

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS: S3**

### **COLTRA 500, 500 mg, Suppositories**

#### **Mesalazine (5-aminosalicylic acid)**

#### **Read all of this leaflet carefully before you start using COLTRA 500**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- COLTRA 500 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 COLTRA 500 is and what it is used for
2. What you need to know before you use COLTRA 500
3. How to use COLTRA 500
4. Possible side effects
5. How to store COLTRA 500
6. Contents of the pack and other information

#### **1. What COLTRA 500 is and what it is used for**

COLTRA 500 contains mesalazine, which is an anti-inflammatory medicine used for:

- The treatment and maintenance of remission in ulcerative colitis.
- Treatment of mild to moderate proctitis and proctosigmoiditis.

Ulcerative colitis is a disease of the large bowel (colon) and back passage (rectum), in which the lining of the bowel becomes inflamed (red and swollen). COLTRA 500 act locally in the rectum to

reduce this inflammation. They can also be used to prevent further episodes of ulcerative colitis. COLTRA 500 are particularly useful when the symptoms of ulcerative colitis affect the rectum.

## **2. What you need to know before you use COLTRA 500**

### **Do not use COLTRA 500:**

- If you are hypersensitive (allergic) to mesalazine or to the other ingredient of COLTRA 500 (listed in section 6).
- If you are hypersensitive (allergic) to aspirin or other salicylates.
- If you have had serious kidney or liver problems.
- If you are pregnant or breastfeeding your infant.
- This medicine should not be used by children.
- If you have bleeding tendencies.
- If you have a cardiac hypersensitivity due to mesalazine.
- Salicylate sensitive asthma.

### **Warnings and precautions**

Take special care with COLTRA 500:

Before using the COLTRA 500 it is important to tell your doctor if any of the conditions listed below apply to you. If they do, you may need check-ups more often or your doctor may decide not to prescribe COLTRA 500 for you.

- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using COLTRA 500.
- If you have ever had any kidney problems, especially if you are elderly.
- In elderly patients, COLTRA 500 is only recommended for use if kidney and liver function is normal and caution should generally be exercised.
- If you have a liver disease.
- If you have blood dyscrasia, a condition in which different constituents of blood, such as white blood or red blood cells and platelets, are either high or too low in counts.
- If you have any lung problems, e. g. asthma.

- COLTRA 500 may interact with other medicines for pain and inflammation (NSAIDS).
- COLTRA 500 may interact with other medicines such as, azathioprine (an immunosuppressant), as well as mercaptopurine and thioguanine (medicines to treat cancer) see “Other medicines and COLTRA 500”.
- If you have ever had allergic reactions of your heart such as inflammation of the heart muscle or heart sac. If you have had previous suspected mesalazine-induced allergic reactions of your heart, then COLTRA 500 must not be used. COLTRA 500 can be used with care if you have had a previous allergic reaction of the heart not caused by mesalazine.
- Caution is advised in patients with a history of hypersensitivity reactions and therapy with COLTRA 500 should be stopped immediately if symptoms of cramps, abdominal pain, fever, severe headache or rash occur.
- If you have ever had any blood disorders, especially while taking medicines such as sulphasalazine.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported in association with COLTRA 500 treatment. Stop using COLTRA 500 and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Kidney stones may develop with use of COLTRA 500. Symptoms may include pain in sides of abdomen and blood in urine. Take care to drink sufficient amount of liquid during treatment with COLTRA 500.

*Test for your liver, kidney and blood*

When you start using COLTRA 500, your doctor may test your blood from time to time.

As a guideline, follow-up tests are recommended 14 days after commencement of treatment and then every 4 weeks for the following 12 weeks. If the findings are normal, follow-up tests should be carried out every three months. If additional signs appear, these tests should be performed immediately.

If you have an ulcer of the stomach or intestine, you may use COLTRA 500 with care.

Mesalazine as contained in COLTRA 500 may produce red-brown urine discoloration after contact with sodium hypochlorite bleach in the toilet water. It concerns a chemical reaction between mesalazine and bleach and is harmless.

### **Children and adolescents**

There is little experience and only limited documentation for an effect of COLTRA 500 in children.

### **Other medicines and COLTRA 500**

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Medicines that prevent the formation of blood clots (anticoagulants, e.g., warfarin).

COLTRA 500 may increase the effects of azathioprine, thioguanine and 6-mercaptopurine, (both immunosuppressive medicines). Your doctor may need to do blood tests.

NSAIDS (Medicines for pain and inflammation).

### **Pregnancy, breastfeeding and fertility**

Safety in pregnancy and breastfeeding has not been established.

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 healthcare provider for advice before using COLTRA 500.

### **Driving and using machines**

COLTRA 500 have no or negligible influence on the ability to drive and use machines.

It is not always possible to predict to what extent COLTRA 500 may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which COLTRA 500 affects you.

### **3. How to use COLTRA 500**

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

Always use COLTRA 500 exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Do not swallow your suppositories. They should be inserted into the back passage (rectum).

The information below tells you how to insert a suppository:

1. Empty your bowels (if necessary) and wash your hands.
2. Remove the plastic wrapping from the suppository.
3. Squat or bend forward.
4. Gently, but firmly, place the suppository – pointed end first, into the back passage. If necessary, grease the tip of the suppository with petroleum jelly.
5. Wash your hands again.
6. Try not to empty your bowels for at least an hour after inserting the suppository.

The usual adult dosage of COLTRA 500 is:

One suppository inserted rectally up to three times a day, with the last dose at bedtime.

The pharmacist's label on your carton will tell you how many suppositories your doctor would like you to use. Please read the label carefully.

**Do not use more suppositories than your doctor has recommended.**

COLTRA 500 are not recommended for children.

Keep using your suppositories until the prescribed course is finished. Your symptoms may come back if you stop your treatment too early.

If you have the impression that the effect of COLTRA 500 is too strong or too weak, talk to your doctor or pharmacist.

#### **If you use more COLTRA 500 than you should**

You should only use as many suppositories as your doctor or pharmacist has told you. In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take your suppository pack with you.

If you have swallowed an COLTRA 500 by mistake, drink plenty of water and tell your doctor or hospital casualty department straight away. Take your suppository pack with you.

#### **If you forget to use COLTRA 500**

If you forget to insert a suppository at the right time, insert it as soon as you remember. Then go on as before. Do not use more than two suppositories in one hour. Do not use a double dose to make up for forgotten individual doses. If you have any doubts speak to your doctor or pharmacist for advice.

#### **4. Possible side effects**

COLTRA 500 can have side effects.

Not all side effects reported for COLTRA 500 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using COLTRA 500, please consult your healthcare provider for advice.

If any of the following happens, stop using COLTRA 500 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,

- rash or itching,
- fainting,
- If you develop unexplained bruising (without injury), bleeding under your skin, purple spots or patches under your skin, 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), reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of the mouth, throat, nose, genitals and eyes, widespread rash, fever and enlarged lymph nodes. These serious skin rashes can be preceded by fever and flu-like symptoms.

These are all very serious side effects. If you have them, you may have had a serious reaction to COLTRA 500. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

*Less frequent side effects*

- severe reduction in blood cells which can cause weakness, bruising or make infections more likely, low blood cell counts; reduction in blood platelets which increases the risk of bleeding
- an excessive amount of eosinophils (a specific type of white blood cells) that can lead to inflammation and damage in various tissues and organs, depending on where the allergic reaction is occurring e.g., the airways or digestive system
- headache
- dizziness
- inflammation of the heart muscle or the thin saclike membrane surrounding your heart
- nausea (feeling sick)
- diarrhoea
- wind (flatulence)
- stomach pain
- allergic reactions such as rash or skin eruption
- immune system disease that can involve organs and joints
- fever that occurs while taking the medicine and which disappears when the medicine is stopped (drug fever)

- pain in the chest that increases with deep breathing or coughing (symptoms of pericarditis, pleuro-pericarditis) as well as a rash
- ulcerative colitis involving the entire large intestine
- damage to peripheral nerves giving rise to numbness and tingling
- lung disease (scarring of lung tissue, allergic reaction) resulting in difficulty in breathing, cough, wheezing and collection of fluid in the lungs
- inflammation of the lungs
- inflammation of the pancreas
- abnormal liver function tests, hepatitis (inflammation of the liver giving rise to flu-like symptoms and jaundice)
- increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)
- hair loss
- muscle or joint pain
- kidney problems
- inflammation of the spaces between tubules (small tubes) inside the kidney (acute or chronic)
- reduced kidney function
- reversible decrease in sperm production

*Unknown frequency*

- atypical, widespread rash, which may occur in conjunction with high body temperature and enlarged lymph nodes
- inflammation of the membranes of the pleural cavity surrounding the lungs (pleurisy)
- type of lung infection or inflammation that affects the tissue and spaces between the air sacs (alveoli) in the lungs
- worsening of symptoms of colitis and include bloody diarrhoea, abdominal cramps and pain, and an inability to move the bowels despite the urge to do so
- kidney condition which causes problems with the way they filter waste and excess fluid from the body
- kidney failure (can be reversed once treatment is stopped)

- kidney stones and associated kidney pain (see also section 2)
- intolerance to mesalazine sometimes with worsening symptoms of underlying disease
- local reaction/ irritation

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, pharmacist or nurse. 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 COLTRA 500.

### **5. How to store COLTRA 500**

- Store at or below 25 °C in a cool place, protected from light.
- Store all medicines out of reach of children.
- Do not use the suppositories after the expiry date printed on the pack.
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets)

### **6. Contents of the pack and other information**

#### **What COLTRA 500 contains**

Active ingredient: mesalazine (also known as 5-aminosalicylic acid).

The other ingredient is hard fat.

#### **What COLTRA 500 looks like and contents of the pack**

An opaque, pale beige, torpedo-shaped suppository with a faint fatty odour.

Cartons of 20 suppositories, in white opaque cavity-formed PVC strips, printed on one side.

**Holder of Certificate of Registration**

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