

ACCOLATE®

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.

Ask your doctor if you want more information.

Your doctor may have prescribed Accolate for another reason.

There is no evidence that Accolate is addictive.

This medicine is available only with a doctor's prescription.

Before you use Accolate

When you must not use it

Do not take Accolate if you have an allergy to:

- **Zafirlukast or any of the ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Accolate if you are pregnant unless your doctor says so. Ask your doctor about the risks and benefits involved.

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

Do not take 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.

Do not take Accolate after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are unsure whether you should start taking this medicine, talk to your doctor.

Before you start to use it

You must tell your doctor if:

- **you have allergies to any other medicines, foods, dyes or preservatives.**
- **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 be affected by Accolate or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Accolate.

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

How to take Accolate

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the directions on the label, ask your doctor or pharmacist for help.

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 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.

Continue taking Accolate for as long as your doctor tells you.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that

you or anyone else may have taken too much Accolate. Do this even if there are no signs of discomfort or poisoning.

While you are using Accolate

Things you must do

If you are about to be started on any 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.

If you become pregnant while taking Accolate, tell your doctor immediately.

Things you must not do

Do not take Accolate to relieve acute attacks of asthma.

Follow your doctor's instructions on using 'reliever' medicine for these attacks.

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

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

Side effects

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.

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

- headache
- fever
- stomach discomfort/pain, nausea, vomiting or diarrhoea
- back, muscle, joint or generalised pain
- swelling of hands, ankles or feet (oedema)
- hair loss
- sleeplessness (insomnia)
- general unwell feeling or weakness

These side effects are usually mild.

Tell you doctor immediately if you notice any of the following:

- an increase in number of infections, persistent fever or frequent sore throat
- unexplained bruising or bleeding
- combination of symptoms which may include: flu-like illness, rash, pins and needles or numbness of arms/legs, and severe sinusitis.

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

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

- symptoms of allergic reaction: shortness of breath, wheezing or difficulty breathing, swelling of the face/lips/tongue/other parts of the body, rash, itching or hives on the skin.
- symptoms of liver disease: loss of appetite, nausea/vomiting, feeling generally unwell, flu-like symptoms, itching, yellowing of the skin/eyes (jaundice), pain on right side of your stomach just below your ribs.

Very rarely severe liver injury including liver failure (a life-threatening condition) has been reported.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

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

Other side effects not listed above may occur in some patients.

After using Accolate

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 Accolate in a cool dry place where the temperature stays below 30 degrees C.

Do not store Accolate or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine, or if the expiry date has passed, ask your pharmacist what to do with any tablets that is left over.

Product description

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

ABN 54 009 682 311

Alma Road

NORTH RYDE NSW 2113

This leaflet was prepared in November 2007

Australian Registration Number

Accolate 20mg 55091

Trademarks herein are the property of the AstraZeneca group.