

Package leaflet: Information for the user

RELPATM 20 mg and 40 mg film-coated tablets eletriptan

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.

What is in this leaflet

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1. What Relpax is and what it is used for

Relpax contains the active substance eletriptan. Relpax is one of a group of medicines called serotonin receptor agonists. Serotonin is a natural substance found in the brain that helps to narrow the blood vessels.

Relpax can be used to treat migraine headache with or without aura in adults. Before the start of a migraine headache, you may experience a phase called an aura, which can involve vision disorders, numbness and speech disorders.

2. What you need to know before you take Relpax

Do not take Relpax:

- If you are allergic (hypersensitive) to eletriptan, or any of the other ingredients of this medicine (listed in section 6).
- If you have severe liver or kidney disease.
- If you have moderate to severe high blood pressure or untreated mild high blood pressure.
- If you have ever had heart problems, [e.g. heart attack, angina, heart failure or significant abnormal heart rhythm (arrhythmia), temporary, sudden narrowing of one of the coronary arteries].
- If you have poor circulation (peripheral vascular disease).
- If you have ever had a stroke (even a mild one that lasted for only a few minutes or hours).
- If you have taken ergotamine or medicines like ergotamine (including methysergide) within 24 hours before or after taking Relpax.

If you are taking any other medicines that end in 'triptan' (for example sumatriptan, rizatriptan, naratriptan, zolmitriptan, almotriptan and frovatriptan).

Please consult your doctor and do not take Relpax, if these statements apply to you now or have applied to you at any time in the past.

Warnings and precautions

Talk to your doctor or pharmacist before taking Relpax if:

- you have diabetes.
- you smoke or use nicotine replacement therapy.
- you are male and over 40 years.
- you are female and post-menopausal.
- you or anybody in your family have coronary artery disease.
- you have ever been told that you may have an increased risk of heart disease, discuss this with your doctor before using Relpax.

Repeat use of migraine medicines

If you repeatedly use Relpax or any medicines for the treatment of migraine over several days or weeks, this can cause daily long-term headaches. Tell your doctor if you experience this as you might need to stop treatment for a while.

Other medicines and Relpax

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Taking Relpax together with some medicines may cause serious side effects. Do not use Relpax if:

- you have taken ergotamine or medicines like ergotamine (including methysergide) within 24 hours before or after taking Relpax.
- you are taking any other medicines that end in ‘triptan’ (for example sumatriptan, rizatriptan, naratriptan, zolmitriptan, almotriptan and frovatriptan).

Some medicines can affect the way Relpax works, or Relpax itself can reduce the effectiveness of other medicines taken at the same time. These include:

- Drugs used to treat fungal infections (e.g. ketoconazole and itraconazole).
- Drugs used to treat bacterial infections (e.g. erythromycin, clarithromycin and josamycin).
- Drugs used to treat AIDS and HIV (e.g. ritonavir, indinavir and nelfinavir).

The herbal preparation St John’s wort (*Hypericum perforatum*) should not be taken at the same time as this medicine. If you already take St John’s wort, consult your doctor before stopping the St John’s wort preparation.

Tell your doctor before starting treatment with eletriptan, if you are taking some medicines (commonly referred to as SSRIs* or SNRIs**) for depression and other mental disorders. These medicines may increase the risk of developing serotonin syndrome during combined use with certain migraine medications. See Section 4 Possible Side Effects for more information on the symptoms of serotonin syndrome.

*SSRIs- Selective serotonin re-uptake inhibitors **SNRIs
Serotonin norepinephrine re-uptake inhibitors

Relpax with food and drink

Relpax can be used before or after food and drinks.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

It is recommended to avoid breast-feeding for 24 hours after taking this medicine.

Driving and using machines

Relpax or the migraine itself may make you sleepy. This medicine may also make you feel dizzy. Therefore avoid driving and using machines during the migraine attack or after taking your medicine.

Relpax contains Lactose, the dye Sunset Yellow Aluminium Lake (E 110), and Sodium

Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

The dye Sunset Yellow Aluminium Lake (E 110) may cause allergic reactions.

Relpax 20 mg and 40 mg tablets contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Relpax

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults

Your medicine can be taken at any time after the start of the migraine headache, but it is best to take it as soon as possible. **However you should only take Relpax during the headache phase of the migraine. You should not take this medicine to prevent a migraine attack.**

- The usual starting dose is one 40 mg tablet.
- Swallow each tablet whole with a drink of water.
- If the first tablet does not relieve your migraine, do not take a second tablet for the same attack.
- If after a first tablet your migraine is relieved and then comes back, you may take a second tablet. However, after taking the first tablet you must wait at least 2 hours before taking the second tablet.
- You should not take more than 80 mg (2 x 40 mg tablets) within 24 hours.
- If you find that a dose of one 40 mg tablet does not relieve your migraines, tell your doctor – he or she may decide to increase the dose to two 40 mg tablets for future attacks.

Use in children and adolescents under 18 years

Relpax tablets are not recommended for children and adolescents under 18 years of age.

Elderly

Relpax tablets are not recommended for patients over 65 years of age.

Kidney Impairment

This medicine can be used in patients with mild or moderate kidney problems. In these patients a starting dose of 20 mg is recommended, and the total daily dose should not be more than 40 mg. Your doctor will tell you what dose to take.

Liver Impairment

This medicine can be used in patients with mild or moderate liver problems. No dose adjustment is required for mild or moderate liver impairment.

If you take more Relpax than you should

If you accidentally take too much Relpax, contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there is any medicine left or not. Side effects from taking too much Relpax include high blood pressure and heart problems.

If you forget to take Relpax

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a forgotten dose.

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.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine.

- Sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body) as this may be a sign of a hypersensitivity reaction.
- Chest pain and tightness, which may be intense and involve the throat. These may be symptoms of problems of the blood circulation of the heart (Ischaemic heart disease).
- Signs and symptoms of serotonin syndrome which may include restlessness, hallucinations, loss of co-ordination, fast heart beat, increase body temperature, fast changes in blood pressure and overactive reflexes.

Other side-effects that may occur are:

Common

(may affect up to 1 in 10 people)

- Chest pain or tightness or pressure, Heart palpitations, Increased heart rate
- Dizziness, Sensation of spinning or whirling (Vertigo), Headache, Feeling sleepy, Reduced sense of touch or pain
- Sore throat, Throat tightness, Dry mouth
- Abdominal and stomach pain, Indigestion (upset stomach), Nausea (sensation of unease and discomfort in stomach or abdomen with an urge to vomit)

- Stiffness (Increased muscle tone), Muscle weakness, Back pain, Muscle pain
- Generally feeling weak, Feeling hot, Chills, Runny nose, Sweating, Tingling or abnormal sensation, Flushing, Pain

Uncommon

(may affect up to 1 in 100 people)

- Difficulty breathing, Yawning
- Swelling of the face or hands and feet, Inflammation or infection of the tongue, Skin rash, Itching
- Increased sense of touch or pain (Hyperaesthesia), Loss of co-ordination, Slow or reduced movement, Tremor, Slurred speech
- Not feeling oneself (Depersonalisation), Depression, Thinking strangely, Feeling agitated, Feeling confused, Mood swings (Euphoria), Periods of unresponsiveness (Stupor), General feeling of discomfort, Illness or lack of wellbeing (Malaise), Sleeplessness (Insomnia)
- Loss of appetite and weight loss (Anorexia), Taste disturbance, Thirst
- Degeneration of the joints (Arthrosis), Bone pain, Joint pain
- Increased need to pass water (urinate), Problems with urinating, Passing excessive quantity of urine, Diarrhoea
- Abnormal vision, Eye pain, Intolerance to light, Dry or watery eyes
- Ear pain, Ringing in the ears (Tinnitus)
- Poor circulation (Peripheral vascular disorder)

Rare

(may affect up to 1 in 1,000 people)

- Shock, Asthma, Hives (Urticaria), Skin disorder, Swollen tongue
- Throat or chest infection, Swollen lymph glands
- Slow heart rate
- Emotionally fragile (mood swings)
- Degeneration of joints (Arthritis), Muscle disorder, Twitching
- Constipation, Inflamed gullet, Belching
- Breast Pain, Heavy or prolonged menstrual periods
- Eye infection (Conjunctivitis)
- Changes to voice

Other side effects reported include fainting, high blood pressure, inflammation of the large intestine, vomiting, brain and blood vessel-related accident, inadequate heart blood flow, heart attack, heart muscle/artery-related spasm.

Your doctor may also take regular blood samples to test for raised liver enzymes or any blood problems.

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 HPRAs Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Relpax

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 pack or bottle. The expiry date refers to the last day of that month.

PVC/Aclar/Aluminium blister packs: There are no special storage instructions.

HDPE bottles: Keep the tablets in their original container. Keep the container tightly closed when not in use to protect from moisture.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Relpax contains

The active ingredient is eletriptan (as eletriptan hydrobromide).

Each Relpax 20 mg Film-coated tablet contains 20 mg of eletriptan (as eletriptan hydrobromide).

Each Relpax 40 mg Film-coated tablet contains 40 mg of eletriptan (as eletriptan hydrobromide).

The other ingredients are microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate, titanium dioxide (E 171), hypromellose, glycerol triacetate and Sunset Yellow FCF Aluminium Lake (E 110). (see section 2 Relpax contains Lactose, the dye Sunset Yellow Aluminium Lake (E 110), and Sodium).

What Relpax looks like and contents of the pack

Relpax film-coated tablets are orange, round tablets.

Relpax 20 mg film-coated tablets are marked VLE on one side and REP 20 on the other side.

Relpax 40 mg film-coated tablets are marked VLE on one side and REP 40 on the other side.

Relpax is available in opaque PVC/Aclar/Aluminium blister packs containing 2, 3, 4, 5, 6, 10, 18, 30 and 100 tablets or in HDPE bottles with child-resistant HDPE/PP closures containing 30 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Viatrix Healthcare Limited,
Damastown Industrial Park,
Mulhuddart,

Dublin 15
DUBLIN,
Ireland

Manufacturer responsible for batch release within the EU:

Pfizer Italia S.r.l.,
Località Marino del Tronto,
63100 Ascoli Piceno,
Italy

This medicinal product is authorised in the member states of the EEA under the following names:

Relert 20 mg and 40 mg Film Coated Tablets: Belgium, Finland, Luxembourg, Portugal, Spain, United Kingdom.

Relpax 20 mg and 40 mg Film Coated Tablets: Austria, Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Norway, Spain, Sweden, The Netherlands, United Kingdom.

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