines when taken with RELPAX MIGRAINE may increase the risk of serotonin syndrome, a condition caused mainly by an excess in serotonin within the central nervous system. Symptoms include but are not limited to high blood pressure, a fast heart rate, agitation and sweating.

Medicines that may increase the effect of RELPAX MIGRAINE include:

- erythromycin and clarithromycin, medicines used to treat bacterial infections.
- ketoconazole and itraconazole, medicines used to treat fungal infections.
- nefazodone, a medicine to treat depression.
- amprenavir, ritonavir, indinavir, saquinavir and nelfinavir, medicines to treat HIV/AIDS.

Check with your pharmacist or doctor if you are not sure about what medicines, vitamins or supplements you are taking and if these affect RELPAX MIGRAINE.

4. How do I take RELPAX MIGRAINE?

How much to take

- Follow the instructions provided by your pharmacist or doctor
- Take 1 tablet of RELPAX MIGRAINE 40 mg.

- Do not take more than a total of 2 tablets i.e. 80 mg in one day.
- Taking too much of this medicine can lead to constant headaches.
- Swallow the tablets whole with a full glass of water, either with or without food.
- If you have kidney problems, do not take more than 1 tablet per dose unless advised by your doctor .

When to take RELPAX MIGRAINE

- RELPAX MIGRAINE should be taken as soon as possible after the start of the migraine attack. It will also provide relief if taken later during the attack.
- Do not take a second dose of RELPAX MIGRAINE 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 MIGRAINE does not relieve your migraine, do not take a second dose for the same attack.
- You may take something else for the pain, but do not take medicine containing ergotamine, dihydroergotamine or methysergide for at least 24 hours before or after taking RELPAX MIGRAINE.
- RELPAX MIGRAINE will not prevent a migraine attack. If you take it before you get the headache, it will not be effective.

If you take too much RELPAX MIGRAINE

If you think that you or anyone else has taken too much RELPAX MIGRAINE, urgent medical attention may be needed. Serious heart problems may occur after an overdose.

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)** for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking RELPAX MIGRAINE?

Things you should do

Tell your pharmacist or doctor if:

- you become pregnant.
- your migraine headache lasts for longer than 24 hours.
- your pattern of symptoms has changed.
- you feel this headache is different or worse than your usual migraine e.g. more frequent, more persistent, more severe, or you don't recover between attacks.
- you generally have four or more migraine attacks each month.
- you have these symptoms with your migraine headache: weakness on one side of your body, double

vision, clumsy and uncoordinated movements, tinnitus (ringing in the ears), reduced levels of consciousness, seizure like movements, recent rash with a headache.

- Tell your pharmacist, doctor or dentist you visit that you are taking RELPAX.

Things you must not do

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

Driving or using machines

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

Drinking alcohol

Tell your pharmacist or doctor if you drink alcohol.

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.

Looking after your medicine

- Store below 30°C.
- Follow the instructions on the carton on how to take care of your medicine properly.
- Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:
 - o in the bathroom or near a sink, or
 - o in the car or on window sills.

Keep it where young children cannot reach it.

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

When to dispose of your medicine

- If you no longer need to use it
- After the expiry date
- The tamper evident seal has been damaged when you receive it

Getting rid of any unwanted medicine

Take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your pharmacist or doctor if you have any further questions.

Less serious side effects

Less serious side effects	What to do
Nervous system related <ul style="list-style-type: none"> • drowsiness 	Speak to your pharmacist or doctor if you

Less serious side effects	What to do
<ul style="list-style-type: none"> • flushing • sweating • chills, pain • numbness and/or tingling • weakness, lack of energy Gastrointestinal related: <ul style="list-style-type: none"> • stomach pain or cramps • dry mouth • indigestion • tight or sore throat or difficulty in swallowing Musculoskeletal related: <ul style="list-style-type: none"> • muscle tightness • a spinning sensation • back pain 	have any of these less serious side effects.

Serious side effects

Serious side effects	What to do
Cardiovascular related: <ul style="list-style-type: none"> • chest pain or an uncomfortable feeling in the chest, which may spread to the arms or neck • palpitations • fast heart beat Nervous system related: <ul style="list-style-type: none"> • dizziness • headache not relieved by RELPAX MIGRAINE Gastrointestinal related: <ul style="list-style-type: none"> • nausea (feeling sick) • vomiting Allergy related: <ul style="list-style-type: none"> • swelling of the face, lips, or tongue which may cause difficulty in swallowing or breathing 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your pharmacist or doctor if you notice anything else that may be making you feel unwell.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your pharmacist or doctor before you decide to stop taking any of your medicines.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What RELPAX MIGRAINE contains

Active ingredient (main ingredient)	Eletriptan hydrobromide
Other ingredients (inactive ingredients)	Microcrystalline cellulose Lactose monohydrate Croscarmellose sodium Magnesium stearate Opadry Clear YS-2-19114-A USA (ID 3089) / Opadry Clear YS-2-19114-A UK (ID 3088) containing Hypromellose, Sunset Yellow FCF, Titanium Dioxide, Triacetin Opadry Orange OY-LS-23016 UK (ID 3481) / Opadry Orange OY-LS-23016 USA (ID 3482) containing Hypromellose, Sunset Yellow FCF, Titanium Dioxide, Triacetin
Potential allergens	Sugars as lactose

Do not take this medicine if you are allergic to any of these ingredients.

What RELPAX MIGRAINE looks like

RELPAX MIGRAINE are orange, round tablets, marked "REP40" on one side and "VLE" on the other.

AUST R 347050.

Available in blister packs of 2 tablets.

Who distributes RELPAX MIGRAINE

Viatrix Pty Ltd

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000

www.viatrix.com.au

Phone: 1800 274 276

RELPAX® is a Viatrix company trade mark

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