

# ACCOLATE(R)

Zafirlukast

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some of the common questions people ask about Accolate. It does not contain all the information that is known about Accolate.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking Accolate against the benefits it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What Accolate is for

Accolate belongs to a group of medicines called leukotriene antagonists. This means that it reduces the effects of leukotrienes, which are substances in the lung that can cause asthma.

Accolate is used to prevent your asthma from getting worse as well as controlling the symptoms of your asthma. Accolate is not used to treat sudden attacks of asthma. It is a medicine to be taken regularly.

**Your doctor will have explained why you are being treated with Accolate and told you what dose to take.**

**Follow all directions given to you by your doctor carefully.**

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

Accolate is not addictive.

### Before you use Accolate

#### *When you must not use it*

**Do not use Accolate if you are pregnant unless your doctor says to. Ask your doctor about the risks and benefits involved.**

There is only limited information about its effects in pregnant women.

**Do not use Accolate if you are breast feeding.**

Your baby can take in Accolate from breast milk if you are breast feeding.

**Do not give Accolate to children younger than 12 years.**

There is no information about its use in children, so Accolate is not recommended for children. Always ask your doctor before giving medicines to children.

**Do not use after the use by (expiry) date printed on the pack.**

It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

**Do not use Accolate if the packaging is torn or shows signs of tampering.**

**Do not use it to treat any other complaints unless your doctor says it is safe to do so.**

**Do not give this medicine to anyone else.**

#### *Before you start to use it*

**You must tell your doctor if:**

- 1. you have an allergy to any ingredient listed at the end of this leaflet.**

If you have an allergic reaction you may get a skin rash, hayfever, asthma or feel faint.

- 2. you have any problem with your liver.**

It is not safe for you to take Accolate if you have any problems with your liver.

#### *Taking other medicines*

**Tell your doctor if you are taking**

- \* warfarin
- \* aspirin
- \* theophylline
- \* erythromycin
- \* terfenadine
- \* tolbutamide
- \* phenytoin
- \* carbamazepine
- \* celecoxib
- \* any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

These medicines may affect the way Accolate works. Your doctor or pharmacist can tell you what to do if you are taking any other medicines.

If you have not told your doctor about any of these things, tell them before you take any Accolate.

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## Taking Accolate

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### *How to take it*

The usual adult dose is one 20mg tablet taken twice a day. Some people may need to take a higher dose.

**Do not take more than 40mg twice a day.**

Elderly people and people with liver problems may need a lower dose. Your doctor will tell you what dose to take.

**Take Accolate at least one hour before or two hours after food.**

Food reduces the effect of Accolate.

**Swallow Accolate whole with a glass of water.**

### *If you forget to take it*

If you forget to take it and it is more than six hours before your next dose is due, take it as soon as you remember.

If it is less than six hours before your next dose is due, skip that dose and take the next one at the usual time.

**Do not double the dose.**

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

### *If you take too much (overdose)*

**Telephone your doctor or the Poisons Information Centre (13 11 26), or go to casualty at your nearest hospital immediately if you think that you or anyone else may have taken too much Accolate even if there are no signs of discomfort or poisoning.**

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## While you are using Accolate

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### *Things you must do*

**If you are about to be started on a new medicine, tell your doctor and pharmacist that you are taking Accolate.**

**If your doctor changes the dose of any other medicine you take for asthma, follow these directions carefully.**

It is important that your doctor monitors these changes.

### *Things you must not do*

**Do not take Accolate to relieve a sudden attack of asthma.**

Your doctor will have told you which "reliever" medicine to use for these attacks.

**Do not give Accolate to anyone else, even if they have the same condition as you do.**

**Do not stop taking Accolate, even if your asthma gets better or worse, unless your doctor tells you to.**

Please talk to your doctor or pharmacist about these possibilities if you think they may bother you.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Accolate.**

Accolate helps most people with asthma, but it may have unwanted side-effects in a few people. All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have about the possible side effects of Accolate.**

**Tell your doctor if you notice any of the following and they worry you:**

- \* headache
- \* indigestion or stomach upsets
- \* nausea (feeling sick) and vomiting
- \* diarrhoea
- \* stomach, back, muscle, joint or generalised pain
- \* swelling of hands, ankles or feet (oedema)
- \* fever
- \* hair loss
- \* sleeplessness (insomnia)
- \* general feeling of discomfort

These are all mild side effects of Accolate.

**Tell your doctor immediately or go to casualty at your nearest hospital if you notice any of the following:**

- \* an increase in number of infections
- \* itchy skin, rash, blisters
- \* yellowing of the skin or eyes

These are all serious side effects.

You may need urgent medical attention.

**Rarely Accolate may cause some changes to occur in your liver, which may be of a serious nature. In some people these changes could make you:**

- \* lose your appetite
- \* feel sick or be sick
- \* have a pain on the right side of your stomach, just below your ribs
- \* feel itchy
- \* feel tired or have no energy
- \* feel like you have the flu
- \* a yellow colouring of your skin or eyes (jaundice)

**Tell your doctor immediately or go to casualty at your nearest hospital as you may need urgent medical attention.**

**If any of the following happen, stop taking Accolate and tell your doctor immediately or go to casualty at your nearest hospital.**

- \* unexplained bruising or bleeding

- \* swollen lips, throat or face
- \* pain in the lungs

These are very serious side effects. If you have them, you may have had a serious reaction to Accolate. You may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

Some people may get other side effects while taking Accolate.

**Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.**

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## After using it

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### **Storage**

**Keep your tablets in the blister pack until it is time to take them.**

If you take Accolate out of the blister pack it will not keep well.

**Keep it in a cool dry place where the temperature stays below 30 degrees**

**Do not store it or any other medicine in the bathroom or near a sink.**

Heat and dampness can destroy some medicines.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Do not leave it in the car on hot days.**

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## Disposal

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**Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or if they have expired.**

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## Product description

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### **What Accolate looks like**

Accolate 20mg tablets are 8mm in diameter and are white, round, biconvex and film-coated.

They are imprinted on one side with ACCOLATE and 20.

### **Ingredients**

Each Accolate tablet contains:

Zafirlukast 20mg as the active ingredient plus the following inactive ingredients:

- \* croscarmellose sodium
- \* lactose
- \* microcrystalline cellulose (460)
- \* povidone
- \* magnesium stearate (572)
- \* hypromellose
- \* titanium dioxide (171)

Accolate 20mg tablets come in packs of 56 (4 x 14) tablets.

Accolate does not contain gluten, sucrose, tartrazine or any other azo dyes.

### **Sponsor**

AstraZeneca Pty Ltd

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