MEDICATION GUIDE
SIRTURO™ (ser toor' oh)
(bedaquiline)
TABLETS

Read this Medication Guide before you start taking SIRTURO™ and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT SIRTURO™?

SIRTURO™ is an antibiotic prescription medicine used to treat multi-drug resistant tuberculosis (TB) of the lungs in people with limited treatment options. Multi-drug resistant tuberculosis is a serious disease that can result in death and for which there are few treatment choices. More people treated with SIRTURO™ cleared TB from their sputum compared to people who did not receive SIRTURO™.

It is important to complete the full course of treatment with SIRTURO™ and your other TB medicines and not skip doses. Skipping doses may decrease the effectiveness of the treatment and increase the likelihood that your TB disease will not be treatable by SIRTURO™ or other medicines.

SIRTURO™ can cause serious side effects.

- In one clinical trial, more deaths were seen in people who were treated with SIRTURO™ compared to people who did not receive SIRTURO™.
- Heart rhythm problems can happen with SIRTURO™.
- Talk with your healthcare provider about whether SIRTURO™ is right for you.

WHAT IS SIRTURO™?

SIRTURO™ is an antibiotic prescription medicine used to treat resistant tuberculosis (TB) of the lungs.

It is not known if SIRTURO™ is safe and effective in:

- people who do not have active TB
- people who have TB that is not resistant to antibiotics
- people who have types of TB other than TB of the lungs
- people who have an infection caused by a bacteria other than TB
- children under 18 years of age

Before you take SIRTURO™, tell your healthcare provider if you:

- have had an abnormal heart rhythm (ECG) or other heart problems.
- anyone in your family has or has had a heart problem called "congenital long QT syndrome".
- have liver or kidney problems or any other medical conditions, including HIV infection.
- are pregnant or plan to become pregnant. It is not known if SIRTURO™ will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if SIRTURO™ passes into breast milk. You and your healthcare provider should decide if you will take SIRTURO™ or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

HOW SHOULD I TAKE SIRTURO™?

- SIRTURO™ must always be taken with other medicines to treat TB. Your healthcare provider will decide which other medicines you should take with SIRTURO™.
- Take SIRTURO™ with food. Swallow the tablets whole with water.
- Take SIRTURO™ exactly as your healthcare provider tells you to take it. Take SIRTURO™ for a total of 24 weeks.

Week 1 and Week 2:

Take 400 mg (4 tablets) **1 time each day.**

Week 3 to Week 24:

- Take 200 mg (2 tablets) a day 3 times a week.
- For example, you may take SIRTURO™ on Monday, Wednesday and Friday every week.
- **Do not** take more than 600 mg (6 tablets) SIRTURO™ during a 7 day period.
- You may need to take your other TB medicines for longer than 24 weeks. Check with your healthcare provider.
- **Do not skip SIRTURO™ doses. If you skip doses,** or do not complete the total 24 weeks of SIRTURO™ your treatment may not work as well and your TB may be harder to treat.
- If you take more SIRTURO™ than you should, talk to a healthcare provider right away.
- **If you miss your SIRTURO™ dose during Week 1 or Week 2:**
  - **Do not** take a double dose to make up for the missed dose.Take the next dose as usual.

If you miss your SIRTURO™ dose during Week 3 to Week 24:

- Take the missed dose as soon as possible and resume the three times a week schedule.
- **Do not** take more than 600 mg (6 tablets) in total during a 7 day period. You should take 2 tablets per day, three time a week.

If you miss a dose and you are not sure what to do, talk to your healthcare provider.

- **Do not** stop taking SIRTURO™ without first talking to your healthcare provider.

WHAT SHOULD I AVOID WHILE TAKING SIRTURO™?

- You should not drink alcohol while taking SIRTURO™.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF SIRTURO™?

SIRTURO™ may cause serious side effects, including:

- **See "What is the most important information I should know about SIRTURO™?"**
- **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 colored bowel movements, dark colored urine, yellowing of your skin or the white of your eyes.

Side effects of SIRTURO™ include nausea, joint pain, headache, an abnormal lab test associated with damage to the pancreas, coughing up blood, chest pain, loss of appetite, and/or rash.

These are not all the possible side effects of SIRTURO™. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW SHOULD I STORE SIRTURO™?

- Store SIRTURO™ at 77°F (25°C).
- Keep SIRTURO™ in the original container, and keep SIRTURO™ out of light.

GENERAL INFORMATION ABOUT THE SAFE AND EFFECTIVE USE OF SIRTURO™.

- This Medication Guide summarizes the most important information about SIRTURO™. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about SIRTURO™ that is written for health professionals.

WHAT ARE THE INGREDIENTS IN SIRTURO™?

Active ingredient: bedaquiline.

Inactive ingredients: colloidal anhydrous silica, croscarmellose sodium, hypromellose 2910, lactose monohydrate, magnesium stearate, cornstarch, microcrystalline cellulose, polysorbate 20, purified water (removed during processing).

Product of Switzerland

Finished Product Manufactured by: Kemwell Pvt. Ltd., Bangalore, India

Manufactured for: Janssen Therapeutics, Division of Janssen Products, LP Titusville, NJ 08560

This Medication Guide has been approved by the U.S. Food and Drug Administration

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