

Package leaflet: Information for the user

Colazide 750 mg hard capsules

Balsalazide disodium

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 Colazide is and what it is used for
2. What you need to know before you take Colazide
3. How to take Colazide
4. Possible side effects
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1. What Colazide is and what it is used for

Colazide is used for the treatment of ulcerative colitis (ulceration of the large intestine). It may also be used to keep the disease under control by preventing further episodes. It works as an anti-inflammatory agent.

This medicine contains balsalazide disodium as the active ingredient.

2. What you need to know before you take Colazide

Do not take Colazide:

- if you are allergic to balsalazide or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to mesalazine, aspirin or other salicylates
- if you have a severe liver disease
- if you have a moderate to severe kidney disease
- if you are pregnant or breast feeding

Warnings and precautions

- asthma
- any blood disorders
- a mild kidney disorder
- a confirmed liver disease
- an active ulcer

If any of these apply to you, talk to your doctor or pharmacist before taking Colazide.

Tests on your liver, kidney and blood

Before you start treatment with Colazide you will have a blood and urine test to check how well your kidneys are

working and what your blood is doing.

During treatment your doctor will check how well your liver, kidney and blood is working by taking blood and urine samples periodically during your treatment.

Children

Colazide is not recommended for use in children.

Other medicines and Colazide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular digoxin (used to treat heart problems), methotrexate (used as treatment for some autoimmune diseases, including rheumatoid arthritis, psoriasis, psoriatic arthritis, lupus, some inflammatory bowel diseases (Crohn's disease) and some types of cancer, among other diseases), azathioprine (used to prevent rejection following organ transplantation, and to treat rheumatoid arthritis, some inflammatory bowel diseases (Crohn's disease and ulcerative colitis) and multiple sclerosis among other diseases) and 6-mercaptopurine(used to treat leukaemia and inflammatory bowel diseases such as Crohn's disease and ulcerative colitis).

Colazide with food

Colazide should be taken preferably with or after food.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should **not** take Colazide during pregnancy or while breast-feeding.

Driving and using machines

There is no evidence of any effect of Colazide on your ability to drive or use machines.

3. How to take Colazide

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults and elderly patients:

Treatment of ulcerative colitis:

The recommended dose is 3 capsules three times daily to be taken with or after food. Swallow the capsules whole, with a glass of water if necessary.

Treatment may be given for a maximum of 12 weeks.

Your doctor may also give you steroids at the same time as Colazide.

Maintenance treatment to prevent further episodes:

The starting dose is 2 capsules twice daily (3 g daily) to be taken with or after food. Swallow the capsules whole, with a glass of water if necessary. Your doctor may adjust your treatment based on your response to the medicine.

There may be an additional benefit with a dose up to 6 g daily.

Whilst taking this medicine ensure you drink adequate fluids to remain well hydrated, especially after severe or prolonged episodes of vomiting and/or diarrhoea, high fever or heavy sweating. This is to avoid problems with your kidneys.

During your treatment with Colazide your doctor will carry out blood and urine tests.

Use in children:

Colazide is **not** recommended for use in children.

If you take more Colazide than you should

If you think you have taken too many capsules **contact your doctor or pharmacist**. Take any remaining capsules and the packaging with you.

If you forget to take Colazide

If you forget to take a dose at the right time, take it as soon as possible after food.

If you miss a dose completely, do not take a double dose to make up for a forgotten dose. Take the next dose as usual.

4. Possible side effects

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

Immediate medical attention must be sought if you experience:

- a severe allergic reaction including swelling of the face, tongue, throat and lips
- unusual bleeding, bruising, rash, fever, sore throat or excessive tiredness.

A blood count will be performed and the drug stopped immediately if there is suspicion of a blood disorder.

Other side effects that may occur with Colazide are:

- rash,
- diarrhoea, stomach pain, nausea, vomiting, headache,
- gallstones, worsening of ulcerative colitis,
- problems with the blood,
- difficulty breathing, cough, fever,
- abnormal sensation or function (such as weakness or numbness), joint pains, muscle ache,
- hair loss,
- hypersensitivity.

Problems with the kidneys including renal malfunction have been reported. Symptoms may include:

- blood or any other changes in your urine,
- rash, fever,
- loin or joint pain,
- fluid retention,
- decreased urine.

Inflammation of the heart, liver and pancreas have been reported. Symptoms of these are:

- **Inflammation of the heart:** chest pain, palpitations, breathlessness and fatigue.
- **Inflammation of the liver:** flu like symptoms, jaundice (yellowing of the skin and whites of the eyes) and abdominal pain.
- **Inflammation of the pancreas:** abdominal pain, nausea and vomiting.

Systemic lupus erythematosus (SLE) like syndrome has been reported. Symptoms are:

- inflammation of the joints, connective tissue, tendons and organs such as the heart, lungs, kidneys or skin.

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 Yellow Card Scheme, Website:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Colazide

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP.
No special precautions for storage.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Colazide contains

- The **active** substance is balsalazide
Each capsule contains 750 mg of balsalazide (as balsalazide disodium)
- The **other** ingredients (excipients) are magnesium stearate, colloidal anhydrous silica, gelatine, shellac, titanium dioxide (E 171) and red, yellow and black iron oxide (E 172)

What Colazide looks like and contents of the pack

Colazide is a hard beige-coloured capsule.

Colazide is available in bottles with child-resistant screw caps containing 130 capsules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Almirall, S.A.; Ronda General Mitre, 151; 08022 Barcelona (Spain)

Manufacturer:

Catalent Germany Schorndorf GmbH, Steinbeisstrasse 1 + 2, D-73614 Schorndorf, Germany.

United Kingdom Colazide 750 mg hard capsules

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