

# 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 5 years of age 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 5 years of age or weighing less than 33 pounds (15 kg).

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 **Sirturo**®  
bedaquiline tablets  
20mg/100mg

## Before you take SIRTURO® (bedaquiline), 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.

### 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® (bedaquiline) 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® (bedaquiline) 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 container, add more soft food and swallow mixture immediately.
- SIRTURO® 20-mg tablets may also be given through certain nasogastric 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®?” on the front page.**
- **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, 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 12 years to less than 18 years of age include** joint pain, nausea, and stomach pain.

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

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.
- 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.**



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

**Janssen Therapeutics, Division of Janssen Products, LP**

