PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ZYLAMENE SR 1 200 prolonged-release tablets

Mesalazine

Sugar free.

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

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

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

ZYLAMENE SR contains the active substance mesalazine, which is an anti-inflammatory medicine, used 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, ZYLAMENE SR acts through the entire colon and rectum to treat the inflammation and reduce symptoms. ZYLAMENE SR can also be taken to help prevent recurrence of ulcerative colitis.

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

Do not take ZYLAMENE SR:

- If you are allergic (hypersensitive) to mesalazine or any of the other ingredients of ZYLAMENE SR (listed in section 6 of this leaflet).
- If you are allergic (hypersensitive) to a family of medicines known as salicylates (which include aspirin).
- If you have severe kidney and/or severe liver problems.

Warnings and precautions:

Talk to your doctor before taking ZYLAMENE SR if you:

- Are an elderly patient.
- Have any mild or moderate kidney or liver problems.
- Have previously had inflammation of the heart (which may be the result of an infection in the heart).
- Have had a previous allergic reaction to sulfasalazine (another medicine used to treat ulcerative colitis).
- Have narrowing or blockage of the stomach or the gut.
- Have lung problems (such as asthma).

Tell your doctor immediately if you:

- Develop unexplained bleeding, bruising, fever or a sore throat (see section 4).
- Experience stomach pains and cramping, bloody diarrhoea, fever, headache or a rash, while taking ZYLAMENE SR (see section 4).

Kidney stones may develop with the use of ZYLAMENE SR. Symptoms may include pain in the sides of the abdomen and blood in the urine. Take care to drink enough liquids during treatment with ZYLAMENE SR.

Before and during treatment with ZYLAMENE SR, your doctor may take samples of your urine and blood to check that your kidneys and liver are working well.

Children and adolescents:

ZYLAMENE SR is not recommended for use in children below the age of 18 years, due to a lack of data on safety and efficacy.

Other medicines and ZYLAMENE SR:

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

ZYLAMENE SR may interact with some other medicines. Tell your doctor or pharmacist if you are taking:

- Sulfasalazine (taken for treatment of ulcerative colitis).
- Nonsteroidal anti-inflammatory drugs (for example medicines containing aspirin, ibuprofen or diclofenac).
- Azathioprine or 6-mercaptopurine or other medicines known to affect how your bone marrow works (i.e. immunosuppressants, which reduce the activity of your body’s immune system).

- Coumarin-type anticoagulants (medicines which increase the time it takes for your blood to clot), e.g. warfarin.

If you are undergoing urine tests, it is important to tell the doctor or nurse that you are taking, or have recently taken ZYLAMENE SR, as it can affect some test results.

Pregnancy and breastfeeding:

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.

Safety in pregnancy and breastfeeding has not been established.
Mesalazine is excreted in breast milk. You should not breastfeed your baby while you are taking ZYLAMENE SR.

Mesalazine, as in ZYLAMENE SR, have shown no sustained effect on male fertility.

Driving and using machines:

ZYLAMENE SR can cause side effects, such as dizziness or drowsiness. You should not drive a vehicle or operate machinery until you know how ZYLAMENE SR affects you.
It is not always possible to predict to what extent ZYLAMENE SR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ZYLAMENE SR affects them.

ZYLAMENE SR contains sodium:

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

3. How to take ZYLAMENE SR

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

Always take ZYLAMENE SR exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended starting dose for adults is two to four tablets (2,4 g to 4,8 g) taken once a day with or without food. ZYLAMENE SR must not be crushed or chewed.

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

If you take more ZYLAMENE SR than you should:

If you take too many ZYLAMENE SR tablets, you may have one or more of the following symptoms: ringing in ears, dizziness, headache, confusion, drowsiness, shortness of breath, dehydration (excess loss of water), low blood sugar (which can cause light-headedness), rapid breathing.

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

If you forget to take ZYLAMENE SR:

If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose and then continue with your normal schedule. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

ZYLAMENE SR can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash, hives or itching.
- Developing fever, an extensive skin rash and enlarged lymph nodes (small glands that filter the lymph in your body and play a crucial role in your immune system).
- Fainting.

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

- If you develop unexplained bruising (without injury), rash, anaemia (feeling tired, weak and looking pale, especially on your lips, nails and inside of eyelids), fever (high temperature), sore throat or unusual bleeding (e.g. nose bleeds) (see section 2).
- If you experience symptoms such as cramping, severe stomach pain, bloody and excessive stools (diarrhoea), fever, headache or rash. These symptoms could be a sign of acute intolerance syndrome which can happen during an acute episode of ulcerative colitis. This is a serious condition which occurs rarely, but means your treatment would have to be stopped

immediately (see section 2).

- Changes in the way your heart beats, for example, if you notice it beating faster.
- Inflammation of your heart muscle or the lining around your heart (fever, changes in the way your heart beats, weakness, chest pain, shortness of breath).
- Shortness of breath, dry cough, tightness in your chest, difficulty breathing, wheezing.
- Constipation and anal bleeding, which is due to the formation of rectal polyps (non-cancerous growth in your back passage).
- Liver problems, such as hepatitis or liver toxicity, with signs such as yellowing of the skin and eyes, dark urine, flu-like symptoms and tiredness.
- Abnormal liver function results when tests are done.
- Symptoms similar to systemic lupus erythematosus, a disease in which the immune system attacks its own tissues, causing widespread inflammation and tissue damage in the affected organs. It can affect your joints, skin, brain, lungs, kidneys and blood vessels. You may experience symptoms such as fatigue, joint pain, rash and fever.
- Kidney problems, such as producing less urine than is normal for you, kidney stones and associated pain (see section 2).
- If you develop increased pressure in your brain causing headache, which may originate behind your eyes and worsen with eye movements, with blurred or dimmed vision, double vision, seeing light flashes, difficulty seeing to the side, and brief or permanent vision loss. These may be associated with dizziness, nausea, vomiting, ringing in ears.
- A severe, painful, blistering and peeling skin rash known as Stevens-Johnson syndrome.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache.

- Swollen, bloated, painful stomach with pain that worsens when eating, diarrhoea, heartburn, nausea (feeling sick), vomiting (being sick), excessive wind (flatulence), stomach upset.
- Joint pain, back pain.
- Weakness, fatigue, fever.
- Facial swelling due to the build-up of excessive fluid.

Less frequent side effects:

- Abnormal blood test results showing a reduction in blood platelets which increases the risk of bleeding and bruising, or a low number of granulocytes (a type of white blood cell).
- Dizziness, drowsiness.
- Tremor (uncontrolled shaking).
- Ear pain.
- High blood pressure (hypertension), low blood pressure.
- Sore throat.
- Pancreatitis (inflammation of your pancreas causing severe pain and tenderness of your stomach area radiating to your back, nausea, vomiting, fever).
- Pimples (acne), hair loss (temporary), red, itchy skin.
- Sensitivity to sunlight (photosensitivity).
- Muscle pain.

The following side effects may occur, but the frequency is unknown:

- Neuropathy (damage to your nerves causing weakness, numbness and pain in your hands or feet).
- Aplastic anaemia, low white blood cell count.
- Low sperm count (reversible).

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. 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 ZYLAMENE SR.

5. How to store ZYLAMENE SR

- Store at or below 25 °C
- Keep the bottle well closed until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton or container.
- 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 contains:

The active substance is mesalazine.

Each ZYLAMENE SR tablet contains 1 200 mg mesalazine.

The other ingredients are: colloidal silicon dioxide, magnesium stearate, sodium carboxymethyl cellulose, sodium starch glycolate, hypromellose, microcrystalline cellulose, methacrylic acid copolymer, triethyl citrate, talc, isopropyl alcohol and Opadry 03F565028 Brown (which contains hypromellose, talc, macrogol, titanium dioxide, iron oxide red, iron oxide yellow).

What ZYLAMENE SR looks like and contents of the pack:

Pale red-brown, oval shaped, biconvex, bevelled, film-coated tablets debossed with the ‘711’ on one side and plain on other side.

225 mL white HDPE bottle with child resistant PP cap and activated carbon cannister.

Pack sizes: 60 or 120 tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration:

Zydus Healthcare SA (Pty) Ltd

Southdowns Office Park, Building B, Ground Floor

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Centurion

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