

PACKAGE LEAFLET

Package leaflet: Information for the patient

Eletriptan Pensa 20mg film-coated tablets

Eletriptan Pensa 40mg 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

1. What Eletriptan Pensa is and what it is used for
2. What you need to know before you take Eletriptan Pensa
3. How to take Eletriptan Pensa
4. Possible side effects
5. How to store Eletriptan Pensa
6. Contents of the pack and other information

1. What Eletriptan Pensa is and what it is used for

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

Eletriptan Pensa 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 Eletriptan Pensa

Do not take Eletriptan Pensa:

- If you are allergic 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 (heart) 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 Eletriptan Pensa.
- 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 Eletriptan Pensa, 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 Eletriptan Pensa:

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

Children and adolescents under 18 years

Eletriptan is not recommended for children and adolescents under 18 years of age.

Elderly

Eletriptan is not recommended for patients over 65 years of age

Repeat use of migraine medicines

If you repeatedly use eletriptan 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 Eletriptan Pensa

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

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

- you have taken ergotamine or medicines like ergotamine (including methysergide) within 24 hours before or after taking Eletriptan Pensa
- 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 Eletriptan Pensa works, or Eletriptan Pensa itself can reduce the effectiveness of other medicines taken at the same time. These include:

- Medicines used to treat fungal infections (e.g. ketoconazole and itraconazole).
- Medicines used to treat bacterial infections (e.g. erythromycin, clarithromycin and josamycin).
- Medicines 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 which are medicines normally used for depression e.g. citalopram, fluoxetine.

**SNRIs – Serotonin norepinephrine reuptake inhibitors which are medicines normally used for depression e.g. venlafaxine or duloxetine (which can also be used for urinary problems).

Pregnancy and breast-feeding

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

Pregnancy

Eletriptan Pensa may be recommended by your doctor during pregnancy, but only if it is needed.

Breast-feeding

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

Driving and using machines

Eletriptan 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.

Eletriptan Pensa contains lactose, sunset yellow (E110) 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 colouring sunset yellow (E110) may cause allergic reactions.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Eletriptan Pensa

Always take this medicine exactly as your doctor or pharmacist 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 Eletriptan Pensa during the headache phase of the migraine. You should not take this medicine to prevent a migraine attack.**

- The recommended starting dose is one 40mg tablet
- Swallow each tablet whole with a drink of water, before or after food.
- 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 80mg (4 x 20 mg or 2 x 40mg tablets) within 24 hours.
- If you find that a dose of one 40mg tablet does not relieve your migraines, tell your doctor – he or she may decide to increase the dose to two 40mg tablets for future attacks.

Kidney impairment

This medicine can be used in patients with mild or moderate kidney problems. In these patients a starting dose of 20mg is recommended, and the total daily dose should not be more than 40mg. 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 Eletriptan Pensa than you should

If you accidentally take too much Eletriptan Pensa 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 eletriptan include high blood pressure and heart problems.

If you forget to take Eletriptan Pensa

You should only take this medicine during the headache phase of a migraine. If you forget to take a dose, take it as soon as you remember. 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.

If you notice any of the following serious side effects, stop using Eletriptan Pensa and tell your doctor immediately or go to your nearest hospital emergency department as you may need urgent medical treatment:

- Chest pain and tightness, which may be intense and involve the throat. You may also feel clammy, short of breath and notice pain spreading into the jaw and arms. These may be symptoms of problems of the blood circulation of the heart (ischaemic heart disease), heart muscle/artery spasm or a heart attack.
- Feeling weak, particularly down one side of the body, difficulty with speech or lifting both arms up above your head. These may be symptoms of a stroke (a blockage of blood flow to the brain or leakage of blood from the blood vessels in the brain).
- Allergic reactions: You may notice symptoms of sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).
- Serotonin syndrome: Signs and symptoms of serotonin syndrome may include restlessness, hallucinations (seeing, feeling or hearing things that are not there), loss of co-ordination, fast heart beat, increased body temperature, fast changes in blood pressure and overactive reflexes.
- Insufficient blood flow to the gut (intestines) – you may notice bloody diarrhoea, stomach pain or be sick.

Other side-effects that may occur are:

Common side effects

(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, general pain
- Generally feeling weak, feeling hot, chills, runny nose, sweating, tingling or abnormal sensation, flushing

Uncommon side effects

(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 side effects

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

- Shock, asthma (bronchial disorder), hives (urticaria), skin disorder, swollen tongue
- Throat or chest infection, swollen lymph glands
- Slow heart rate
- Emotionally fragile (mood swings)
- Inflammation of the joints (arthritis), muscle disorder, twitching
- Constipation, inflamed gullet, belching
- Breast pain, heavy or prolonged menstrual periods
- Eye infection (conjunctivitis)
- Changes to voice
- Fainting (syncope)

Other side effects reported include high blood pressure.

Your doctor may also take regular blood samples to test for raised liver enzymes, levels of a substance called bilirubin or any blood problems.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via **[To be completed nationally]**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Eletriptan Pensa

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the packaging after EXP. The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

What Eletriptan Pensa contains

The active substance is eletriptan

Each film-coated tablet contains eletriptan hydrobromide corresponding to 20 mg eletriptan.

Each film-coated tablet contains eletriptan hydrobromide corresponding to 40 mg eletriptan.

The other ingredients are microcrystalline cellulose, lactose anhydrous, croscarmellose sodium and magnesium stearate, titanium dioxide (E171), talc (E553b), sunset yellow FCF aluminium lake (E110), soya (bean) lecithin (E322), xanthum gum (E415) (see section 2 “Eletriptan Pensa contains lactose, sunset yellow (E110) and sodium”).

What Eletriptan Pensa looks like and contents of the pack

20mg: Round (6.4mm), biconvex orange coloured tablets debossed with “M” on one side of the tablet and “EL1” on the other.

40mg: Round (8.2mm), biconvex orange coloured tablets debossed with “M” on one side of the tablet and “EL2” on the other.

Eletriptan Pensa is available in blisters in packs containing 3, 4, 6, 6 x 1, 10, 10 x 1 (40 mg tablets only), 18, 20 film-coated tablets

Not all pack sizes may be marketed

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

McDermott Laboratories Limited trading as Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13.

Mylan Hungary Kft, Mylan utca 1., Komárom, 2900, Hungary.

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark:	Eletriptan Pensa
Norway:	Eletriptan Pensa 20 mg, 40mg filmdrasjerte tablett
Sweden:	Eletriptan Pensa 20 mg, 40mg filmdragerade tablett
Finland:	Eletriptan WH

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