Approved Patient Information Leaflet for Medicines for Human Use:

LAGATRIM AND LAGATRIM FORTE

SCHEDULING STATUS: S4

LAGATRIM 80 mg/400 mg tablet

LAGATRIM FORTE 160 mg/800 mg tablet

Trimethoprim and Sulphamethoxazole

Sugar free

LAGATRIM 80 mg/400 mg tablet

Each tablet contains 0,1 % *m/m* nipasept (preservative).

Read all of this leaflet carefully before you start taking LAGATRIM and LAGATRIM FORTE

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

1. What LAGATRIM and LAGATRIM FORTE is and what it is used for

LAGATRIM and LAGATRIM FORTE contains the active substance called trimethoprim and sulphamethoxazole which belongs to the group of medicines called antibacterials for systemic use.

LAGATRIM and LAGATRIM FORTE works by killing bacteria.

LAGATRIM and LAGATRIM FORTE is used for:

- Upper and lower lung infections
- Urinary bladder or urinary tract infections
- Gastrointestinal tract (your mouth, oesophagus (gullet), stomach and intestines) infections
- Genital tract (reproductive track including sexually transferred diseases) infections
- Skin infections
- Other infections with bacteria sensitive to LAGATRIM and LAGATRIM FORTE.

2. What you need to know before you take LAGATRIM and LAGATRIM FORTE

Do not take LAGATRIM and LAGATRIM FORTE

- if you are hypersensitive (allergic) to sulphamethoxazole, sulphonamide or trimethoprim or any of the other ingredients of LAGATRIM and LAGATRIM FORTE (listed in section 6).
- if you have been told that you have porphyria.
- if you have severe liver or severe kidney problems.
- if you have been told that you have an anaemia due to not having enough folic acid.
- if you are pregnant or breastfeeding.
- LAGATRIM and LAGATRIM FORTE should not be given to infants during the first 6 weeks of life.

Warnings and precautions

Take special care with LAGATRIM and LAGATRIM FORTE

- If you have skin rashes, often accompanied by flu-like symptoms after taking LAGATRIM and LAGATRIM FORTE. The rash may progress to widespread blistering or peeling of the skin. This

can be a serious skin reaction to LAGATRIM and LAGATRIM FORTE. Stop taking LAGATRIM and LAGATRIM FORTE and seek urgent advice from your doctor.

- There have been very rare reports about excessive immune reactions due to a dysregulated activation of white blood cells resulting in inflammations (haemophagocytic lymphohistiocytosis), which can be life-threatening if not diagnosed and treated early. If you experience multiple symptoms such as fever, swollen glands, feeling weak, lightheaded, shortness of breath, bruising, or skin rash simultaneously or with a slight delay, contact your doctor immediately.
- If you develop an unexpected worsening of cough and shortness of breath, inform your doctor immediately.
- If you are elderly, you may have more severe side effects, e.g. problem with your blood causing bruises or bleeding (thrombocytopenia). This can happen more frequently if you are also taking water tablets, e.g. thiazides.
- When your treatment is over a long period, your doctor may monitor your blood more regularly.
- If you have kidney problems your doctor might reduce your LAGATRIM and LAGATRIM FORTE dosage (see section 3). You should take enough fluids, especially if you are underweight or malnourished.
- If you don’t have enough folic acid (a vitamin) in your body, which can make your skin pale and make you feel tired, weak and breathless. This is known as anaemia. Your doctor might prescribe additional folic acid with your LAGATRIM and LAGATRIM FORTE treatment.
- If you have a disease called glucose-6-phosphate dehydrogenase deficiency, which can cause jaundice or spontaneous destruction of red blood cells.
- If you have severe allergies or asthma.
- If you have a problem with your metabolism called phenylketonuria and are not on a special diet to help your condition.
- If you have been told that you are at risk for a rare blood disorder called porphyria.
- If you have been told by your doctor that you have a lot of potassium in your blood. Concomitant administration of LAGATRIM and LAGATRIM FORTE with certain medicines, potassium

supplements and food rich in potassium may lead to severe hyperkalaemia (increased potassium blood level). The symptoms of severe hyperkalaemia might include muscle cramps, irregular heart rhythm, diarrhoea, nausea, dizziness, or headache.

- If you have a severe blood disorder, such as a low number of red blood cells (anaemia), a low number of white blood cells (leucopenia) or a low number of platelets, which may cause bleeding and bruising (thrombocytopenia).
- If you are suffering from AIDS or are having special treatment that lowers your immune system, e.g. after an organ transplant. You can experience more severe side-effects.

Children

Do not give LAGATRIM and LAGATRIM FORTE to premature or new-born infants during the first 6 weeks of life.

Other medicines and LAGATRIM and LAGATRIM FORTE

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

LAGATRIM and LAGATRIM FORTE can change the results of some laboratory tests.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- Zidovudine used in the treatment of HIV, as it can increase your risk of developing less blood cells.
- Ciclosporin, used after organ transplant surgeries
- Rifampicin (an antibiotic)
- Pyrimethamine, used to treat and prevent malaria, and to treat diarrhoea, as you can develop side effects, e.g. anaemia
- If you are taking any of the following, as the effect of these medicines can become stronger, and your doctor might monitor you more closely:

  - Blood thinners such as warfarin.
  - Phenytoin, used to treat epilepsy (fits)
  - Methotrexate, a medicine used to treat certain cancers or certain diseases affecting the immune system.
- Medicines to treat problems with the way the heart beats such as digoxin or procainamide.
- Amantadine used to treat Parkinson's disease, multiple sclerosis, flu or shingles.
- Lamivudine used in the treatment of HIV (Human Immunodeficiency Virus), as LAGATRIM FORTE can increase the effect of lamivudine.
- Medicines used to treat diabetes, such as glibenclamide, glipizide or tolbutamide (sulphonylureas) and repaglinide.
- Medicines that can increase the amount of potassium in the blood, such as diuretics (water tablets, which help increase the amount of urine produced, such as spironolactone), steroids (like prednisolone) and digoxin or ACE inhibitors (may be used to treat high blood pressure or some heart problems). These medicines can increase the amount of potassium to dangerously high levels in your blood.
- Folinic acid, a supplement can lower the effect of LAGATRIM and LAGATRIM FORTE
- Contraceptives can become less effective when taking with LAGATRIM and LAGATRIM FORTE. You should use additional protection while on LAGATRIM and LAGATRIM FORTE treatment.
- Azathioprine may be used in patients following organ transplant or to treat immune system disorders or inflammatory bowel disease. Your doctor might monitor your blood cells more closely.
- Para-aminobenzoic acid (PABA) is a supplement and can increase your risk of side effects, e.g. crystals forming in your urine.

LAGATRIM and LAGATRIM FORTE with food and drink

Your child should take LAGATRIM and LAGATRIM FORTE with some food or drink. This will stop them feeling sick (nausea) or having diarrhoea. Although it is better to take it with food, they can still take it on an empty stomach.

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 LAGATRIM and LAGATRIM FORTE. You should not take LAGATRIM and LAGATRIM FORTE while you are pregnant or breastfeeding your baby.

Driving and using machines

It is not always possible to predict to what extent LAGATRIM and LAGATRIM FORTE may interfere with your daily activities. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which LAGATRIM and LAGATRIM FORTE affects them.

LAGATRIM contains nipastat

LAGATRIM contains nipastat, a mixture of parahydroxybenzoate esters. It may cause allergic reactions (possibly delayed).

3. How to take or give LAGATRIM and LAGATRIM FORTE

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

Always take or give LAGATRIM and LAGATRIM FORTE exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

LAGATRIM

For adults and children over 12 years

The usual dose is two tablets every 12 hours after meals. The maximum dose (for particularly severe cases) is three tablets every 12 hours. The minimum dosage for long term treatment is one tablet every 12 hours.

Shanur Healthcare (Pty) Ltd, R20.2.1/241-2, Lagatrim and Lagatrim forte, Trimethoprim 80/160 mg; Sulphamethoxazole 400/800 mg, tablets

For children 6 – 12 years

The usual dose is ½ to 1 tablet every 12 hours.

LAGATRIM FORTE

For adults and children over 12 years

The usual dose is one tablet every 12 hours after meals. The maximum dose (for particularly severe cases) is one and a half tablets every 12 hours. The minimum dosage for long term treatment (more than 14 days) is half a tablet every 12 hours.

Renal Impairment

Your doctor will do a blood test and calculate your dosage depending on the results.

No Information is available for children with renal failure.

Duration of administration

Your doctor will tell you how long your treatment with LAGATRIM and LAGATRIM FORTE will last. Do not stop treatment early because the infection can start again. If you have the impression that the effect of LAGATRIM and LAGATRIM FORTE is too strong or too weak, tell your doctor or pharmacist.

Method of administration

- LAGATRIM and LAGATRIM FORTE is for oral use.
- You can take LAGATRIM and LAGATRIM FORTE with meals, with beverages or independently of meals. If you have a sensitive stomach, you should best take LAGATRIM and LAGATRIM FORTE after meals.

If you take more LAGATRIM and LAGATRIM FORTE than you should

When more LAGATRIM and LAGATRIM FORTE is taken than you should, you may feel nauseous, vomit, dizzy and confused.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take LAGATRIM and LAGATRIM FORTE

If you forget to take a dose, take it as soon as you remember it.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

LAGATRIM and LAGATRIM FORTE can have side effects.

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

If any of the following happens, stop taking LAGATRIM and LAGATRIM FORTE 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
- a type of allergic reaction to a medicine causing skin lesions (fixed drug eruption)
- severe blistering of the skin. These serious skin reactions include toxic epidermal necrolysis (Lyell's syndrome), Steven-Johnson syndrome (SJS), systemic lupus erythematosus to name a few (see also section 2)
- unexpected worsening of cough and shortness of breath
- increase in liver enzymes (blood tests) and inflammation of the liver sometimes with jaundice (liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching,

yellowing of the skin and eyes, and dark coloured urine

- sudden headache or stiffness of your neck, accompanied by fever. This can be meningitis aseptic.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- a fungal infection called thrush or candidiasis which can affect your child's mouth or vagina
- high levels of potassium in your blood, which can cause abnormal heart beats (palpitations)
- headache
- feeling sick (nausea)
- diarrhoea
- skin rashes.

Less frequent side effects:

- pseudomembranous colitis (infection of the colon resulting in watery and sometimes bloody stools)
- changes in the blood cells, resulting in feeling weak, tired or listless, pale skin, and more frequent infections
- cyanosis (bluish or greyish colour of the skin, nails, lips or around the eyes)
- hypothyroidism where the thyroid doesn't create and release enough thyroid hormone into your bloodstream. This makes you feel tired, gain weight and unable to tolerate cold temperatures.
- low blood sugar
- low sodium concentration in your blood
- decreased appetite

- build-up of acid in your body (metabolic acidosis)
- depression
- seeing strange or unusual sights (hallucination)
- fits (convulsions or seizures)
- tingling or numbness in your hands and feet
- loss of balance and coordination (ataxia)
- dizziness
- feeling tired
- difficulty to sleep
- vision disorders, seeing flickering or flashing lights
- inflammation of the eye which causes pain and redness
- feeling unsteady or giddy
- ringing or other unusual sounds in your ears
- inflammation of blood vessels
- vomiting
- swollen and inflamed tongue
- inflammation of the pancreas with severe upper stomach pain, often with nausea and vomiting (pancreatitis)
- the appearance of a rash or sunburn when your child has been outside (even on a cloudy day)
- arthralgia (pains in the joints)
- myalgia (pains in the muscles)
- problems with your urine, difficulty passing urine, passing more or less urine than usual
- blood or cloudiness in your urine
- kidney problems
- muscle pain and/or muscle weakness in HIV patients
- problems controlling movements.

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Side effects with frequency unknown:

- psychotic disorder (a mental state in which you may lose touch with reality)(changes in behaviour)
- plum coloured, raised, painful sores on the limbs and sometimes on the face and neck with a fever (Sweets syndrome)
- drug reaction with eosinophilia and systemic symptoms (an allergic type of reaction in which you may develop fever, skin rash, and abnormalities in blood and liver function tests - these may be signs of a multi-organ sensitivity disorder).

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 nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of LAGATRIM and LAGATRIM FORTE.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@shanur.co.za.

5. How to store LAGATRIM and LAGATRIM FORTE

Store all medicines out of reach of children.

Store in a cool place, at or below 25 °C.

Protect from light.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LAGATRIM and LAGATRIM FORTE contains

- The active substance is trimethoprim and sulphamethoxazole.
- The other ingredients for LAGATRIM are microcrystalline cellulose, povidone, maize starch, magnesium stearate and nipasept.
- The other ingredients for LAGATRIM FORTE are povidone, sodium starch glycollate, sodium lauryl sulphate and magnesium stearate.

LAGATRIM 80 mg/400 mg tablet

Each tablet contains trimethoprim 80 mg and sulphamethoxazole 400 mg.

Contains 0,1 % *m/m* nipasept (preservative).

Sugar free.

LAGATRIM FORTE 160 mg/800 mg tablet

Each tablet contains trimethoprim 160 mg and sulphamethoxazole 800 mg.

Sugar free.

What LAGATRIM and LAGATRIM FORTE looks like and contents of the pack

LAGATRIM 80 mg/400 mg tablet:

A white scored biconvex tablet.

The tablet can be divided into equal halves.

LAGATRIM FORTE 160 mg/800 mg tablet:

A white scored capsule-shaped tablet.

The tablet can be divided into equal halves.

LAGATRIM is supplied in packs of 28, 56, 100 & 1 000.

LAGATRIM FORTE is supplied packs of 1 000.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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LAGATRIM 80 mg/400 mg tablets: R/20.2.1/241

LAGATRIM FORTE 160 mg/800 mg tablets: R/20.2.1/242

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL: https://shanur.co.za/product-info/

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