

COLAZIDE®

Balsalazide sodium capsules

Consumer Medicine Information

What is in this leaflet

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

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 Colazide® against the benefits they expect 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 Colazide® is for

Colazide® capsules are used to treat active ulcerative colitis and for maintenance of remission in patients who are intolerant to sulfasalazine. Ulcerative colitis is when the lining of the lower bowel becomes inflamed (swollen and irritated). Colazide® reduces the swelling and irritation.

Your doctor will have explained why you are being treated with Colazide® 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.

Colazide® capsules are not addictive.

Before you take Colazide®

When you must not take it

Do not take Colazide® if you

- are allergic to any ingredient in Colazide®
- have a history of hypersensitivity to aspirin-type products
- are very prone to bleeding
- have severe liver problems
- have moderate to severe kidney problems
- are taking any medications that prevent blood clotting
- have an active peptic ulcer
- are in the last weeks of pregnancy.

Pregnant women should not take Colazide® unless your doctor says so. Ask your doctor about the risks and benefits involved.

Do not take Colazide® while you are breastfeeding.

Your baby can take in Colazide® from breast milk if you are breastfeeding.

Do not use Colazide® 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 Colazide® 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.

Do not give this medicine to anyone else.

Before you start to take it

You must tell your doctor if:

1. **you have any allergies to**
 - any ingredient listed at the end of this leaflet
 - aspirin and aspirin-type products
 - other medicines used to treat ulcerative colitis
 - any other medicines, foods, dyes or preservatives.

If you have an allergic reaction, you may get a skin rash or hay fever, have difficulty breathing or feel faint.

2. **you have any of these medical conditions**

- mild liver problems
- mild or history of kidney problems
- asthma
- stomach ulcer
- bleeding problems.

It may not be safe for you to take Colazide® if you have any of these conditions.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- digoxin
- methotrexate or similar-type drugs
- oral antibiotics
- any other medicine that you buy at the chemist, supermarket or health food shop.

These medicines may affect the way Colazide® works.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

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

Taking Colazide®

How to take it

When you have symptoms:

The usual dose is 3 capsules taken 3 times a day (a total of 9 a day). Take this until your symptoms are better. Do not take this dose for more than 12 weeks without discussing it with your doctor.

To prevent symptoms returning:

The usual dose is 2 capsules taken twice daily. Your doctor may adjust this dose up or down depending on how you respond.

Swallow Colazide® capsules whole, with food.

If you forget to take it

If you forget to take a dose, take it as soon as you remember as long as it is 4 hours before it is due, and then go back to taking it as normal.

If it is less than 4 hours until your next dose, skip the dose you missed and take your next dose when you are meant to.

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

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, 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 Colazide® even if there are no signs of discomfort or poisoning.

If you take too many Colazide® capsules you may have a headache and stomach pains.

While you are taking Colazide®

Things you must do

You must contact your doctor if you notice any unusual bleeding or bruising.

Unusual bleeding or bruising may be a sign that you are experiencing a serious side effect of Colazide®.

Use Colazide® exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Colazide®.

Tell your doctor if you become pregnant while you are taking Colazide®.

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

Side effects

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

Colazide® helps most people with ulcerative colitis, 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
- stomach pain or heartburn
- diarrhoea
- nausea (feeling sick) or vomiting
- bloating or wind
- worsening of colitis.

These are all mild side effects of Colazide®.

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

- unusual bleeding or bruising sudden signs of allergic reactions such as rash, itching or hives, shortness of breath, wheezing, coughing, or swelling of limbs, face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing
- fever
- excessive tiredness
- muscle aches or pains.

These are all serious side effects. You may need urgent medical attention.

Serious side effects are rare.

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

Some people may get other side effects while taking Colazide®.

After using it

Storage

Keep your capsules in the bottle until it is time to take them.

If you take Colazide® out of the bottle it will not keep well.

Keep the capsules in a cool dry place where the temperature stays below 25°C.

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.

Disposal

Ask your pharmacist what to do with any capsules you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Product description

What Colazide® looks like

Colazide® capsules are beige and are marked with "CZ" in black.

Ingredients

Each Colazide® capsule contains 750 mg balsalazide sodium as the active ingredient, plus the excipients:

Magnesium stearate (E 572)

Silica-colloidal anhydrous

Gelatin (E 441)

Shellac

The gelatin capsules are coloured with titanium dioxide (E 171), iron oxide red CI77491 (E 172), iron oxide yellow CI77492 (E 172), and iron oxide black CI77499 (E 172).

Colazide® is registered in bottles of 130, 180 and 280 capsules (not all pack sizes are available).

Colazide® does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Manufacturer

Fresenius Kabi Australia Pty Limited
Level 2, 2 Woodland Way,
Mount Kuring-gai NSW 2080
Australia

Tel: (02) 9391 5555

This leaflet was prepared 7 April 2017

Australian Registration Number

AUST R 77358

® Registered trademark