Package leaflet: Information for the patient

Eletriptan 20 mg Film-coated Tablets
Eletriptan 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

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

1. What Eletriptan is and what it is used for

This medicine contains the active substance eletriptan. Eletriptan 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.

Eletriptan 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

Do not take Eletriptan:
- 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 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.
- 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, 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 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 has coronary artery disease (develops when the major blood vessels that supply your heart become damaged or diseased).
- You have ever been told that you may have an increased risk of heart disease, discuss this with your doctor before using Eletriptan.

Children and adolescents
Eletriptan is not recommended for children and adolescents under 18 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
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Taking Eletriptan together with some medicines may cause serious side effects. Do not use Eletriptan if:
- You have taken ergotamine or medicines like ergotamine (including methysergide).
- 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 works, or Eletriptan 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 (Selective serotonin re-uptake inhibitors) or SNRIs (Serotonin norepinephrine re-uptake inhibitors), 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.

Eletriptan with food and drink
Eletriptan can be used before or after food and drinks.

Pregnancy, breast-feeding and fertility
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
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 contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. How to take Eletriptan

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 Eletriptan 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 – your doctor may decide to increase the dose to two 40 mg tablets for future attacks.

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

Children and Adolescents under 18 years
Eletriptan tablets are not recommended for patients under 18 years of age.

Kidney Impairment
Do not take Eletriptan tablets if you have severe kidney disease.
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
Do not take Eletriptan tablets if you have severe liver disease.
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 than you should
If you accidentally take too much Eletriptan, 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
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 heartbeat, 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 well-being (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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Eletriptan

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 after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Eletriptan contains
The active ingredient is eletriptan (as eletriptan hydrobromide).

Each Eletriptan 20 mg Film-coated tablet contains 20 mg of eletriptan (as Eletriptan hydrobromide).
Each Eletriptan 40 mg Film-coated tablet contains 40 mg of eletriptan (as Eletriptan hydrobromide).

The other ingredients (excipients) are microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate, polyvinyl alcohol, titanium dioxide (E171), polyethylene glycol, talc.

What Eletriptan looks like and contents of the pack
Eletriptan film-coated tablets are white, round, convex shaped film-coated tablets.
Eletriptan 20 mg film-coated tablets are plain on one side and embossed with “20” on the other side.
Eletriptan 40 mg film-coated tablets are plain on one side and embossed with “40” on the other side.

Eletriptan 20 mg Film-coated Tablets
Opaque PVC/PCTFE/Aluminium blister packs containing 1, 2, 3, 4, 6, 10 and 18 tablets.

Eletriptan 40 mg Film-coated Tablets
Opaque PVC/PCTFE/Aluminium blister packs containing 1, 2, 3, 4, 6, 10, 18 and 20 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Consilient Health Ltd.,
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Manufacturer
Chanelle Medical Unlimited Company
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