CLEAN PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

Schedule 4

SIRTURO® 100 mg Tablets

Bedaquiline

Contains sugar: each tablet contains 145 mg of lactose (as monohydrate).

Read all of this leaflet carefully before you are given SIRTURO

- Keep this leaflet. You may need to read it again.
- Do not share SIRTURO with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What SIRTURO is and what it is used for

SIRTURO is a type of antibiotic. Antibiotics are medicines that kill bacteria that cause disease.

SIRTURO is used to treat tuberculosis (TB) when it has become resistant to other antibiotics.

This is called multi-drug resistant TB.

SIRTURO must always be taken together with other medicines for treating tuberculosis.

It is used in adults aged 18 years and over.

2. What you need to know before you take SIRTURO

Do not take SIRTURO

If you are hypersensitive (allergic) to bedaquiline or any of the other ingredients of SIRTURO (see above WHAT SIRTURO CONTAINS).

Warnings and precautions

Tell your doctor, pharmacist or nurse before taking SIRTURO, if:

Take slecial care with SIRTURO:

- You have had an abnormal heart tracing (ECG) or heart failure.
- You have a personal or family history of a heart problem called “congenital long QT syndrome”.
- You have any other diseases, including HIV infection.
- You have liver or kidney problems.
- You have a decreased thyroid gland function. This can be seen in a blood test.

Children and adolescents

Do not give SIRTURO to children and adolescents (under 18 years of age). This is because it has not been studied in this age group.

Other medicines and SIRTURO

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

SIRTURO with food, drink and alcohol

- Take SIRTURO with food.
- Swallow the tablets whole with water.
- Do not drink alcohol while you are using SIRTURO.

Pregnancy and Breastfeeding

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

Driving and using machines

You may feel dizzy after taking SIRTURO. If this happens don't drive or operate machinery.

SIRTURO contains lactose.

SIRTURO contains lactose (a type of sugar) 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 or galactose intolerance should not take SIRTURO

3. How to take SIRTURO

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

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

The usual dose is:

First two weeks:

- Take 400 mg (4 tablets of 100 mg) **once a day**

From week 3 to week 24:

- Take 200 mg (2 tablets of 100 mg) a day **for 3 days of each week** only
- There must be at least 48 hours in between each time you take SIRTURO. For example, you may take SIRTURO on Monday, Wednesday and Friday every week from week 3 onwards.

After week 2, do not take a total dose of more than 600 mg (6 tablets of 100 mg) SIRTURO in total during a 7 day period.

You take SIRTURO for a 24 week course.

You may need to continue treatment beyond the 24 week course if you have extensive resistance to TB medicines in order to be cured. This may only be considered based on individual cases by your doctor.

You may need to keep taking your other medicines for TB for longer than 24 weeks. Check with your doctor or pharmacist.

Do not stop early because your TB infection could get worse or become resistant to SIRTURO and other medicines. If you have the impression that the effect of SIRTURO is too strong or too weak, tell your doctor or pharmacist.

SIRTURO must always be taken together with other medicines for treating TB. Your doctor will decide which other medicines you should take with SIRTURO.

Take SIRTURO with food.

Do not skip doses

Skipping doses or not completing the full course of therapy may:

- make your treatment ineffective and your TB could get worse and
- increase the chance that the bacteria will become resistant to SIRTURO. This means your disease may not be treatable by SIRTURO or other medicines in the future.

If you take more SIRTURO than you should

If you take more SIRTURO than you should, talk to your doctor straight away. Take the medicine pack with you.

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 SIRTURO

During the first two weeks

- Do not take a double dose to make up for a forgotten dose.
- Take the next dose as usual.

From week 3 onwards

- Take the missed dose as soon as possible.
- Take the next planned dose no earlier than 24 hours.
- Do not take a dose of more than 600 mg (6 tablets of 100 mg) in total during a 7 day period. This should be taken as three doses of 200 mg per day at least 24 hours apart.

If you have missed a dose and you are not sure what to do, talk to your doctor or pharmacist.

If you stop taking SIRTURO:

Do not stop taking SIRTURO without first talking to your doctor. If you stop taking SIRTURO earlier than you should, your TB infection could get worse or become resistant to SIRTURO and other medicines.

If you have further questions on the use of SIRTURO, ask your doctor, pharmacist or nurse.

4. Possible side effects

SIRTURO can have side effects.

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

Serious heart rhythm changes (QT prolongation):

Tell your healthcare provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you faint.

Liver problems (hepatotoxicity):

Call your healthcare provider right away if you have unexplained symptoms such as nausea or vomiting, stomach pain, fever, weakness, itching, unusual tiredness, loss of appetite, light coloured bowel movements, dark coloured urine, yellowing of your skin or the white of your eyes (jaundice).

Frequent side effects:

- headache
- joint pain
- feeling dizzy
- feeling sick (nausea) or being sick (vomiting).

- diarrhea
- increased liver enzymes shown in blood tests
- aching muscles, tender or weak muscles, not caused by exercise
- abnormal ECG called “QT prolongation”

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, pharmacist or nurse. You can also report side effects to SAHPRA via “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 SIRTURO.

Alternatively, you may report side effects experienced with SIRTURO directly to Janssen Pharmaceutica (see section ‘Holder of the Certificate of Registration’ for contact details or visit www.janssen.com).

5 How to store SIRTURO

- Store at or below 30 °C.
- Store SIRTURO in the original container in order to protect from light.
- Do not use SIRTURO after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of the month.
- Store all medicines out of reach of children
- 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 SIRTURO contains:

- The active substance is bedaquiline.
- Each SIRTURO tablet contains bedaquiline fumarate equivalent to 100 mg of the active substance bedaquiline.
- The other ingredients are colloidal anhydrous silica, croscarmellose sodium, hypromellose 2910, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose and polysorbate 20.

What SIRTURO looks like and contents of the pack

Uncoated, white to almost white round biconvex tablet, 11 mm in diameter, with debossing “T” over ‘207” on one side and “100” on the other side.

188 tablets packaged in a white high density polyethylene (HDPE) bottle with a child resistant polypropylene (PP) closer with induction seal liner.

OR

An aluminium/aluminium blister with heat seal coating. Each packaging contains one or more blister(s) of six (6) tablets.

Holder of certificate of registration

JANSSEN PHARMACEUTICA (Pty.) Ltd.

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Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.