1.5.5 Clinical Professional Information and Patient Information Leaflet amendments/updates

1.5.5.2 Clean Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

DELTYBA™ (film-coated tablets)

Delamanid, 50 mg

Contains sugar (lactose monohydrate, 100 mg per tablet)

Read all of this leaflet carefully before you start taking DELTYBA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- DELTYBA 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 DELTYBA is and what it is used for.
2. What you need to know before you take DELTYBA**.**
3. How to take DELTYBA**.**

4. Possible side effects.

5. How to store DELTYBA**.**

6. Contents of the pack and other information.

1. What DELTYBA is and what it is used for

DELTYBA contains an antibiotic for the treatment of tuberculosis in the lung caused by bacteria that are not killed by the most commonly used antibiotics to treat tuberculosis. It must always be taken together with other medicines for treating tuberculosis.

DELTYBA is used in adults, adolescents and children who are weighing at least 30 kg.

2. What you need to know before you take DELTYBA

Do not take DELTYBA:

- if you are hypersensitive (allergic) to delaminid or any of the other ingredients of DELTYBA;
- if you have severe liver disease;
- if you have heart rhythm disturbances (slow or fast rate or palpitations);
- if you take other medicines that prolong the QT time on your electrocardiogram to unsafe values;
- if you have heart failure;
- if you have congenital QT prolongation;
- if you have very low levels of albumin, in the blood;
- if you are taking medicines that strongly induce a certain liver enzyme called “CYP 450 3A4” (e.g carbamazepine).

Warnings and precautions

Take special care with DELTYBA:

- Before you start taking DELTYBA, and during the treatment, your doctor may check your heart's electrical activity using an ECG (electrocardiogram) machine (electrical recording of the heart).
- Your doctor may also perform a blood test to check the concentration of some minerals and proteins which are important for the function of your heart.

Tell your doctor if you have any of the following conditions:

- if you have been told that you have reduced levels of albumin, potassium, magnesium or calcium in the blood;
- if you have been told that you have heart problems, for example a slow heart rhythm (bradycardia) or have a history of heart attack (myocardial infarction);
- if you have a condition called congenital long QT syndrome or have a serious heart disease or problems with heart rhythm;
- if you have liver disease or kidney disease;
- if you have HIV.

Children and adolescents

DELTYBA is not suitable for children with a body weight of less than 30 kg because there are not enough data available in those patients to determinate the correct doses.

Other medicines and DELTYBA

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

Tell your doctor if you are taking any of the following medicines:

- if you are taking medicines to treat an abnormal heart rhythm (e.g. amiodarone, disopyramide, dofetilide, ibutilide, procainamide, quinidine, hydroquinidine, sotalol);

- if you are taking medicines to treat psychoses (e.g. phenothiazines, sertindole, sultopride, chlorpromazine, haloperidol, mesoridazine, pimozide, or thioridazine) or depression;
- if you are taking certain antimicrobial medicines (e.g. erythromycin, clarithromycin, moxifloxacin, sparfloxacin, bedaquiline or pentamidine;
- if you are taking triazole antifungal medicines (e.g. fluconazole, itraconazole, voriconazole);
- if you are taking certain medicines to treat allergic reactions (e.g. terfenadine, astemizole, mizolastine);
- if you are taking certain medicines to treat malaria (e.g. halofantrine, quinine, chloroquine, artesunate/amodiaquine, dihydroartemisinin/piperaquine);
- if you are taking any of the following: cisapride (used to treat stomach disorders), droperidol (used against vomiting and migraine), domperidone (used against nausea and vomiting), diphemanil (used to treat stomach disorders or excessive sweating), probucol (lowers the level of cholesterol in the bloodstream), levomethadyl or methadone (used for the treatment of opiate addiction), vinca alkaloids (anti-cancer medicines), or arsenic trioxide (used to treat certain types of leukaemia);
- if you are taking HIV-medicines containing lopinavir/ritonavir or saquinavir;
- You may be more at risk for dangerous changes of the heart rhythm.

Keep a complete list of all the medicines that you are taking. Make a new list when medicines are added or stopped. Give copies of this list to your doctor, pharmacist or healthcare professional every time you visit them or fill a prescription.

DELTYBA with food and drink and alcohol

- DELTYBA should be taken during or just after a meal.
- Swallow the tablets with water.

Pregnancy and breastfeeding and fertility

Safety of DELTYBA during pregnancy and whilst breastfeeding women has not been established.

You should not take DELTYBA during pregnancy.

If you are a woman who could become pregnant during treatment with DELTYBA, you must use an effective method of contraception for the duration of treatment to avoid becoming pregnant.

It is not known whether DELTYBA passes into breast milk. You should not breastfeed your baby if you are on treatment with DELTYBA.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking DELTYBA.

Driving and using machinery

It is not always possible to predict to what extent DELTYBA 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 DELTYBA affects them.

DELTYBA contains lactose

DELTYBA tablets contain lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take DELTYBA.

3. How to take DELTYBA

- Do not share medicines prescribed for you with any other person.
- Always take DELTYBA exactly as your doctor or pharmacist has told you.
- Check with your doctor or pharmacist if you are not sure.

Adults:

- Adults, adolescents and children with a body weight of 50 kg or more: two 50 mg film-coated tablets taken twice a day (morning and evening) for 24 weeks.
- Children with a body weight of 30 kg or more and less than 50 kg: one 50 mg film-coated tablet taken twice daily for 24 weeks.
- The tablets should be taken during or just after a meal.
- Swallow the tablets with water.
- If you have the impression that the effect of DELTYBA is too strong or too weak, talk to your doctor or pharmacist.
- Your doctor will tell you how long your treatment with DELTYBA will last.

If you take more DELTYBA 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.
- Remember to take the pack with you so that it is clear what medicine you have taken.

If you forget to take a dose of DELTYBA

It is important that you do not miss any doses. If you miss a dose of **DELTYBA**, take it as soon as possible and then take your next scheduled dose at its regular time. If it is almost time for your next dose, do not take the missed dose. Wait and take the next dose at the regular time.
Do not take a double dose to make up for forgotten individual doses.

If you stop taking DELTYBA

Effects when treatment with DELTYBA is stopped:

- You should not stop treatment unless your doctor instructs you to.

- When your DELTYBA supply starts to run low, get more from your healthcare provider or pharmacy.
- This is very important because the amount of bacteria in your blood may increase if the medicine is stopped for even a short time.
- The bacteria may develop resistance to DELTYBA and become harder to treat.

4. Possible side effects

DELTYBA can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting;
- serious liver problems. The following are signs of the liver problems:
  - Yellow discolouration of the skin and the white part of your eyeballs
  - Darkening of your urine
  - Your bowel movements turn lighter in colour
  - You feel sick to your stomach (nausea)
  - You have stomach pain

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

- changes in the way you heart beats, for example, if you notice it beating faster (palpitations)
- Signs of QT prolongation:

  - unexplained fainting

  - seizures

  - fluttering feelings in the chest
- hallucinations

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

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Decreased appetite
- Sensations of irregular and/or forceful beating of the heart
- Vomiting
- Nausea
- Diarrhoea
- Stomach pain
- Headache
- A tingling, burning or pricking sensation or numbness of the skin (paraesthesia)
- Shaking (tremor)
- Dizziness
- Hearing a persistent sound in your ear when no sound exists (tinnitus)
- Joint or muscle pain
- Weakness or lack of energy

- Difficulties with falling or staying asleep (Insomnia)
- Increase in immature red blood cells (Reticulocy-tosis)
- Low blood potassium level (Hypokalaemia)
- Increased blood uric acid level (Hyperuricaemia)
- Coughing up blood
- Changes found in investigations (electrocardiogram, ECG) of the heart

The following side effects have been reported less frequently:

- Anaemia
- Increase of certain white blood cells (eosinophilia)
- Increased blood triglycerides
- Psychotic disorder
- Agitation
- Anxiety
- Depression
- Restlessness
- Nerve damage causing numbness or pain (burning) or tingling feeling in hands or feet
- Drowsiness
- Reduced sensation
- Dry eye
- Decreased tolerability of the eyes for bright light
- Ear pain
- Increase of blood pressure (hypertension)
- Decrease of blood pressure (hypotension)
- Bruising

- Hot flushes
- Shortness of breath
- Cough
- Pain in the mouth or throat
- Throat irritation
- Dry throat
- Runny nose
- Gastritis
- Constipation
- Indigestion
- Dermatitis
- Hives
- Itching
- Papules (small skin elevations)
- Rash
- Acne
- Increased sweating
- A bone disease called osteochondrosis
- Muscular weakness
- Pain in bones
- Flank pain
- Pain in arms or legs
- Blood in urine
- Fever
- Chest pain

- Feeling unwell
- Chest discomfort
- Foot, leg or ankle swelling
- Increased values for blood investigations for the hormone cortisol
- Shingles
- Oral thrush
- Yeast infection of the skin (tinea versicolor)
- Low white blood cell count (leukopenia)
- Low blood platelets count (thrombocytopaenia)
- Dehydration
- Low blood calcium level
- High blood cholesterol level
- Aggression
- Paranoia
- Panic attacks
- Adjustment disorder with depressed mood
- Neurosis
- Feeling of emotional and mental discomfort
- Mental aberration
- Problems with sleeping
- Increase of libido
- Lethargy
- Balance disorder
- Regional pain
- Allergic conjunctivitis

- Heart rhythm problems
- Swallowing problems
- Abnormal feeling in the mouth
- Tenderness in the abdomen
- Hair loss
- Itchy or red skin including around the hair roots.
- Urine retention
- Painful urination
- Increased need to urinate at night
- Feeling hot
- Abnormal values for blood investigations related to coagulation (prolonged APPT)
- Abnormal blood values related to the function of the liver, biliary system or pancreas
- Decreased values for blood investigations for the hormone cortisol
- Increased blood pressure

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. 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/. By reporting side effects, you can help provide more information on the safety of DELTYBA.

5. How to store DELTYBA

- Store at or below 30 °C.

- Store in the original container to protect from moisture.
- Do not remove from carton until required for use.
- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Do not remove the tablets from the blister strips until required for use.
- Store all medicines out of reach of children.
- Do not store in a bathroom

6. Contents of the pack and other information

What DELTYBA contains:

- The active substance is:

Each DELTYBA film-coated tablet contains 50 mg delamanid

- The other ingredients are:

Tablet core:

Carmellose calcium, cellulose microcrystalline, hypromellose phthalate, magnesium stearate, povidone (K-25), silica colloidal hydrated, sodium starch glycolate (type A)

Film-coating:

Hypromellose, iron oxide yellow (E172), macrogol 8000, titanium dioxide, talc

Contains antioxidant (All-rac-α-tocopherol)

Contains sugar (Lactose monohydrate) 100 mg

What DELTYBA looks like and contents of the pack

What DELTYBAS looks like:

DELTYBA 50 mg film-coated tablets are round, and yellow, debossed with “DLM” and “50” on one side and plain on the other side.

Contents of pack:

DELTYBA film-coated tablets is supplied as follows:

The tablets are packaged in silver aluminum/aluminum foil blisters. Each blister strip contains 8 separately blistered tablets. 6 blister strips are placed into a carton. Pack size 48’s.

Holder of Certificate of Registration and Manufacturer

Viatris Healthcare (Pty) Ltd.

4 Brewery Street,

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1601

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website