PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ZYLAMENE SR 800 mg modified-release tablets

Mesalazine

Sugar free.

Read all of this leaflet carefully before you start taking ZYLAMENE SR 800.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- ZYLAMENE SR 800 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 ZYLAMENE SR 800 is and what it is used for
2. What you need to know before you take ZYLAMENE SR 800
3. How to take ZYLAMENE SR 800
4. Possible side effects
5. How to store ZYLAMENE SR 800
6. Contents of the pack and other information.

1. What ZYLAMENE SR 800 is and what it is used for

ZYLAMENE SR 800 contains the active substance mesalazine.

Mesalazine is an anti-inflammatory medicine used in the treatment of ulcerative colitis – a disease of the large bowel (colon) and back passage (rectum) in which the lining of the bowel becomes inflamed (red and swollen). Symptoms can include rectal bleeding, frequent diarrhoea and abdominal pain. ZYLAMENE SR 800 acts locally in the colon to reduce inflammation and can also prevent further episodes (flares) of ulcerative colitis.

2. What you need to know before you take ZYLAMENE SR 800

Do not take ZYLAMENE SR 800

- If you are hypersensitive (allergic) to mesalazine or any of the other ingredients of ZYLAMENE SR 800 (listed in section 6).
- If you are allergic to aspirin or any other salicylate.
- If you have had kidney problems or blood abnormalities while taking other medicines, such as sulfasalazine.
- If you have severe kidney problems.
- If you have severe liver problems.
- If you have a stomach or duodenal ulcer.
- If you bleed easily.

Warnings and precautions

Your doctor will perform blood and urinary tests before you start taking ZYLAMENE SR 800 and during treatment with ZYLAMENE SR 800. A follow-up test will be scheduled 14 days after treatment has started and then every 4 weeks for the following 12 weeks. If the results are normal, your doctor will schedule follow-up tests every 3 months. If needed, the follow-up test can be performed earlier.

Take special care with ZYLAMENE SR 800:

- If you are an elderly person. ZYLAMENE SR 800 is only recommended for use if your kidney and liver function is normal, and caution should generally be exercised.
- If you develop symptoms of intolerance, such as vomiting, cramps, abdominal pain, fever, severe headache or a rash after starting treatment with ZYLAMENE SR 800. You should stop taking ZYLAMENE SR 800.
- If you ever had problems with your kidneys.

- If you suddenly develop a serious skin reaction (painful, blistering or peeling skin rash) after you started treatment with ZYLAMENE SR 800. You should stop taking ZYLAMENE SR 800 and seek medical attention.
- If you have liver problems.
- If you have any lung problems, e.g. asthma. Your doctor may want to check your breathing from time to time.
- If you have a history of hypersensitivity reactions affecting the heart (myocarditis and pericarditis), irrespective of their cause.
- If you keep noticing tablets in your stools, you should consult your doctor.

When you start taking ZYLAMENE SR 800 and during treatment with ZYLAMENE SR 800, your doctor may consider regular examinations to check that your blood, liver, kidneys and lungs are normal. It is recommended that you keep all appointments for tests arranged by your doctor. The treatment will be stopped if it affects your liver or kidneys.

Very rarely, serious blood problems have been reported with the use of ZYLAMENE SR 800. Your doctor may perform regular blood tests when you are taking ZYLAMENE SR 800 to check that your blood counts (the number of cells in the blood) are normal. Further blood tests will be necessary if signs of changes in the blood develop. These signs include:

- any unexplained bleeding;
- easy bruising and bleeding under your skin;
- a deficiency of red blood cells (anaemia);
- persistent fever;
- sore throat.

Children and adolescents

Use in children and adolescents is not recommended.

Other medicines and ZYLAMENE SR 800

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

Tell your doctor or pharmacist if you are currently using:

- digoxin (a medicine used to treat heart problems);
- medicines that prevent the formation of blood clots (anticoagulants, e.g. warfarin);
- medicines that reduce the activity of the immune system (e.g. azathioprine, 6-mercaptopurine or thioguanine);
- nonsteroidal anti-inflammatory drugs (NSAIDs) (used to treat pain and inflammation);
- sulfinpyrazone (a medicine to treat gout);
- furosemide, a diuretic (water tablet).

ZYLAMENE SR 800 should not be taken with medicine that can lower the stool pH, e.g. lactulose (a medicine used to treat constipation).

ZYLAMENE SR 800 with food, drink and alcohol

See section 3.

Pregnancy, breastfeeding 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 ZYLAMENE SR 800.

Safety during pregnancy and breastfeeding has not been established.

ZYLAMENE SR 800 is excreted in breastmilk.

Driving and using machines

ZYLAMENE SR 800 may influence your ability to drive vehicles or operate machines. It is not always possible to predict to what extent ZYLAMENE SR 800 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 ZYLAMENE SR 800 affects you.

ZYLAMENE SR 800 contains sodium

ZYLAMENE SR 800 contains less than 1 mmoL sodium (23 mg) per modified-release tablet, that is to say it is essentially sodium free.

3. How to take ZYLAMENE SR 800

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

Always take ZYLAMENE SR 800 exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The tablets should be swallowed whole with a glass of water one hour before a meal. Do not break, crush or chew the tablets.

The usual dose is:

Adults:

- ***Treating ulcerative colitis:***

  3 to 6 tablets once daily or divided throughout the day (as advised by your doctor).

- ***Preventing further episodes of ulcerative colitis:***

  2 to 3 tablets once daily or divided throughout the day (as advised by your doctor).

For example:

- a daily dosage of 3 tablets may be taken as 3 tablets once a day or divided in two to three times daily (as advised by your doctor),
- a daily dosage of 6 tablets must be taken in divided doses, 2 tablets three times a day or as advised by your doctor.

DO NOT take more than 6 tablets a day, or more than 3 tablets at once.

Elderly patients:

The normal dose should be used unless kidney or liver function is severely impaired.

Children:

ZYLAMENE SR 800 is not recommended for use in children under the age of 18 years.

Your doctor will tell you how long your treatment with ZYLAMENE SR 800 will last. Do not stop treatment early because you think you are cured.

If you have the impression that the effect of ZYLAMENE SR 800 is too strong or too weak, tell your doctor or pharmacist.

If you take more ZYLAMENE SR 800 than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the remaining ZYLAMENE SR 800 with you so the doctor will know what you have taken.

If you forget to take ZYLAMENE SR 800

If you forget to take a dose at the required time, take it as soon as you remember and continue taking your tablets as before. Do not take a double dose to make up for forgotten individual doses.

If you stop taking ZYLAMENE SR 800

Keep taking the tablets for as long as your doctor tells you. Your symptoms may come back if you stop treatment too early.

Remember to get a repeat prescription at the right time so that you do not miss a day of treatment.

4. Possible side effects

ZYLAMENE SR 800 can have side effects.

Not all side effects reported for ZYLAMENE SR 800 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZYLAMENE SR 800, please consult your health care provider for advice.

If any of the following happens, stop taking ZYLAMENE SR 800 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZYLAMENE SR 800. 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:

- chest pain, shortness of breath, palpitations (rapid heartbeat);
- frequent infections such as fever, severe chills, sore throat or mouth ulcers;
- bleeding or bruising more easily than normal;
- ulcerative colitis involving the entire large intestine (stomach cramps, pain, fatigue, severe bouts of bloody diarrhoea and excessive weight loss);
- pneumonia (fever, chills, shortness of breath, cough, sometimes coughing up greenish or yellow mucus or even bloody mucus);
- inflammation of your pancreas (nausea, vomiting, fever, pain of your stomach area that radiates to your back, increased heart rate);
- yellowing of your skin and eyes, dark urine and tiredness, which may be symptoms of liver problems;
- painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome or toxic epidermal necrolysis (TEN);

- kidney problems including kidney failure (drowsiness, shortness of breath, fatigue, confusion, nausea, fits, passing less urine than is normal for you).

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;
- indigestion, nausea (feeling sick), vomiting (being sick), diarrhoea, pain in your stomach area;
- muscle pain, joint pain.

Less frequent side effects

- anaemia (fatigue, loss of energy, pale skin, cramps in your legs, difficulty with concentration);
- higher than normal level of disease-fighting white blood cells;
- reduction in number of red and white blood cells as well as platelets (pancytopenia);
- tingling or numbness of your hands and feet (pins and needles), dropping things from your hands regularly, feeling of weakness or heaviness in your arms and legs, sharp stabbing pains;
- ringing in your ears;
- dizziness;
- sensation of swaying or spinning;
- cough, difficulty in breathing (dyspnoea), chest tightness;
- flatulence (wind), worsening of the symptoms of colitis;
- abnormal liver function tests;
- hives (red, itchy rash);
- increased sensitivity of your skin to the sun;
- hair loss (temporarily);
- raised red rash, sometimes with target-shaped lesions (erythema multiforme);
- semen with a low concentration of sperm (oligospermia) (this is reversible);

- fever, including fever that occurs while taking ZYLAMENE SR 800 and then disappears when ZYLAMENE SR 800 is stopped.

Frequency unknown side effects

- blood disorders (causing symptoms such as weakness, shortness of breath and pale skin, especially the nail beds);
- immune system disorders (lupus-like syndrome), which may affect your organs (inflammation of both the pericardium and pleura) and joints;
- intolerance to mesalazine, as contained in ZYLAMENE SR 800, sometimes with worsening symptoms of the underlying disease;
- decreased body mass;
- laboratory test results outside the normal range.

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. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8
By reporting side effects, you can help provide more information on the safety of ZYLAMENE SR 800.

5. How to store ZYLAMENE SR 800

- Store at or below 25 °C.
- Keep in the original container until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the packaging.
- 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 ZYLAMENE SR 800 contains

Each modified-release tablet contains 800 mg mesalazine.

The other ingredients are:

Core: Colloidal silicon dioxide, magnesium stearate (E572), microcrystalline cellulose [E460(i)], povidone, sodium starch glycolate and talc (E553b).

Coating: Acetyl tributyl citrate, iron oxide red (E172), methacrylic acid copolymer, talc (E553b), titanium dioxide (E171).

Black ink: Opacode Black [containing ammonium hydroxide (E527), black iron oxide (E172), propylene glycol (E1520), shellac (E904)].

What ZYLAMENE SR 800 looks like and contents of the pack

Reddish brown coloured, capsule-shaped, biconvex enteric-coated tablets imprinted with “435” on one side and plain on other side.

White HDPE bottle with a child-resistant closure containing 60 or 90 tablets.

Holder of certificate of registration

Zydus Healthcare SA (Pty) Ltd

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