

Package leaflet: Information for the user

Accolate® 20 mg film-coated tablets

zafirlukast

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

1. What Accolate is and what it is used for

Accolate contains a medicine called zafirlukast. This belongs to a group of medicines called 'leukotriene antagonists'. This means that it reduces the effects of 'leukotrienes'. These are natural substances in the lung that cause asthma.

- Accolate is used to control the symptoms of your asthma.
- It is also used to prevent your asthma from getting worse.

Do not take Accolate to treat sudden (acute) asthma attacks. Your doctor will provide you with other inhalers to treat sudden attacks.

2. Before you take Accolate

Do not take Accolate if:

- You are allergic (hypersensitive) to zafirlukast or any of the other ingredients of this medicine (listed in Section 6).
- You have a chronic liver condition.

Do not take Accolate if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Accolate.

Warnings and precautions

Talk to your doctor or pharmacist before taking Accolate if:

- You have had problems with your liver that were caused by taking Accolate.

If you are not sure if this applies to you, talk to your doctor or pharmacist before taking Accolate.

If you go into hospital let the medical staff know that you are taking Accolate.

Children

Accolate should not be given to children under the age of 12 years.

Other medicines and Accolate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Accolate can affect the way some medicines work and some medicines can have an effect on Accolate.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Theophylline (used to treat asthma).
- Erythromycin (an antibiotic).
- Terfenadine (used to treat hayfever).
- Warfarin (used to thin the blood).
- Aspirin.
- Fluconazole (used to treat fungal infections).

Pregnancy and breast-feeding

- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will decide whether you can take Accolate during this time.
- Do not take Accolate if you are breast-feeding.

Driving and using machines

Accolate is not likely to affect you being able to drive or use any tools or machines.

Accolate contains lactose

Accolate contains lactose, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

3. How to take Accolate

Always take this medicine exactly as your doctor has told you. Read the label on the container to remind you what the doctor said. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take Accolate every day as prescribed by your doctor.
- The recommended dose is one 20 mg tablet taken twice a day. This is usually one tablet at the start of the morning and one tablet last thing at night.
- Your doctor may decide to increase your dose, depending on your condition.
- Try to take your medicine at the same times each day.
- Swallow each tablet whole with a drink of water.
- Do not take your tablets with a meal.
- Continue to take Accolate even when your asthma is not causing you any problems.
- Do not stop taking your tablets when you are feeling well, unless your doctor tells you to.

If your asthma gets worse while you are taking Accolate, follow the advice that your doctor has given you for treating sudden (acute) asthma attacks and see your doctor as soon as possible.

If you take more Accolate than you should

If you take more Accolate than prescribed by your doctor, ask your doctor or pharmacist for advice.

If you forget to take Accolate

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

4. Possible side effects

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

Allergic reactions (uncommon, may affect up to 1 in 100 people)

The signs include:

- Skin rash, itching and blistering of the skin.
- Swelling around your lips, face, tongue and throat.

If any of these happen, **stop taking Accolate and tell your doctor straight away.**

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Liver problems

Accolate may affect your liver. These liver effects range from non-serious increases in liver enzymes (**common, may affect up to 1 in 10 people**) which are detected by blood tests to serious conditions such as liver failure (**very rare, may affect up to 1 in 10,000 people**). A very small number of people have died from liver failure. Your doctor may ask you to have blood tests before and during treatment with Accolate to check whether there are any problems with your liver.

The signs of liver problems include:

- Yellowing of your skin or the whites of your eyes (jaundice).
- Pain on the right side of your stomach and just below your ribs.
- Loss of appetite.
- Feeling itchy.
- Feeling tired, having no energy or feeling like you have flu.
- Feeling as though you are going to be sick or actually being sick.

If any of these happen, stop taking Accolate and **tell your doctor straight away**.

Infection (very common, may affect more than 1 in 10 people)
Infections are usually mild and mainly affecting the upper airways. Signs of infection may include fever, sore throat, and runny nose. **Tell your doctor** if you have any of these symptoms.

Bleeding problems (rare, may affect up to 1 in 1,000 people)
The signs include:

- Bruising more easily.
- Bleeding tendencies.

If any of these happen, **tell your doctor**.

Unusual conditions
An unusual condition called 'Churg-Strauss syndrome' has been seen in a very small number of people taking Accolate for asthma. The signs include a combination of the following:

- Sinusitis. This can cause a feeling of fullness in the nose, cheeks and behind your eyes.
- Feeling like you have flu.
- Feeling more and more breathless.
- Pain in the area of your stomach or gut.
- Skin rash.
- A feeling of 'pins and needles' or numbness of your arms or legs.

If you notice more than one of these signs, **tell your doctor straight away**.

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

- Stomach and gut problems, such as feeling or being sick, diarrhoea or stomach pain. These effects are usually mild.
- Headache. This is usually mild.
- Pain in the muscles.

Uncommon (may affect up to 1 in 100 people)

- Swelling.
- Difficulty in sleeping.
- Pain in the joints.
- Feeling of discomfort or generally feeling unwell.
- Reduced feeling in the skin/tingling feeling such as 'pins and needles'.
- Feeling dizzy.
- Nightmares.

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

- Marked decrease in the number of circulating white blood cells.

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

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

Malta

ADR Reporting
The Medicines Authority
Post-Licensing Directorate
203 Level 3, Rue D'Argens
GŻR-1368 Gżira
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

5. How to store Accolate

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C.
- Keep your tablets in the container they came in.
- Do not use this medicine after the expiry date which is stated on the container. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines that you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Accolate contains
The active substance is zafirlukast. Each tablet contains 20mg of zafirlukast.
The other ingredients are croscarmellose sodium, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, povidone and titanium dioxide. See section 2.

What Accolate looks like and contents of the pack
Accolate 20 mg white, round biconvex, film-coated tablets intagliated with 'Accolate 20' on one side and plain on the reverse.

Accolate 20 mg tablets are available in aluminium laminate/foil blisters in pack sizes of 10, 14, 20, 28, 30, 50, 56, 60, 98, 100, 392 and 420 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Accolate in Ireland and Malta is held by AstraZeneca UK Ltd, 600 Capability Green, Luton, LU1 3LU, UK.
Accolate is manufactured by either AstraZeneca UK Ltd, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK or AstraZeneca, Parc Industriel Pompelle, Chemin de Vrilly, Box 1050, 51689 Reims Cedex 2, France.

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

Name of the Member State	Name of the medicinal product
Ireland	Accolate 20 mg
Portugal	ACCOLATE 20 mg

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