SIRTURO® TABLETS

Bedaquiline fumarate (100mg)

What is in this leaflet

What SIRTURO® is used for

SIRTURO® contains the active substance bedaquiline, which is a type of antibiotic. Antibiotics are medicines that kill bacteria that cause disease.

SIRTURO® is used to treat tuberculosis that affects the lungs when the disease has become resistant to at least rifampicin and isoniazid, which is also antibiotics.

SIRTURO® must always be taken together with other medicines for treating tuberculosis. It is used in adults aged 18 years and older.

How SIRTURO® works

In pulmonary tuberculosis, SIRTURO® acts by inhibiting the enzyme responsible for the generation of energy in the bacteria causing the disease, thereby killing the bacteria.

Before you use SIRTURO®

- *When you must not use it*

- You are allergic to bedaquiline or any other ingredients of this medicine. Do not take SIRTURO if this applies to you. If you are not sure, talk to your doctor or pharmacist before taking SIRTURO®.
- If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist before taking this medicine.
- Do not give this medicine to children and adolescent (under 18 years of age). This is because this medicine has not been studied in these patients.

- *Before you start to use it*

Talk to your doctor, pharmacist or nurse if:

- you have had an abnormal heart reading (ECG) or heart failure;
- you have a personal or family history of a heart problem called "congenital long QT syndrome";
- you have a decreased thyroid gland function. This can be seen in blood tests;
- you have liver disease or you drink alcohol on a regular basis;
- you have human immunodeficiency (HIV) infection.

- *Taking other medicines*

Other medicines may affect SIRTURO®. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following are examples of medicines patients with pulmonary tuberculosis may take and which may potentially interact with SIRTURO®:

- Rifampicin, rifapentine, rifabutin – to treat some infections like tuberculosis. (antimycobacterials);
- Efavirenz, etravirine,– to treat HIV infection. (antiretroviral non-nucleoside reverse transcriptase inhibitors);
- Carbamazepine, phenytoin – to treat epileptic fits. (anticonvulsants);
- St. John's wort – an herbal product to relieve anxiety. (Hypericum perforatum)

How to use SIRTURO®

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

Take SIRTURO® with food. The food is important to get the right levels of medicine in your body.

Swallow the tablets whole with water.

- *How much to use*

The treatment duration is for 24 weeks.

First 2 weeks:
Take 400 mg (4 tablets of 100 mg) **once a day**.

From week 3 until week 24:
Take 200 mg (2 tablets of 100mg) once 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.

You may need to keep taking your other medicines for tuberculosis for longer than 6 months. Check with your doctor or pharmacist.

- *When to use it*

Use as directed as your doctor or pharmacist.

- *How long to use it*

You will take SIRTURO® for a 24-week course.

Do not stop taking SIRTURO® without first talking to your doctor.
Skipping doses or not completing the full course of therapy may:

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

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

- *If you forget to use it*

During the first 2 weeks

- Skip the missed dose and take the next dose as usual.
- Do not take a double dose to make up for the missed dose

From week 3 onwards
- Take the missed dose of 200 mg as soon as possible.
- Resume the three times a week schedule.
- Make sure that there is at least 24 hours between taking the missed dose and the next scheduled dose.
- Do not take more than the prescribed weekly dose in a 7-day period.

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

- *If you use too much (overdose)*
If you use SIRTURO® more than you should, you should talk to your doctor straight away. Take the medicine pack with you.

While you are using it
- *Things you must do*
Take your medicine exactly as your doctor has told you.

Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*
You should not drink alcohol while taking SIRTURO®.

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give SIRTURO® to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*
You may feel dizzy after taking SIRTURO®. If this happens, do not drive or operate machinery.

SIRTURO® contains "lactose" (a type of sugar). If you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

Side effects

Like all medicines, SIRTURO® can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Very common side effects (may affect more than 1 of 10 people):
- Headache
- Joint pain
- Feeling dizzy
- Feeling or being sick (nausea or vomiting)
- Increased liver enzymes (shown in blood tests)
- Abnormal reading on the electrocardiogram, called "QT prolongation". Tell your doctor right away if you faint.

Common side effects (may affect up to 1 in 10 people):
- Diarrhea
- Aching or tender muscles, not caused by exercise

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of SIRTURO®
- *Storage*
Keep out of reach of children.

Store below 30ºC.

Do not use this medicine after the expiry date. See expiry date on the outer pack.

Store SIRTURO® in the original container or package in order to protect it from light.

Once the bottle is opened, a shelf life of 24 weeks is applicable not to exceed the expiry of the product.

- *Disposal*
This medicine may pose a risk to the environment. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description
- *What it looks like*
Oral tablet: uncoated, white to almost white round biconvex tablet, 11 mm in diameter, with debossing of "T"over "207" on one side and "100" on the other side.

- *Ingredients*
  - Active ingredient
  Bedaquiline fumarate.

  - Inactive ingredients
  Colloidal anhydrous silica, corn starch, croscarmellose sodium, hypromellose 2910 15 mPa.s, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polysorbate 20 and purified water (removed during processing).

- *MAL number:*
MAL20076070ACZ

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