

Package leaflet: Information for the user

ALMERG 180mg film coated tablets

Fexofenadine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after taking this medicine.

What is in this leaflet

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

1. What ALMERG is and what they are used for

The active ingredient in your tablets is fexofenadine hydrochloride, which belongs to a group of medicines called antihistamines. It is used in adults and adolescents of 12 years and older to relieve the symptoms of urticaria (red, raised itchy skin) which is often known as hives or nettle rash.

ALMERG is not suitable for children under 12 years of age.

You must talk to a doctor if you do not feel better or if you feel worse after taking this medicine.

2. What you need to know before you take ALMERG

Do not take ALMERG

- If you are allergic to fexofenadine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking ALMERG if you:

- have problems with your liver or kidneys
- are elderly
- have or ever had heart problems, as fexofenadine, like other antihistamines may cause your heart to beat faster (tachycardia) or you feel your heart beating (palpitations).

If any of these apply to you, or if you are not sure, tell your doctor or pharmacist before taking this medicine.

Other medicines and ALMERG

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine. This is especially important for the following medicines:

- Erythromycin (an antibiotic)
- Ketoconazole (a treatment for fungal infections)

Indigestion remedies containing aluminium and magnesium may affect the action of ALMERG by lowering the amount of medicinal product absorbed.

It is recommended that you leave about 2 hours between the time that you take ALMERG and your indigestion remedy.

ALMERG with food and drink

ALMERG should be taken before meals with water.

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.

ALMERG should not be taken during pregnancy and whilst breast-feeding unless advised by a doctor.

Driving and using machines

ALMERG is unlikely to affect your ability to drive or operate machinery. However, you should check that these tablets do not make you feel sleepy or dizzy before driving or operating machinery.

ALMERG contain sodium

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

3. How to take ALMERG

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

Adults and adolescents aged 12 years and over

The recommended dose is one tablet (180 mg) daily. Take your tablet with water before a meal.

This medicine starts to relieve your symptoms within 1 hour and lasts for 24 hours.

If the symptoms of allergic skin reactions persist, or gets worse or other symptoms appear, you should stop the treatment and consult a doctor.

Do not exceed the stated dose. Do not give to adolescents below 12 years of age.

If you take more ALMERG than you should

If you have accidentally taken more than this leaflet recommended, contact your nearest hospital emergency department or tell your doctor or pharmacist immediately. Remember to take the pack and any remaining tablets with you.

The most common signs of overdose are dizziness, drowsiness, fatigue and dry mouth.

If you forget to take ALMERG

Do not take a double dose to make up for a forgotten tablet.

If you stop taking ALMERG

Tell your doctor if you want to stop taking ALMERG before you have finished your course of treatment. If you stop taking ALMERG earlier than planned, your symptoms may return.

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 get any of the following symptoms after taking these tablets you should contact your doctor or pharmacist immediately as these may be signs of a serious allergic reaction:

- Swelling of the face, lips, tongue or throat and difficulty breathing.

The following side effects have also been reported:

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

- headache
- drowsiness
- feeling sick (nausea)
- dizziness

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

- tiredness or sleepiness

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

- difficulty sleeping (insomnia)
- sleeping disorders
- bad dreams
- nervousness
- fast or irregular heart beat
- diarrhoea
- skin rash and itching
- hives
- serious allergic reaction which can cause swelling of the face, lips, tongue or throat
- difficulty breathing

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 ALMERG

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

Do not take 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 the month.

Store in the original package.

This medicinal product does not require any special temperature storage condition.

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 ALMERG contains

The active substance is fexofenadine hydrochloride. Each film-coated tablet contains 180 mg of fexofenadine hydrochloride, which is equivalent to 168 mg of fexofenadine.

The other ingredients are:-

- *Tablet core:* Microcrystalline cellulose, maize starch, magnesium stearate, croscarmellose sodium, povidone.
- *Film coating:* Hypromellose (E464), macrogol (PEG 400), macrogol (PEG 4000), titanium dioxide (E171), iron oxide yellow (E172).

What ALMERG looks like and the contents of the pack:

ALMERG 180 mg film-coated tablet are yellow coloured, oblong, biconvex, film coated tablets, plain on one side and with a central breakline on the reverse side. The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

ALMERG is available in PVC/PVDC/Alu blister packs of 7, 10, 14, 15, 20, 21, 28 or 30 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and manufacturer

Marketing Authorisation Holder

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