ข้อมูลยาสำหรับผู้ป่วยฉบับภาษาอังกฤษ
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:

- **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 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 12 years of age or weighing less than 66 pounds (30 kg).

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. 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.
        - lighter than usual stool color or stool that is pale or light brown.
        - darker than usual urine color.

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.**

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?"**
- **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.

Adverse reactions, such as dizziness, may affect the ability to drive or use machines, although no studies on this effect with bedaquiline have been performed. Patients should be advised not to drive or operate machinery if they experience dizziness while taking SIRTURO.

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.

How should I store SIRTURO?

- Do not store SIRTURO above 30°C.
- Keep SIRTURO in the original container, and keep SIRTURO out of light.

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

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)

Product description
Product Appearance: White to almost white round biconvex tablet with debossing of "T" over "207" on one side and "100" on the other.
Strength: Bedaquiline 100 mg.
Product quantity: Packaging White Plastic (HDPE) Bottles, 188 tablets per bottle, packed/unpacked from a paper box, 1 bottle.

Market authorization number

1C 5/60 (N)

Date of authorization

24 August 2017

Date of SMP Released Approval

16 January 2023

Date of revision of the text

USPIL version Oct-2023 and Effect on ability to drive and use machine CCDS version 3-Aug-2023

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Recipharm Pharmaservices Pvt. Ltd.
Bangalore, India

Imported by

Janssen-Cilag Ltd., Bangkok, Thailand

To report Suspected Adverse Reactions, please contact us at aepqcjacth@its.jnj.com

For any product information, please contact us at medinfosea@its.jnj.com

Please see full prescribing information at https://ndi.fda.moph.go.th