

Patient Information Leaflet

SCHEDULING STATUS:

S3

COLIZEM (Mesalazine 1,2 g) enteric coated prolonged–release tablets

Sugar Free

Read all of this leaflet carefully before you start taking COLIZEM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- COLIZEM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What COLIZEM is and what it is used for
2. What you need to know before you take COLIZEM
3. How to take COLIZEM
4. Possible side effects
5. How to store COLIZEM
6. Contents of the pack and other information

1. What COLIZEM is and what it is used for

COLIZEM contains the active substance mesalazine, which is an anti-inflammatory drug for the treatment of ulcerative colitis.

Ulcerative colitis is a disease of the colon (large bowel) and rectum (back passage), where the lining of the gut becomes red and swollen (inflamed) resulting in symptoms of frequent and bloody stools together with stomach cramps.

When given for an acute episode of ulcerative colitis, COLIZEM acts through the entire colon and rectum to treat the inflammation and reduce symptoms. The tablets can also be taken to help prevent recurrence of

ulcerative colitis.

2. What you need to know before you take COLIZEM

Do not take COLIZEM :

- If you are hypersensitive (allergic) to salicylates (which include aspirin);
- If you are hypersensitive (allergic) to mesalazine or any of the other ingredients of COLIZEM (listed in section 6.1);
- If you have severe kidney or severe liver problems.

Warnings and precautions

Take special care with COLIZEM:

- If you have any kidney problem;
- If you have lung problems (especially asthma. Asthma is a disease where the lining of the lungs becomes inflamed (red and swollen), making it difficult to breathe. Symptoms of asthma may include breathlessness, wheezing, a cough sometimes brought on by exercise, and a feeling of tightness in the chest);
- If you develop unexplained bleeding, bruising, skin discolouration, fever or a sore throat contact your doctor. COLIZEM may cause abnormality in the blood's cellular components.
- If you have previously had inflammation of the heart or lining around the heart (which may be the result of an infection in the heart)
- If you experience symptoms such as stomach cramps, abdominal pain, bloody and excessive stools (diarrhoea), fever, headache or rash, contact your doctor. These symptoms could be a sign of acute intolerance syndrome, a condition with symptoms similar to those of ulcerative colitis.
- If you have any liver problem
- have had a previous allergic reaction to sulphasalazine (another medicine used to treat ulcerative colitis)
- have narrowing or blockage of the stomach or the gut
- porphyria (a rare blood pigment disorder).

Before and periodically during treatment with COLIZEM, your doctor may take samples of your urine and blood to check that your kidneys and liver are working well and that your blood is healthy.

Kidney stones may develop with the use of COLIZEM. Symptoms may include pain in the sides of the abdomen and blood in the urine. Drink sufficient amount of liquid during treatment with COLIZEM.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using COLIZEM.

Children

COLIZEM should not be given to under 18 years of age due to lack of data on safety and efficacy.

Other medicines and COLIZEM

Always tell your health care provider if you are taking any other medicine (This includes all complementary or traditional medicines)_

- Mesalazine or sulphasalazine (for treatment of ulcerative colitis)_
- Non-steroidal anti-inflammatory medicines (for example medicines containing aspirin, ibuprofen or diclofenac)_
- Azathioprine or 6-mercaptopurine or other medicines known to affect how your bone marrow works (known as 'immunosuppressant' medicines which reduce the activity of your body's immune system). Bone marrow is the material inside your bones that produces blood cells.
- Anticoagulants (used to prevent the clotting of blood), e.g. warfarin. COLIZEM can decrease the anticoagulants ability to prevent blood clotting.
- If you need to go for a urine test, tell the doctor that you are taking COLIZEM, as it may interfere with the results.

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Since mesalazine crosses the placenta in pregnancy and is excreted in breast milk in small quantities, you should not use COLIZEM during pregnancy or whilst breast-feeding if your doctor tells you to. Adverse outcomes [including low blood counts (white blood cells, red blood cells, and platelets)] were reported in

infants born to mothers who took mesalazine during pregnancy. Diarrhoea has been reported in breastfed infants of mothers who took mesalazine.

Driving and using machines

COLIZEM is unlikely to have any effect on your ability to drive or use machines. You should not drive or operate machines until you know how COLIZEM affects you.

It is not always possible to predict to what extent COLIZEM may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which COLIZEM affects you.

COLIZEM contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per the maximum recommended dose, that is to say essentially 'sodium-free'.

3. How to take COLIZEM

COLIZEM with food, drink and alcohol

COLIZEM should be taken with food at the same time each day. The tablets should be swallowed whole and must not be crushed or chewed.

Do not share medicines prescribed for you with any other person.

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

Take your tablets at the same time each day with food. The tablets should be swallowed whole and must not be crushed or chewed.

The usual daily dose for adults for initiation of remission is 2,4 g to 4,8 g (two to four tablets) taken once a day.

The highest daily dose of 4,8 g (four tablets) daily is recommended for adults, if they do not respond to the lower doses of COLIZEM.

If you are taking four tablets a day, your doctor should check how you are responding to your treatment, 8 weeks after starting treatment.

Once your symptoms have cleared and to help prevent recurrence of another episode, your doctor should direct you to take 2,4 g (two tablets) once a day.

The safety of using COLIZEM in patients having kidney or liver problems has not been established.

If you take more COLIZEM than you should

If you take too much COLIZEM you may have one or more of the following symptoms: tinnitus (ringing in ears), dizziness, headache, confusion, drowsiness, shortness of breath, excess loss of water (associated with sweating, diarrhoea and vomiting), low blood sugar (which can cause light-headedness), rapid breathing, changes in the blood chemistry and increased body temperature.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take your tablet pack with you.

If you forget to take COLIZEM

If you forget to take a dose of this medicine, take it as soon as you remember. Then take your next dose at the usual time. If it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten individual doses.

If you stop taking COLIZEM

Continue taking COLIZEM every day for as long as your doctor tells you.

You may have to stay on the treatment for a long period of time. Do not stop taking COLIZEM unless your doctor tells you to.

Your doctor will tell you how long your treatment with COLIZEM will last. If you have the impression that the effect of COLIZEM is too strong or too weak, tell your doctor or pharmacist.

4. Possible side effects

COLIZEM can have side effects.

Not all side effects reported for COLIZEM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking COLIZEM, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking COLIZEM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Hypersensitivity (allergic reaction. Symptoms may include swelling of your face, difficulty breathing or low blood pressure which may cause fainting or collapse).
- Anaphylactic reaction (Sudden life threatening allergic reaction. Symptoms include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing).
- Drug Reaction with Eosinophilia and Systemic Symptoms (Flu-like symptoms and a rash on the face followed by an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes).
- Steven Johnson syndrome (severe blistering or peeling of the skin; bleeding in the lips, eyes, mouth, nose and genitals; swelling around the eyes, lips and face, rashes caused by exposure to sunlight).
- Lupus like syndrome (a disease where the immune system attacks various parts of the body and leading to pain, tiredness, stiffness and swelling in joints and red skin, sometimes in the shape of butterfly wings on the face, and arthritis, and overall feeling of sickness).
- Angioedema (Serious allergic reaction characterized by swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing).
- Systemic-lupus erythematosus-like syndrome (allergic condition which causes joint pain, skin rashes and fever).
- Acute Intolerance Syndrome (symptoms include cramping, severe stomach pain, bloody and excessive stools (diarrhoea), fever, headache or rash. These symptoms can happen during an acute episode of ulcerative colitis. This is a serious condition which occurs less frequently, but means your treatment would have to be stopped immediately).

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

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

- Pancreatitis (inflammation of pancreas. Symptoms may include upper abdominal pain, nausea and vomiting, indigestion, loss of appetite, bloating, fast heart rate, weight loss).
- Renal failure (kidney failure. Symptoms may include decreased urine output, fluid retention, causing swelling in your legs, ankles or feet, shortness of breath, tiredness, weakness, irregular heartbeat, confusion).
- Hepatitis (inflammation of liver. Symptoms may include nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine).
- Interstitial nephritis (kidney condition characterized by swelling in between kidney tubules. Symptoms may include blood in urine, fever, increased or decreased urine output, nausea, vomiting, rash, swelling of any area of body, weight gain, mental status changes);
- Nephrotic syndrome (condition which indicates kidney damage and includes large amounts of protein in the urine, low blood albumin levels, high blood cholesterol levels and swelling of the legs, feet or ankles).
- Rash, anaemia (feeling tired, weak and looking pale, especially on lips, nails and inside of eyelids), fever (high temperature), sore throat or unusual bleeding (e.g. nose bleeds).
- Inflammation of the heart (symptoms may include chest pain, fever, trouble breathing, fatigue, racing heartbeat).
- Inflammation of lining around the heart (symptoms may include abdominal or leg swelling, cough, fatigue or general feeling of weakness or being sick, low-grade fever, pounding or racing heartbeat, shortness of breath when lying down).
- Inflammation of the lung (symptoms may include feeling tired after physical activity, a general sense of fatigue, dry or productive cough, trouble breathing, chest discomfort, tightness, or pain, a sense of lung pain, gasping for air).

- Bronchospasm (difficulty in breathing, wheezing or coughing).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache
- Excessive gas in stomach or bowel,
- Nausea (feeling sick);
- Bloating or painful stomach;
- Abdominal pain;
- Colitis (inflammation of the colon (large bowel). Symptoms may include diarrhoea, usually with blood and mucus, stomach pain, fever);
- Diarrhoea (loose stools), indigestion;
- Vomiting (being sick);
- Abnormal liver function test (e.g., ALT; AST, bilirubin)
- Joint pain, back pain;
- Unusual weakness, swelling of face, tiredness, fever.

Less frequent side effects:

- Dizziness, sleepiness, tremor (shaking);
- Ear pain;
- Rapid heartbeat;
- High blood pressure (symptoms may include severe headaches, nosebleed, fatigue or confusion, vision problems, chest pain, difficulty breathing, irregular heartbeat);
- Low blood pressure (symptoms may include dizziness or light-headedness, nausea, fainting, dehydration and unusual thirst, lack of concentration, blurred vision, cold and pale skin);
- Pharyngolaryngeal pain (pain in the back of mouth and throat);
- Inflammation of the pancreas;

- Rectal polyp (abnormal growths rising from the lining of the large intestine (colon or rectum). Most are harmless, but some can develop into cancer. Symptoms may include rectal bleeding, change in stool colour, change in bowel habits);
- Increased alanine aminotransferase (liver enzyme);
- Acne (persistent, recurrent red spots or swelling on the skin, generally known as pimples);
- Unusual hair loss or thinning;
- Prurigo (thickening and itching of the skin due to repeated scratching), itching, rash, hives, increased sensitivity of the skin to sun.

Frequency *unknown*:

- Hepatotoxicity ((liver damage that may present as abnormal liver tests)
- Reversible decrease in sperm production
- Hypersensitivity pneumonitis (rare immune system disorder that affects the lungs. Symptoms may include shortness of breath, tiredness, coughing that lasts weeks or months and weight loss that gets progressively worse. Interstitial Pneumonitis (symptoms may include a dry cough, shortness of breath that can occur either at rest or after exertion, clubbing, or enlargement of the fingertips at the base of the nails). Eosinophilic pneumonitis (symptoms may include cough, shortness of breath, fatigue, muscle aches, night sweats and chest pain worsened by breathing).
- Kidney stones (symptoms may include pain in the back, belly, or side, pain or burning during urination, blood in the urine, cloudy or smelly urine, nausea and vomiting, fever and chills).
- Numbness or weakness in hands or feet.
- Cholelithiasis (gallstones. Symptoms may include pain in the back or upper-right abdomen, indigestion, nausea, or vomiting).
- Aching muscles, muscle tenderness or weakness, not caused by exercise.
- Increased intracranial pressure.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurses. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of COLIZEM

5. How to store COLIZEM

Store all medicines out of reach of children.

- Store at or below 25 °C in the original package, protected from light and moisture.
- Do not remove the blisters from the carton until required for use.
- Remove your COLIZEM from the blister only immediately prior to intake.
- Do not take COLIZEM after the expiry date stated on the blister strips and carton.
- Return all unused or expired medicines to your pharmacist for safe disposal.
- Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What COLIZEM contains

The active substance is mesalazine.

COLIZEM 1,2 g:

Each enteric coated prolonged–release tablet contains mesalazine 1, 2 g.

The other ingredients are:

Tablet Core

Carboxymethyl Cellulose Sodium(Blanose CMC 7MF PH), Carboxymethyl Cellulose Sodium(Blanose CMC 7HXF PH), Colloidal Silicon Dioxide NF, Hypromellose, Sodium Starch Glycollate, Magnesium Stearate, Microcrystalline Cellulose and Purified Water

Enteric Coating

Ferric Oxide NF (Red), Isopropyl Alcohol , Methacrylic Acid and Methyl Methacrylate Copolymer (1:1) NF (Type A) (EUDRAGIT L 100),

Methacrylic Acid and Methyl Methacrylate Copolymer (1:2) NF (Type B) (EUDRAGIT S 100), Polyethylene Glycol 6000 NF (Finegrade, Clariant),
Purified Water , Talc, Titanium Dioxide, Triethyl Citrate NF

Tablet Printing Material

Isopropyl Alcohol, Opacode Black S-1-17823

Opacode Black S-1-17823

Ammonium Hydroxide 28 % NF, Oxide Black NF, Isopropyl Alcohol, N-Butyl Alcohol NF, Propylene Glycol, Shellac Glaze-45 % (20 % esterified) in Ethanol

What COLIZEM looks like and contents of the pack

COLIZEM 1,2 g

Reddish brown, oval shaped film coated tablets printed with RG70 in black color on one side and plain on other side.

HDPE Bottle Pack:

The product can be supplied in a pack size of 120's comprising of an HDPE bottle and a child resistant closure with an induction seal liner.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Laurre Road, Stormill, Ext.1,

Roodepoort, 1724

South Africa

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