

Patient Information for SIRTURO®

What is the most important information I should know about SIRTURO®?

SIRTURO® can cause serious side effects, including:

- **Increased risk of death.** Some people who had pulmonary tuberculosis resistant to other antibiotics (multi-drug resistant tuberculosis) and were treated with SIRTURO®, had an increased risk in death.
- **A serious heart rhythm problem called QT prolongation.** This condition can cause an abnormal heartbeat in people who take SIRTURO® and may lead to death. Your healthcare provider should check your heart and do blood tests before and during treatment with SIRTURO®. Tell your healthcare provider right away if you have a change in your heartbeat (a fast or irregular heartbeat) or if you feel dizzy or faint.

What is SIRTURO®?

SIRTURO® is a diarylquinoline antibiotic prescription medicine used in people 12 years old and older with multi-drug resistant tuberculosis (MDR-TB) of the lungs when other effective treatment options are not possible. It is not known if SIRTURO® is safe and effective in:

- people who have a tuberculosis (TB) infection, but do not show symptoms of TB (also known as latent 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.
- people who are being treated for Human Immunodeficiency Virus (HIV) who also have MDR-TB.
- children under 12 years of age or weighing less than 66 pounds (30 kg).

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Sirturo®
bedaquiline
100mg tablets

Before you take SIRTURO[®], tell your healthcare provider about all your medical conditions, including if you:

- take any other medicines for your heart.
- have had an abnormal heart rhythm (ECG) or other heart problems.
- have a family history of a heart problem called congenital long QT syndrome or heart failure.
- have decreased thyroid gland function (hypothyroidism).
- have liver or kidney problems.
- have 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. Talk to your healthcare provider about the best way to feed your baby while taking SIRTURO[®].
- if you and your healthcare provider decide for you to breastfeed while taking SIRTURO[®], **tell your healthcare provider right away if your baby has:**
 - yellowing of their eyes
 - lighter than usual stool color or stool that is pale or light brown
 - darker than usual urine color

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

You should **not** take certain liver medicines or herbal supplements while taking SIRTURO[®].

How should I take SIRTURO[®]?

- Take SIRTURO[®] exactly as your healthcare provider tells you to take it.
- You will take SIRTURO[®] for a total of 24 weeks. You may need to take your other TB medicines for longer than 24 weeks. If you are not sure you should talk with your healthcare provider.
- SIRTURO[®] must always be taken with other medicines to treat TB. Your healthcare provider will decide which other medicines you should take with SIRTURO[®].
- It is important that you complete the full course of treatment with SIRTURO[®] and not skip doses. Skipping doses may decrease the effectiveness of the treatment and increase the chances that your TB will not be treatable by SIRTURO[®] or other medicines.
- Take SIRTURO[®] with food. Swallow the tablets whole with water.

Week 1 and Week 2:

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

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Week 3 to Week 24:

- Take 200 mg (2 tablets) a day **3 times a week**.
- Take SIRTURO® doses at least 48 hours apart. For example, you may take SIRTURO® on Monday, Wednesday and Friday every week from week 3 to week 24.
- **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 continue taking SIRTURO® on the 3 times a week schedule.
- **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®?” on the front page.**
- **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.

The most common side effects of SIRTURO® in adults include nausea, joint pain, headache, coughing up blood, or chest pain.

The most common side effects of SIRTURO® in children include joint pain, nausea and stomach pain.

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 the FDA at 1-800-FDA-1088.

How should I store SIRTURO®?

- Store SIRTURO® at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep SIRTURO® in the original container, and keep SIRTURO® out of light.

Keep SIRTURO® and all medicines out of reach of children.



Please see full [Product Information](#), including **Boxed WARNINGS**
and [Medication Guide](#) on www.SIRTURO.com

Janssen Therapeutics, Division of Janssen Products, LP

