

MEDICATION GUIDE

SIRTURO® (ser toor' oh)

(bedaquiline)

tablets, for oral use

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 can cause serious side effects, including:

A serious heart rhythm problem called QTc prolongation. This condition can cause an abnormal heartbeat in people who take SIRTURO. 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 as a part of combination therapy in adults and children (2 years of age and older and weighing at least 17.6 pounds) with pulmonary tuberculosis (TB) of the lungs that is resistant to at least rifampin and isoniazid.

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 of the lungs 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 bacteria other than TB.
- children under 2 years of age or weighing less than 17.6 pounds (8 kg).

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

- take any 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 QTc 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. **Do not** breastfeed while taking SIRTURO, and for 27.5 months (2 years 3 months and 2 weeks) after your last dose, unless formula is not available. SIRTURO passes into breast milk. Talk to your healthcare provider about the best way to feed your baby while taking SIRTURO.
 - If you have to breastfeed because formula is not available, **tell your healthcare provider right away if your baby has:**

- yellowing of their eyes.
- darker than usual urine color.
- lighter than usual stool color or stool that is pale or light brown.

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.

Week 1 and Week 2:

Take your prescribed dose **1 time each day**.

Week 3 to Week 24:

- Take your prescribed dose **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.
- 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 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.

SIRTURO 20 mg tablet

- Always take SIRTURO with food.
- **Can swallow whole tablets:**
 - Swallow tablets whole with water **or**
 - Split tablets in half at the score line in the middle of the tablet into 2 equal parts of 10 mg each, then

swallow both half parts of SIRTURO with water.

- **Cannot swallow whole tablets:**

- Use 1 teaspoon (5 mL) of water for a maximum of 5 SIRTURO tablets. Mix well in a drinking cup.
 - Swallow mixture immediately, **or**
 - To help with taking SIRTURO you may add at least 1 more teaspoon (5 mL) of beverage or soft food and mix. Beverages such as water, milk products, apple juice, orange juice, cranberry juice or carbonated beverages may be used. Soft foods such as yogurt, apple sauce, mashed banana or porridge may be used.
 - Swallow mixture immediately.
 - Make sure no remaining medicine is left in the drinking cup, rinse with beverage or soft food and swallow mixture immediately.
 - If you need more than 5 tablets of SIRTURO to get your total dose, repeat the steps above until you reach your prescribed dose.

or

- Crush tablets and mix with soft food. Soft food such as yogurt, apple sauce, mashed bananas or porridge may be used. Swallow mixture immediately. Make sure no remaining medicine is left in the container, add more soft food and swallow mixture immediately.
- SIRTURO 20 mg tablets may also be given through certain feeding tubes by your healthcare provider.

SIRTURO 100 mg tablet

- Always take SIRTURO with food. Swallow tablets whole with water.

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?”**
- **liver problems (hepatotoxicity).** Your healthcare provider should do blood tests to check your liver before you start taking SIRTURO and during treatment. Call your healthcare provider right away if you have unexplained symptoms such as:
 - nausea or vomiting
 - fever
 - itching
 - loss of appetite
 - dark colored urine
 - stomach pain
 - weakness
 - unusual tiredness
 - light colored bowel movements
 - yellowing of your skin or the white of your eyes

The most common side effects of SIRTURO in adults include:

- | | |
|---|---------------------------|
| ○ heart rhythm problem (QTc prolongation) | ○ nausea |
| ○ vomiting | ○ joint pain |
| ○ rash | ○ increased liver enzymes |
| ○ stomach pain | ○ itching |
| ○ dizziness | ○ headache |
| ○ chest pain | ○ trouble sleeping |
| ○ dry skin | ○ heart pounding |
| ○ coughing up blood | |

The most common side effects of SIRTURO in children 12 years to less than 18 years of age include joint

pain, nausea and stomach pain.

The most common side effect of SIRTURO in children 5 years to less than 12 years of age is increased level of liver enzymes in the blood.

The most common side effect of SIRTURO in children 2 years to less than 5 years of age is vomiting.

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 room temperature between 68°F to 77°F (20°C to 25°C).
- Keep SIRTURO in the original container.
- Protect SIRTURO from light.
- The SIRTURO 20 mg container contains a desiccant packet to keep your medicine dry (protect it from moisture). Do not throw away (discard) the desiccant.

Keep SIRTURO and all medicines out of reach of children.

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 fumarate

SIRTURO 20 mg tablets contain the following inactive ingredients: colloidal silicon dioxide, crospovidone, hypromellose 2910 5 mPa.s, polysorbate 20, purified water (removed during processing), silicified microcrystalline cellulose and sodium stearyl fumarate.

SIRTURO 100 mg tablets contain the following inactive ingredients: colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose 2910 15 mPa.s, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polysorbate 20, purified water (removed during processing).

Manufactured for: Janssen Products, LP, Horsham, PA 19044, USA
For patent information: www.janssenpatents.com

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

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