

# RELPAX<sup>®</sup> MIGRAINE

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## Consumer Medicine Information (CMI) summary

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

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### 1. Why am I using 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 using RELPAX MIGRAINE?](#) in the full CMI.

### 2. What should I know before I use RELPAX MIGRAINE?

Do not use 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, or are pregnant or plan to become pregnant or are breastfeeding.**

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

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### 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 use 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 use RELPAX MIGRAINE?](#) in the full CMI.

### 5. What should I know while using RELPAX MIGRAINE?

#### Things you should do

- Remind any pharmacist, doctor or dentist you visit that you are using RELPAX MIGRAINE.
- Call your doctor straight away if
  - you become pregnant

	<ul style="list-style-type: none"> <li>○ your migraine headache lasts for longer than 24 hours.</li> <li>○ your pattern of symptoms has changed.</li> <li>○ 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.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>● Do not give RELPAX MIGRAINE to anyone else, even if they have the same condition as you or their symptoms seem similar.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>● Avoid driving, using machinery (or doing anything that may be dangerous) if you become drowsy during a migraine or after taking RELPAX MIGRAINE.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>● Migraine sufferers should probably avoid alcoholic drinks,</li> </ul>

	<p>especially during a headache.</p> <ul style="list-style-type: none"> <li>● Alcohol can make headaches worse or may cause new headaches to occur.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>● RELPAX MIGRAINE should be stored below 30°C.</li> </ul>

For more information, see Section [5. What should I know while using 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.

# RELPAX<sup>®</sup> MIGRAINE

**Active ingredient(s):** *eletriptan hydrobromide*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using RELPAX MIGRAINE. **You should also speak to your pharmacist or doctor if you would like further information or if you have any concerns or questions about using RELPAX MIGRAINE.**

**Where to find information in this leaflet:**

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

## 1. Why am I using RELPAX MIGRAINE?

**RELPAX MIGRAINE contains the active ingredient eletriptan hydrobromide.**

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

**RELPAK MIGRAINE is used to treat a migraine attack.**

RELPAK MIGRAINE tablets do not work in other types of headache, which are not migraine.

RELPAK MIGRAINE tablets should not be used to prevent migraine attacks from occurring.

## **2. What should I know before I use RELPAK MIGRAINE**

### **Warnings**

#### **Do not use RELPAK 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 RELPAK 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:
  - angina, stroke, heart attack,
  - dizzy or fainting spells,
  - pains in the chest,
  - cold hands or feet,
  - pain in the calves when walking.
- you have taken, within the last 24 hours, medicines similar to RELPAX MIGRAINE such as sumatriptan, zolmitriptan, rizatriptan.
- 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.
- 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,
  - antidepressant called nefazodone,
  - and 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 RELPAX 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 intend to become pregnant.



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

## **Use in children and adolescents (under 18 years)**

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

## **Use in patients over 65 years**

Use with caution as effects on blood pressure may be more marked than in younger adults.

### **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 use RELPAX MIGRAINE?**

### **How much to take / use**

- 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 problems with your kidneys, do not take more than 1 tablet a day.

## **When to take / use 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 use too much RELPAX MIGRAINE**

If you think that you have taken too much RELPAX MIGRAINE, you may need urgent medical attention. Serious heart problems may occur after an overdose.

### **You should immediately:**

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

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using RELPAX MIGRAINE**

### **Things you should do**

#### **Tell your pharmacist or doctor if:**

- you become pregnant.
- Remind any pharmacist, doctor or dentist you visit that you are using RELPAX MIGRAINE.
- 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.

## **Things you should 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 in 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:  
in the bathroom or near a sink, or  
in the car or on window sills.

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **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**

<b>Less serious side effects</b>	<b>What to do</b>
<b>Nervous system related</b> <ul style="list-style-type: none"> <li>• drowsiness</li> <li>• flushing</li> </ul>	<b>Speak to your pharmacist or doctor if you have any of these</b>

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

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Cardiovascular related:</b></p> <ul style="list-style-type: none"> <li>● chest pain or an uncomfortable feeling in the chest, which may spread to the arms or neck</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● palpitations</li> <li>● fast heart beat</li> </ul> <p><b>Nervous system related:</b></p> <ul style="list-style-type: none"> <li>● dizziness</li> <li>● headache not relieved by RELPAX MIGRAINE</li> </ul> <p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"> <li>● nausea (feeling sick)</li> <li>● vomiting</li> </ul> <p><b>Allergy related:</b></p> <ul style="list-style-type: none"> <li>● swelling of the face, lips, or tongue which may cause difficulty in swallowing or breathing</li> </ul>	<p><b>notice any of these serious side effects.</b></p>

**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](http://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

<b>Active ingredient (main ingredient)</b>	<b>Eletriptan hydrobromide</b>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• Microcrystalline cellulose</li><li>• Lactose (monohydrate)</li><li>• Croscarmellose sodium</li><li>• Magnesium stearate</li><li>• Opadry Clear YS-2-19114-A USA (ARTG ID 3089) / Opadry Clear YS-2-19114-A UK (ARTG ID 3088) containing Hypromellose, Sunset Yellow FCF, Titanium Dioxide, Triacetin</li><li>• Opadry Orange OY-LS-23016 UK</li></ul>

	(ARTG ID 3481) / Opadry Orange OY- LS-23016 USA (ARTG ID 3482) containing Hypromellose, Sunset Yellow FCF, Titanium Dioxide, Triacetin
<b>Potential allergens</b>	<b>Lactose (monohydrate)</b>

**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](http://www.viatrix.com.au)

Phone: 1800 274 276

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