

PACKAGE LEAFLET: Information for the user

ALEFAST

Film-coated tablets – 120 mg, 180 mg

(Fexofenadine hydrochloride)

Read all of this leaflet carefully before you start using 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. Do not pass it on to others. It may harm them, even if their symptoms 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 Alefast is and what it is used for
2. What you need to know before you take Alefast
3. How to take Alefast
4. Possible side effects
5. How to store Alefast
6. Further information

1. WHAT ALEFAST IS AND WHAT IT IS USED FOR

Alefast contains fexofenadine hydrochloride, which belongs to a group of medicines known as antihistamines.

Alefast 120 mg tablets are used in adults and adolescents of 12 years and older to relieve the symptoms that occur with hay fever (seasonal allergic rhinitis) such as sneezing, itchy, runny or blocked nose and itchy, red and watery eyes.

Alefast 180 mg tablets are used in adults and adolescents of 12 years and older to relieve the symptoms that occur with long term allergic skin reactions (chronic idiopathic urticaria) such as

itching, swelling and rashes.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ALEFAST

Do not take Alefast if:

- you are hypersensitive (allergic) to fexofenadine hydrochloride or to any of the excipients of this drug.

This medicine is not recommended for children under 12 years of age.

Warnings and precautions

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

- have problems with your liver or kidneys;
- have or have ever had heart disease, because taking this kind of medicine may lead to a fast or irregular heart beat;
- are elderly;
- are epileptic.

Allergy tests: If you are doing an allergy test, this medicine must be discontinued three days before the test.

Other medicines and Alefast

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

It is especially important to talk to your doctor before you take Alefast if you are also taking any of the following medicines:

- erythromycin (an antibiotic used to treat certain bacterial infections);
- ketoconazole (used to treat fungal infections);
- lopinavir / ritonavir (used to treat HIV infection).

These medicines increase the absorbed amount of Alefast tablets, which may lead to more side effects.

Indigestion remedies containing aluminium and magnesium may affect the action of Alefast by lowering the amount of drug absorbed. If you are taking any such indigestion remedies, it is

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

Taking Alefast with food or drinks

Alefast tablets should be taken with water. Fruit juices including grapefruit may reduce the bioavailability of fexofenadine and concomitant use should be avoided. Alcohol should be avoided.

Pregnancy

If you are pregnant, think you might be pregnant or you are planning to become pregnant, ask your doctor or pharmacist for advice before taking Alefast.

Take Alefast during pregnancy only if your doctor considers it to be strictly necessary.

Breastfeeding

It is not recommended to take Alefast if you are breastfeeding.

Driving and using machines

It is unlikely that Alefast will affect your ability to drive or use machines. However, there may be rare exceptions, so please ensure that these tablets do not make you drowsy or dizzy before driving or operating machinery.

3. HOW TO TAKE ALEFAST

Take this medication exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Alefast 120 mg tablets

For the relief of symptoms of seasonal allergic rhinitis, the recommended dose is one tablet, once daily, for adults and children 12 years and older.

Alefast 180 mg tablets

For the relief of symptoms of chronic idiopathic urticaria, the recommended dose is one tablet,

once daily, for adults and children 12 years and older.

Take the tablets with water, before food.

If you think the effects of Alefast are too strong or too weak, please consult your doctor or pharmacist.

If you take more Alefast than you should

Contact your doctor, the nearest emergency room or pharmacist if you have taken more Alefast than stated in this leaflet or more than your doctor has prescribed. Symptoms of overdose include dizziness, drowsiness, fatigue and dry mouth.

If you forget to take Alefast

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

If you forget a dose, take the next dose when it is the normal time to take it.

If you stop taking Alefast

Tell your doctor if you want to stop taking Alefast tablets before you have finished your course of treatment.

If you stop taking Alefast 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, Alefast can cause side effects, although not everybody gets them.

Tell your doctor immediately and stop taking Alefast if you experience:

- swelling of the face, lips, tongue or throat and difficulty breathing, as these may be signs of a serious allergic reaction.

Possible side effects listed below according to frequencies are defined as:

- **Common side effects** (may affect up to 1 in 10 people)
Headache, drowsiness, nausea, dizziness.

- **Uncommon side effects** (may affect up to 1 in 100 people)
Tiredness, sleepiness, blurred vision, dry mouth, gastrointestinal disturbances, psychomotor impairment, difficulty in passing urine.
- **Rare side effects** (may affect up to 1 in 1,000 people)
Anaphylaxis, angioedema, angle-closure glaucoma (in adults), arrhythmias, blood disorders, bronchospasm, confusion, convulsions, depression, dizziness, extrapyramidal effects, hypersensitivity reactions, hypotension, liver dysfunction, palpitations, photosensitivity reactions, rashes, sleep disturbances, tremor.
- **Additional side effects** (frequency not known: cannot be estimated from the available data)
Insomnia, sleeping disorders, nightmares or excessive dreaming, nervousness, diarrhoea, skin rash and itching, hives, serious allergic reactions which can cause swelling of the face, lips, tongue or throat and difficulty in breathing.

5. HOW TO STORE ALEFAST

Keep out of the reach and sight of children!

Do not use Alefast after the expiry date which is stated on the package.

Do not store above 25°C!

Store in the original package in order to protect from light and humidity.

6. FURTHER INFORMATION

What Alefast – film-coated tablets contain

The active substance is fexofenadine hydrochloride.

1 film-coated tablet contains 120 mg or 180 mg fexofenadine hydrochloride.

The excipients are:

tablet core: microcrystalline cellulose, maize starch, croscarmellose sodium, povidone, magnesium stearate;

film coat: Opadry II white (polyvinyl alcohol, titanium dioxide, macrogol, talc).

Content of the pack

Alefast 120 mg: box with 10 film-coated tablets,
 box with 20 film-coated tablets.

Alefast 180 mg: box with 10 film-coated tablets,
 box with 20 film-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

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