V 7.1 (17/09/2021)

Patient Information Leaflet

SCHEDULING STATUS: **S4**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

RIMACTAZID PAED 60/60 (tablets)

Read all of this leaflet carefully before you start taking/giving RIMACTAZID PAED 60/60 tablets

- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, please ask your doctor or pharmacist.**
- **RIMACTAZID PAED 60/60 Tablets have 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.**

1. WHAT RIMACTAZID PAED 60/60 CONTAINS:

The active substances are rifampicin 60 mg and isoniazid 60 mg per tablet.

The other ingredients are acesulfame K, aspartame, colloidal anhydrous silica, cream soda flavour, croscarmellose sodium, microcrystalline cellulose, povidone K30, sodium starch glycolate, and sodium stearate fumarate.

RIMACTAZID PAED 60/60 does not contain sugar.

Contains artificial sweetener (aspartame 2,8 mg and acesulfame K 0,7 mg, per tablet).

2. WHAT RIMACTAZID PAED 60/60 IS USED FOR:

RIMACTAZID PAED 60/60 is used to treat pulmonary tuberculosis (TB) in children.

3. BEFORE YOU TAKE/GIVE RIMACTAZID PAED 60/60:

Do not take/give RIMACTAZID PAED 60/60:

- If you or your child is hypersensitive (allergic) to rifampicin or isoniazid, or to any of the ingredients in the tablets (see “WHAT RIMACTAZID PAED 60/60 CONTAINS”).
- If you or your child have or have had any serious liver disease or jaundice (yellowing of the skin).
- If you are pregnant, trying to become pregnant or breastfeeding your baby.
- If you are taking HIV therapy specifically saquinavir and ritonavir.

Take special care with RIMACTAZID PAED 60/60:

Tell your doctor:

- If you or your child suffer from epilepsy (fits).
- If you or your child suffer from a blood disorder called porphyria (a rare disorder associated with abnormal metabolism of various pigments, where symptoms include abdominal pain, severe skin reactions and sensitivity to light).
- If you suffer from chronic alcoholism or drink alcohol in regular – large quantities.
- If you or your child have a history of gout.
- If you or your child have kidney problems.
- If you or your child suffer from liver problems.
- If you or your child experiences tiredness, weakness, nausea or vomiting.
- If you or your child has any vitamin deficiencies.
- If you or your child have diabetes. Your diabetes may become more difficult to control while taking this RIMACTAZID PAED 60/60.
- If you or your child have or have ever had mental health problems (such as depression or schizophrenia).
- If you or your child feel numb or weak in your arms and legs (peripheral neuropathy).
- If you or your child have an HIV infection.
- If you or your child are underweight or malnourished.
- If you or your child are a black or Hispanic woman.

Special care must be taken to ensure you or your child does not miss a dose as this may give rise to a serious allergic reaction.

Periodic eye examinations during RIMACTAZID PAED 60/60 therapy is suggested.

RIMACTAZID PAED 60/60 may cause your urine, stool, saliva, sputum, sweat and tears to turn orange-red.

RIMACTAZID PAED 60/60 can permanently discolour soft contact lenses. It is best not wear soft contact lenses whilst you are taking these tablets or for 1 week after stopping RIMACTAZID PAED 60/60. Whilst you are taking these tablets, your doctor may want to carry out a number of tests from time to time. This is quite normal and nothing to worry about.

Taking/giving RIMACTAZID PAED 60/60 with food or drink:

RIMACTAZID PAED 60/60 should be taken/given on an empty stomach.

Do not drink/give your child alcohol whilst taking these tablets (e.g. alcohol is found in certain cough medicines).

Foods such as cheese, red wine, skipjack, tuna, other tropical fish should be avoided.

Pregnancy and breastfeeding:

You should not be treated with RIMACTAZID PAED 60/60 if you are pregnant or breastfeeding your baby.

If you are taking RIMACTAZID PAED 60/60 you should not breastfeed your baby, if you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking RIMACTAZID PAED 60/60. It is not yet known if RIMACTAZID PAED 60/60 is safe for your baby or unborn child.

RIMACTAZID PAED 60/60 may make the contraceptive “pill” work less well. This means you should change to a different type of contraception. Instead, you must use a reliable barrier method of contraception such as condoms or an IUD (intrauterine device) while taking RIMACTAZID PAED 60/60. If you have any questions or are unsure about this talk to your doctor or pharmacist.

Driving and using machinery:

RIMACTAZID PAED 60/60 may affect the feeling in your hands or feet. If you notice any numbness, tingling or pain in your hands or feet, do not drive or use machinery. Tell your doctor as soon as possible.

Patients should not drive, operate machinery or take part in any activities where these symptoms (numbness, tingling or pain in your hands or feet) may put either themselves or others at risk when taking RIMACTAZID PAED 60/60.

Taking other medicines with RIMACTAZID PAED 60/60:

Always tell your healthcare professional if you or your child are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor or pharmacist if you or your child are currently using:

- Medicines for epilepsy (e.g. phenytoin).
- Any medicines for heart conditions (e.g. digoxin, disopyramide, quinidine, atenolol, propranolol, nifedipine, verapamil, lorcainide, mexiletine, propafenone, tocainide).
- Medicines used to decrease hormone levels (e.g. tamoxifen, toremifen, gestrinone).
- Psychiatric medicines (e.g. haloperidol, aripiprazole).
- Birth control pills.
- Progestins.
- Antiestrogens (e.g. tamoxifen, toremifen, gestrinone).
- Medicine to treat fungal, bacterial, viral or parasitic infections (e.g. fluconazole, itraconazole, ketoconazole, voriconazole, chloramphenicol, clarithromycin, dapsone, fluoroquinolones, doxycycline, telithromycin).

- Human immunodeficiency virus (HIV) protease inhibitors (medicines for the treatment of HIV infection e.g. zidovudine, saquinavir, ritonavir, indinavir, efavirenz, amprenavir, nelfinavir, atazanavir, lopinavir, nevirapine).
- Medicines for depression or sleeplessness (diazepam, amitriptyline, nortriptyline, zopiclone, zolpidem).
- High blood pressure medicines (e.g. bisoprolol, propranolol, diltiazem, nifedipine, verapamil, nimodipine, isradipine, nicardipine, nisoldipine, losartan).
- Medicines used to suppress the immune system (e.g. corticosteroids, tacrolimus, ciclosporine, sirolimus).
- Blood thinning tablets (e.g. warfarin).
- Medicines used for high blood sugar levels (e.g. sulfonylureas, chlorpropamide, tolbutamide, rosiglitazone).
- Medicines used to treat high cholesterol levels (e.g. clofibrate, simvastatin).
- Anti-cancer medicines (e.g. irinotecan, imatinib).
- Medicines used to treat the thyroid hormone (e.g. levothyroxine).
- Medicines for stomach problems (e.g. antacids, cimetidine, ondansetron).
- Medicines for pain (e.g. morphine, codeine, paracetamol, methadone).
- Medicines used to treat worm infections (e.g. praziquantel).
- Anti-malarial medicines (e.g. quinine).
- Auto-immune disease medicines (e.g. riluzole).
- Medicines used to treat asthma (e.g. theophylline).
- Water retention medicines (e.g. eplerenone).
- Disulfiram (a medicine used to treat drinking problems).
- Alcohol.

4. HOW TO USE/GIVE RIMACTAZID PAED 60/60:

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

Your doctor will determine the correct dosage for your or your child’s condition.

Always take/give RIMACTAZID PAED 60/60 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
Your doctor will tell you how long your treatment with RIMACTAZID PAED 60/60 will last. Do not stop treatment early because this may cause resistance to RIMACTAZID PAED 60/60 which means that if you or your child become sick again with TB, this medicine may not work.

RIMACTAZID PAED 60/60 is recommended in the continuation phase of the treatment of pulmonary tuberculosis/TB.

If you have the impression that the effect of RIMACTAZID PAED 60/60 is too strong or too weak, tell your doctor or pharmacist.

If you take/give more RIMACTAZID PAED 60/60 than you should:
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take/give RIMACTAZID PAED 60/60:
If you forget to take a dose, take it as soon as you remember. Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.

5. POSSIBLE SIDE EFFECTS:

RIMACTAZID PAED 60/60 can have side effects.
Not all side effects reported for RIMACTAZID PAED 60/60 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RIMACTAZID PAED 60/60, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking/giving the RIMACTAZID PAED 60/60. Tell your doctor immediately or go to the nearest hospital:

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, wheezing, swelling of your lips, face, throat or tongue.
- You get blistering, peeling, bleeding, scaling or fluid filled patches on any part of your skin. This includes your lips, eyes, mouth, nose, genitals, hands or feet. You may have a serious skin problem.
- You bruise more easily than usual or you may have a painful rash of dark red spots under the skin which do not go away when you press on them (purpura). This could be because of a serious blood problem.
- You have chills, tiredness, unusually pale skin colour, shortness of breath, fast heartbeat or dark coloured urine. These could be signs of a serious type of anaemia.
- You have blood in your urine or an increase or decrease in amount of urine you produce. You may also get swelling, especially of the legs, ankles or feet. This may be caused by serious kidney problems.
- You have a sudden severe headache. This could be a sign of bleeding in the brain.
- Shortness of breath and wheezing.
- You get confused, sleepy, cold clammy skin, shallow or difficult breathing, a racing heartbeat or your skin is paler than normal. These could be signs of shock.
- You get more infections more easily than normal. Signs include fever, sore throat or mouth ulcers. This could be because you have a low number of white blood cells.
- You have bleeding from your nose, ear, gums, throat, skin or stomach. Signs may include a feeling of tenderness and swelling in your stomach, purple spots on your skin and black or tar-like stools.

These are all very serious side effects. If you or your child have them, you or your child may have had a serious reaction to RIMACTAZID PAED 60/60. You or your child may need urgent medical attention or hospitalisation.

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

- Inflammation of the pancreas, which causes severe pain in the abdomen and back.
- A drug reaction that causes rash, fever, inflammation of internal organs and severe skin damage.

- Skin blistering, red/purple rash, fever headache, cough and joint pain (Stevens-Johnson syndrome, SJS).
- Yellowing of the skin or whites of the eyes, or urine getting darker and stools paler, fatigue, weakness, malaise, loss of appetite, nausea or vomiting caused by liver problems.
- Blurred vision, hearing loss.
- Metallic taste in the mouth.
- Muscle weakness, bone pain.
- Loss of control of bodily movements.
- Convulsions (fits).
- Hallucinations.

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

Tell your doctor if you experience any of the following side effects:

- Water retention (oedema) which may cause swollen face, stomach, arms or legs.
- Being unable to concentrate, feeling nervous, irritable or depressed.
- Unusual skin sensations such as feeling numb, tingling, pricking, burning or creeping on the skin (paraesthesia).
- Nausea, vomiting, diarrhoea, reflux, heartburn, decreased appetite, abdominal pains.
- Flu-like symptoms including chills, fever, headache, dizziness and bone pains.
- Muscle weakness or pain or loss of muscle reflexes.
- Irregular periods (menstrual cycle).
- Increased thirst, going to the toilet more often and feeling tired. Your blood sugar may be high.
- Blurred vision, eye irritation.
- Temporary hearing loss, ringing sound in the ear.
- Feeling very tired and weak or difficulty sleeping (insomnia).
- Short-term memory loss, anxiety, being less alert or responsive.
- Weight loss, night sweats and fever. These could be signs of a blood condition called eosinophilia.

- Aneamia.
- Skin rashes, acne, scaling of the skin.
- Breast enlargement.
- Orange-red discolouration of bodily fluids (e.g. tears, urine).
- Excessive blood loss.

These effects are often mild and may wear off after a few days treatment. If they are severe or last for more than a few days, tell your doctor.

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

6. STORING AND DISPOSING OF RIMACTAZID PAED 60/60:

Store at or below 25 °C and protect from moisture.

Keep blisters in the carton until required for use, or keep container well closed.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use the tablets after the expiry date printed on the blisters and containers.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF RIMACTAZID PAED 60/60:

White opaque, polypropylene (PP) securitainers closed with white opaque plastic lids with intact security seals.

Tablets are packed into securitainers as pack sizes of 80, 120, 500 or 1 000 tablets.

Clear PVC/ PE/ PVLC/ Aluminium foil blister strips of 10 or 14 tablets. Blister strips are packed into a cardboard carton as 28, 56, 80, 120, 500 or 1 000 tablets packed.

Clear round amber glass bottles closed with black opaque plastic lids packed with 80, 120 or 500 tablets.

8. IDENTIFICATION:

Brick red and white mottled, round, flat, bevelled edge, scored tablet.

9. REGISTRATION NUMBER:

32/20.2.3/0548

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Sandoz SA (Pty) Ltd[1]

Waterfall 5-lr

Magwa Crescent West

Waterfall City

Jukskei View

2090

11. DATE OF PUBLICATION OF THIS LEAFLET:

Date of registration: 02 February 1999

Date of most recent approval of patient information leaflet: 06 September 2018

[1]Company Reg. No.: 1990/001979/07