

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Accolate® 20mg Film-coated Tablets**  
zafirlukast

**Read all of this leaflet carefully before you start taking this medicine.**

- 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 any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Accolate is and what it is used for
2. Before you take Accolate
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**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 Accolate (listed in Section 6: Further information).
- You have a chronic liver condition.

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

**Take special care with Accolate**

Check with 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.

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking, or have recently taken, 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.

### **Pregnancy and breast-feeding**

- Talk to your doctor before taking Accolate if you are pregnant or may become pregnant. Your doctor will decide whether you can take Accolate during this time.
- Do not take Accolate if you are breast-feeding.

### **Driving and using tools and machines**

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

### **Important information about some of the ingredients of Accolate**

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 Accolate exactly as your doctor has told you. Read the label on the container to remind you what the doctor said. You should check with your doctor or pharmacist if you are not sure.

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

### **Taking this medicine**

- Take Accolate every day as prescribed by your doctor.
- The usual dose is one 20mg 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.

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.

### **Stopping Accolate**

- 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.

## **4. Possible side effects**

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

### **Allergic reactions** (uncommon, affecting 1 to 10 users 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.**

## **Liver problems**

Accolate may affect your liver. These liver effects range from non-serious increases in liver enzymes (**common**) which are detected by blood tests to serious conditions such as liver failure (**very rare**). 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, affecting more than 1 per 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 straight away** if you have any of these symptoms.

## **Bleeding problems** (rare, affecting 1 to 10 per 10,000 people)

The signs include:

- Bruising more easily.
- Bleeding tendencies.

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

## **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 (affects less than 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** (affects less than 1 in 100 people)

- Swelling.
- Difficulty in sleeping.
- Pain in the joints.
- Feeling of discomfort or generally feeling unwell.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. How to store Accolate**

- Do not take your tablets after the expiry date on the container.
- Do not store above 30°C.
- Store in the original package.
- As with all medicines, keep your tablets in a safe place where children cannot see or reach them
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. This will help to protect the environment.

## **6. Further information**

### **What Accolate contains**

Each tablet contains 20 mg zafirlukast.

Each tablet contains a number of inactive ingredients, which allow it to be made. These are: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, povidone, magnesium stearate. The film coating contains hypromellose and titanium dioxide (E171).

### **What Accolate looks like and contents of the pack**

White, round, biconvex, film-coated tablets intagliated with 'Accolate 20' on one side and plain on the reverse. Accolate comes in a blister pack of 56 tablets contained in an outer cardboard carton.

### **Product procured from within the EU and repackaged and distributed by the parallel product**

**authorisation holder:** PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

### **MANUFACTURER:**

Accolate is manufactured by AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK or AstraZeneca, Z.I. Pompelle, BP 1050 Cedex 2, F-51689, Reims, France.

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