

Package leaflet: Information for the user

Almogran 12.5mg film-coated tablets

almotriptan

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Almogran is and what it is used for

Almogran is an antimigraine agent which belongs to a class of compounds known as selective serotonin receptor agonists. Almogran 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.

Almogran is used to relieve headaches associated with migraine attacks with or without aura.

2. What you need to know before you take Almogran

Do not take Almogran

- 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, pharmacist or nurse before taking Almogran

- 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)
- If you are taking anti-depressants SSRIs (selective serotonin reuptake inhibitors) or SNRIs (serotonin noradrenaline reuptake inhibitors). Also see Other medicines and Almogran, 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 Almogran.

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 Almogran

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 monoamino 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 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.

Only very limited data is available for almotriptan in pregnant patients. Almogran 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

Almogran may cause drowsiness. If you are affected, you should not drive or use any tools or machines.

3. How to take Almogran

Almogran should only be used to treat an actual migraine attack and not to prevent migraine attacks or headaches.

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

Adults (18-65 years old)

The recommended 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 **Almogran** 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 Almogran 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 Almogran

Try to take Almogran 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, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common side effects (may affect up to 1 in 10 people)

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

Uncommon side effects (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 side effects (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)

Frequency unknown (frequency cannot be estimated from the available data)

- allergic reactions (hypersensitivity reactions), including mouth, throat or hand edema (angioedema)
- severe allergic reactions (anaphylactic reactions)
- convulsion (seizure)
- visual impairment, vision blurred (visual disorders may also occur during a migraine attack itself)

During treatment with Almogran, 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 Almogran tablets.

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:

United Kingdom

Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard

Ireland

Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.imb.ie, e-mail: imbpharmacovigilance@imb.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Almogran

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 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 Almogran contains

The active substance is almotriptan 12.5 mg (as almotriptan D,L-hydrogen malate).

The other ingredients are:

Tablet core: Mannitol (E-421), microcrystalline cellulose, povidone, sodium starch glycolate, sodium stearyl fumarate

Coating material: Hypromellose, titanium dioxide (E-171), Macrogol 400, carnauba wax

Printing ink: Hypromellose, propylene glycol, indigo carmine (E-132)

What Almogran looks like and contents of the pack

Almogran is available as a white, circular, biconvex film-coated tablet with a blue A printed on one side.

Almogran is available in blister packs containing 2, 3, 4, 6, 7, 9, 12, 14 or 18 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Almirall, S.A. General Mitre 151, 08022 Barcelona, Spain

Manufacturer

Industrias Farmacéuticas Almirall, S.L. Ctra. Nacional II, Km. 593 08740 Sant Andreu de la Barca - Barcelona, Spain

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

Belgium	Almogran 12.5 mg filmomhulde tabletten
Denmark	Almogran 12.5 mg filmovertrukne tabletter
Germany	Almogran 12.5 mg Filmtablette
Greece	Almogran 12.5 mg Επικαλυμμένα με λεπτό υμένιο δισκία
Finland	Almogran 12.5 mg tabletti, kalvopäällysteinen
France	Almogran 12.5 mg comprimé pelliculé
Iceland	Almogran 12.5 mg filmuhúðaðar töflur
Ireland	Almogran 12.5 mg Film-coated tablet
Italy	Almogran 12.5 mg compresse rivestite con film
Luxembourg	Almogran 12.5 mg comprimés pelliculés
Netherlands	Almogran 12.5 mg omhulde tablet
Norway	Almogran 12.5 mg filmdrasjert tablett
Portugal	Almogran 12.5 mg comprimidos revestidos por película
Sweden	Almogran 12.5 mg filmdragerad tablett
Spain	Almogran 12.5 mg comprimidos recubiertos con película
United Kingdom	Almogran 12.5 mg Film-coated tablet

This leaflet was last revised in 08/2013