PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PULERTTAN 5 film-coated tablets

PULERTTAN 10 film-coated tablets

Ambrisentan

Contains sugar:

PULERTTAN 5 tablets contain 36,5 mg lactose monohydrate per tablet.

PULERTTAN 10 tablets contain 73 mg lactose monohydrate per tablet.

Read all of this leaflet carefully before you start taking PULERTTAN:

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

1. What PULERTTAN is and what it is used for

PULERTTAN contains the active substance ambrisentan. It belongs to a group of medicines called other antihypertensives (used to treat high blood pressure).

PULERTTAN is used to treat pulmonary arterial hypertension (PAH). PAH is high blood pressure in the blood vessels (the pulmonary arteries) that carry blood from the heart to the lungs. In people with PAH, these arteries get narrower, so the heart has to work harder to pump blood through them. This causes people to feel tired, dizzy and short of breath.

PULERTTAN widens the pulmonary arteries, making it easier for the heart to pump blood through them. This lowers the blood pressure and relieves the symptoms.

PULERTTAN may also be used in combination with other medicines used to treat PAH.

2. What you need to know before you take PULERTTAN

Do not take PULERTTAN:

- If you are hypersensitive (allergic) to ambrisentan or to any of the other ingredients of PULERTTAN listed in section 6 of this leaflet.
- If you have severe liver problems.
- If you have scarring of the lungs of unknown cause (idiopathic pulmonary fibrosis).
- If you are pregnant or breastfeeding your baby.
- If you can become pregnant and are not using effective contraception.
- If your liver enzyme levels (AST or ALT) are more than 3 times the upper limit of normal.

Warnings and precautions:

Talk to your doctor before taking PULERTTAN if you have any of the following:

- If you have anaemia (a reduced number of red blood cells).
- If you have liver disease.
- If you have swelling (oedema).
- If you have a lung disease where the veins in the lungs are blocked (pulmonary veno-occlusive disease).

Your doctor will decide whether PULERTTAN is suitable for you.

You will need regular blood tests:

Before you start taking PULERTTAN and at regular intervals while you are taking it, your doctor will take blood to check:

- Whether you have anaemia (a reduced number of red blood cells).
- Whether your liver is working properly.

It is important that you have these regular blood tests for as long as you are taking PULERTTAN.

Children and adolescents:

PULERTTAN is not recommended for children and adolescents aged under 18 years as the safety and effectiveness are not known in this age group.

Other medicines and PULERTTAN:

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

- Your doctor may need to adjust your dose of PULERTTAN if you start taking ciclosporin A (a medicine used after transplant or to treat psoriasis).
- Tell your doctor or pharmacist if you are taking rifampicin (a medicine often used to treat tuberculosis and some other infections). Rifampicin may temporarily increase the amount of PULERTTAN in your body when you first start taking it, but this effect does not last. After about a week, rifampicin does not change how PULERTTAN works. You do not need a dose adjustment of PULERTTAN if you are taking rifampicin.

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

PULERTTAN. Do not take PULERTTAN if you are pregnant or breastfeeding.

PULERTTAN may harm unborn babies, conceived before, during or soon after treatment. If it is possible, you could become pregnant, use a reliable form of birth control (contraception) while you're taking PULERTTAN. Talk to your doctor about this.

Do not take PULERTTAN if you are pregnant, if you are planning to become pregnant, or if you could become pregnant because you are not using reliable birth control (contraception). If this applies to you, tell your doctor and do not take PULERTTAN.

Driving and using machines:

PULERTTAN may cause side effects, such as low blood pressure, dizziness and tiredness (see section 4), that may affect your ability to drive or use machines.

It is not always possible to predict to what extent PULERTTAN may interfere with your daily activities. You should ensure that you do not engage in activities until you are aware of the measure to which PULERTTAN affects you.

PULERTTAN contains lactose:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking PULERTTAN.

3. How to take PULERTTAN

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

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

The usual dose is one 5 mg tablet, once a day. Your doctor may decide to increase your dose to 10 mg, once a day.

If you take PULERTTAN with another medicine called tadalafil, the usual dose is 10 mg once a day.

If you take PULERTTAN with ciclosporin A, do not take more than one 5 mg tablet of PULERTTAN, once a day.

You can take PULERTTAN with or without food.

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

If you take more PULERTTAN than you should:

If you take too many tablets, you may be more likely to have side effects, such as headache, flushing, dizziness, nausea (feeling sick), or low blood pressure that could cause light-headedness. 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 rest of the remaining tablets with you so the doctor will know what you have taken.

If you forget to take PULERTTAN:

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.

If you stop taking PULERTTAN:

Continue to take PULERTTAN for as long as your doctor prescribes it.

You should not stop taking PULERTTAN without talking to your doctor first.

4. Possible side effects

PULERTTAN can have side effects.

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

your health care provider for advice.

If any of the following happens, stop taking PULERTTAN 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.
- Fainting.

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

- *Heart failure:* This is due to the heart not pumping out enough blood. Symptoms include shortness of breath, extreme tiredness, swelling in the ankles and legs.
- *Liver function:* PULERTTAN may affect the levels of your liver enzymes which may cause damage to your liver. Your doctor will be doing regular blood tests to ensure that this does not happen. Signs that your liver may not be working properly include loss of appetite, feeling sick (nausea), being sick (vomiting), high temperature (fever), pain in your stomach, yellowing of your skin or the whites of your eyes (jaundice), dark-coloured urine and itching of your skin. If you notice any of these signs, tell your doctor immediately.
- *Anaemia (a reduced number of red blood cells):* Anaemia can cause tiredness, weakness, shortness of breath and generally feeling unwell. Your doctor will be doing regular blood tests to ensure that this does not happen. If you notice any of these signs, tell your doctor immediately. In some instances, a blood transfusion may be required.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache.
- Dizziness.
- Palpitations (fast or irregular heartbeat).
- Worsening shortness of breath getting worse shortly after starting PULERTTAN.
- A runny or blocked nose, congestion or pain in the sinuses.
- Nausea (feeling sick) and vomiting (being sick).
- Diarrhoea.
- Feeling tired.
- Blurry or other changes to vision.
- Ringing in the ears (tinnitus).
- Fainting.
- Abnormal blood test results for liver function.
- Constipation.
- Pain in your stomach (abdomen).
- Chest pain or discomfort.
- Flushing (redness of the skin).
- Low blood pressure (hypotension).
- Swelling (oedema), especially of the ankles and feet.
- Feeling weak.
- Nosebleed.
- Rash.

Less frequent side effects:

- Sudden hearing loss.

Side effects with frequency unknown:

- Anaemia that requires blood transfusion.
- Heart failure (associated with swelling/oedema).
- Low blood pressure.
- Liver injury.
- Inflammation of the liver caused by the body's own defences (autoimmune hepatitis).

If you are using PULERTTAN with tadalafil you may also experience the following side effects more frequently:

- Ringing in the ears (tinnitus).
- Being sick (vomiting).

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 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 PULERTTAN.

5. How to store PULERTTAN

- Store at or below 25 °C.
- Keep the blister strips in the outer carton.
- 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 PULERTTAN contains:

The active substance is ambrisentan.

Each film-coated tablet contains 5 mg or 10 mg ambrisentan.

The other ingredients are:

Lactose monohydrate, microcrystalline cellulose (PH 102), croscarmellose sodium, magnesium stearate.

PULERTTAN 5 also contains Opadry II Yellow (containing polyvinyl alcohol, titanium dioxide, macrogol 4000/PEG 3350, talc, iron oxide yellow, iron oxide red).

PULERTTAN 10 contains Opadry II Pink (containing polyvinyl alcohol, titanium dioxide, macrogol 4000/PEG 3350, talc, iron oxide red).

What PULERTTAN looks like and contents of the pack:

PULERTTAN 5: Yellow coloured, capsule shaped, biconvex film coated tablets, scored on both sides, debossed with “A” and “5” on one side, and plain on the other side, free from physical defects.

PULERTTAN 10: Pink coloured, oval shaped, biconvex, film coated tablets, debossed with “A” on one side and “10” on the other side.

PULERTTAN tablets are packed into PVC/PVdC aluminium blister strips containing 10 tablets each.

Pack size: 30 tablets.

Holder of certificate of registration:

LeBasi Pharmaceuticals (Pty) Ltd

San Domenico Building, Unit 6, Ground Floor

10 Church Street

Durbanville 7551

Tel. no.: 087 551 3245

This leaflet was last revised:

Not applicable.

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PULERTTAN 5: 59/7.1.3/0710.708

PULERTTAN 10: 59/7.1.3/0711.709

Date of registration:

22 May 2026