Package leaflet: Information for the patient

Almotriptan 12.5 mg Film-coated tablets

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 Almotriptan 12.5 mg Film-coated tablets is and what it is used for

Almotriptan 12.5 mg Film-coated tablets is an antimigraine agent which belongs to a class of compounds known as selective serotonin receptor agonists. Almotriptan 12.5 mg Film-coated tablets is believed to reduce the inflammatory response associated with migraines by binding to the serotonin receptors in the brain (cranial) blood vessels and causing them to narrow.
Almotriptan 12.5 mg Film-coated tablets is used to relieve headaches associated with migraine attacks with or without aura.

2. What you need to know before you take Almotriptan 12.5 mg Film-coated tablets

Do not take Almotriptan 12.5 mg Film-coated tablets
- if you are allergic to almotriptan or any of the ingredients of this medicine (listed in section 6)
- if you have or have ever suffered from diseases that restrict the blood supply to the heart such as:
  - heart attack
  - chest pain or discomfort that normally occurs with activity or stress
  - heart problems without pain
  - chest pain that occurs when you are resting
  - severe hypertension (severe high blood pressure)
  - uncontrolled mild or moderate high blood pressure.
- if you have had a stroke or experienced a reduction in the blood flow to the brain
- if you have had obstruction of the large arteries in the arms or legs (peripheral vascular disease)
- if you are taking other medicines used to treat migraines including ergotamine, dihydroergotamine and methysergide or other serotonin agonists (e.g. sumatriptan)
- if you suffer from severe liver disease

Warnings and precautions:
Talk to your doctor or pharmacist before taking Almotriptan 12.5 mg Film-coated tablets:
- if your type of migraine has not been diagnosed
- if you are allergic (hypersensitive) to antibacterial medicines mainly used for treatment of urinary tract infections (sulphonamides)
- if your headache symptoms are different from your usual attacks i.e. you have a noise in your ears or vertigo, you have short lived paralysis of one side of the body or paralysis of the muscles that control eye movement or if you have any new symptoms.
- if you are at risk of heart disease, this includes uncontrolled high blood pressure, high cholesterol, obesity, diabetes, smoking, clear family history of heart disease, postmenopausal females or males over the age of 40
- if you have mild to moderate liver disease
- if you suffer from severe kidney disease
- if you are over 65 years of age (as you are more likely to experience blood pressure increases)
- you are taking anti-depressants SSRIs (selective serotonin reuptake inhibitors) or SNRIs (serotonin noradrenaline reuptake inhibitors). Also see Other medicines and Almotriptan 12.5 mg Film-coated tablets below

It has been suggested that excessive use of an anti-migraine medicinal product can lead to daily chronic headache.

Children and adolescents
Children under the age of 18 should not take Almotriptan 12.5 mg Film-coated tablets.

Elderly (over 65 years of age)
If you are over 65 years of age you should speak to your doctor before using this medicinal product.

Other medicines and Almotriptan 12.5 mg Film-coated tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Please tell your doctor:
- if you are taking medicines used to treat depression such as monoamine oxidase inhibitors (e.g. moclobemide), selective serotonin reuptake inhibitors (e.g. fluoxetine) or serotonin noradrenaline reuptake inhibitors (e.g. venlafaxine) as these may cause serotonin syndrome, a potentially life-threatening drug reaction. The symptoms of serotonin syndrome include; confusion, restlessness, fever, sweating, uncoordinated movements of the limbs or eyes, uncontrollable muscle twitches or diarrhoea
- if you are taking herbal St John's Wort (Hypericum perforatum) as this may increase the likelihood of side effects.

Almotriptan should not be taken at the same time as ergotamine-containing medicines, which are also used to treat migraine. However, the medicines may be taken after one another: provided a suitable amount of time is left between taking each medicine
- following use of almotriptan, it is advised to wait at least 6 hours before taking ergotamine.
- following use of ergotamine, it is advised to wait at least 24 hours before taking almotriptan.

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

Only very limited data is available for almotriptan in pregnant patients. Almotriptan 12.5 mg Film-coated tablets should only be used during pregnancy if instructed by your doctor and only after they have carefully considered the benefits and risks.

Caution should be taken when using this medicine whilst breast-feeding. You should avoid breast-feeding for 24 hours after taking this medicine.

Driving and using machines
Almotriptan 12.5 mg Film-coated tablets may cause drowsiness. If you are affected, you should not drive or use any tools or machines.

3. How to take Almotriptan 12.5 mg Film-coated tablets

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

Almotriptan 12.5 mg Film-coated tablets should only be used to treat an actual migraine attack and not to prevent migraine attacks or headaches.

Adults (18-65 years old)

The usual dose is one 12.5 mg tablet which should be taken as early as possible after the onset of the migraine attack. If your migraine attack does not subside, do not take more than one tablet for the same attack.

If you experience a second migraine attack within 24 hours, a second 12.5 mg tablet can be taken but you must leave at least two hours between your first and second tablet.

The maximum daily dose is two (12.5 mg) tablets within 24 hours.

Tablet(s) should be swallowed with liquid (e.g. water) and can be taken with or without food.

You should take Almotriptan 12.5 mg Film-coated tablets as soon as possible after the onset of the migraine, although it is still effective if taken at a later stage.

Severe kidney disease

If you have severe kidney disease do not take more than one 12.5 mg tablet every 24 hours.

If you take more Almotriptan 12.5 mg Film-coated tablets than you should

If you accidentally take too many tablets, or if someone else or a child takes this medicine, talk to a doctor or pharmacist immediately.

If you forget to take Almotriptan 12.5 mg Film-coated tablets

Try to take Almotriptan 12.5 mg Film-coated tablets as you have been prescribed. Do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Almotriptan 12.5 mg Film-coated tablets can cause side effects, although not everybody gets them.

Common: (may affect up to 1 in 10 people)

- dizziness
- sleepiness (somnolence)
- nausea
- vomiting
- tiredness

Uncommon: (may affect up to 1 in 100 people)

- sensation of tingling, pricking or numbness of the skin (paraesthesia)
- headache
- ringing, roaring or clicking noise in the ears (tinnitus)
- heart pounding (palpitations)
- tightening of the throat
- diarrhoea
- discomfort when digesting food (dyspepsia)
- dry mouth
- muscle pain (myalgia)
- bone pain
- chest pain
- feeling weak (asthenia)

Very rare: (may affect up to 1 in 10,000 people)

- spasm of the heart blood vessels (coronary vasospasm)
- heart attack (myocardial infarction)
- increased heart rate (tachycardia)

Not known: (frequency cannot be estimated from the available data)

- convulsion (seizure)
- allergic reactions (hypersensitivity reactions), including mouth, throat and hand oedema (angioedema)
- severe allergic reactions (anaphylactic reactions)
- visual impairment, vision blurred (visual disorders may occur also during the migraine attack itself)
- Intestinal vasospasm, which may result in intestinal damage (intestinal ischemia). You may experience abdominal pain and bloody diarrhoea.

During treatment with Almotriptan 12.5 mg Film-coated tablets, tell your doctor straight away:

- if you have chest pain, tightness in your chest or throat, or any other symptoms that resembles a heart attack. Please tell your doctor straight away and do not take any more Almotriptan 12.5 mg Film-coated tablets.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes or if you notice any side effects not listed in this leaflet. You can also report side effects directly via the UK Yellow Card Scheme,
Website: 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 thesafety of this medicine.

5. How to store Almotriptan 12.5 mg Film-coated tablets

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

Do not use Almotriptan 12.5 mg Film-coated tablets after the expiry date which is stated on the blister and carton 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 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 Almotriptan 12.5 mg Film-coated tablets contains

The active substance is Almotriptan.

Each film-coated tablet contains 12.5 mg Almotriptan as Almotriptan malate. The other ingredients are:
Tablet core: Mannitol (E421), microcrystalline cellulose, povidone, sodium starch glycolate Type A, sodium stearyl fumarate
Coating material: Hypromellose (E464), titanium dioxide (E171), Macrogol 400, carnauba wax

What Almotriptan 12.5 mg Film-coated tablets looks like and contents of the pack

Almotriptan 12.5 mg Film-coated tablets is available as a white to off white coloured, round, biconvex film-coated tablet.
Almotriptan 12.5 mg Film-coated tablets are available in blister packs containing 2, 3, 4, 6, 9, 12 and 14 tablets.
Not all pack sizes may be marketed.

PL Holder: Clydesdale Pharma Ltd., Unit 3-4 Campbell Court, Campbell Road, Tadley, RG26 5EG, United Kingdom.

Manufacturer: Chanelle Medical, Loughrea, Co. Galway, Ireland
JSC Grindeks, 53 Krustpils street, Riga, LV-1057, Latvia

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