
Medication Guide for Sirturo[®] Tablets 100mg



What is Sirturo® Tablets?

Sirturo® Tablets is a medicine used to treat “multi-drug resistant pulmonary tuberculosis.”

»» What is multi-drug resistant pulmonary tuberculosis?

Bacteria that no longer respond to various treatments for tuberculosis are called “multi-drug resistant *Mycobacterium tuberculosis*,” and multi-drug resistant pulmonary tuberculosis caused by these bacteria is defined as tuberculosis that no longer responds to at least 2 anti-tuberculosis drugs, isoniazid and rifampicin. Resistance to these 2 drugs makes treatment very difficult and time-consuming.

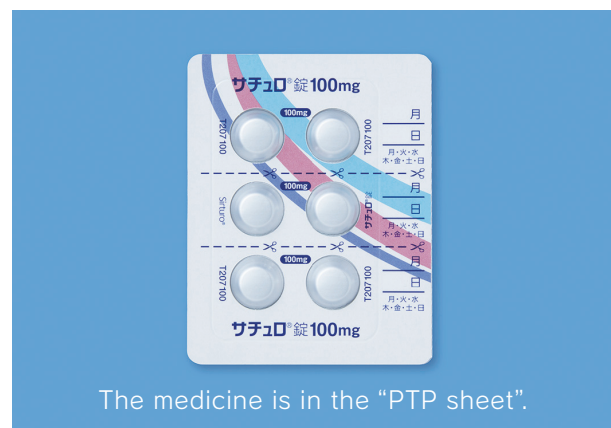
In general, patients with multi-drug resistant pulmonary tuberculosis are treated with 4 or more potentially effective anti-tuberculosis drugs other than isoniazid and rifampicin.

Reference: Yotsumoto H, Yamagishi F: Knowledge of Tuberculosis for Healthcare Professionals. Igaku-Shoin Ltd.





Photo of Sirturo® Tablets



How should I store Sirturo® Tablets?

- Keep Sirturo® Tablets in blister pack, and protect them from light, heat and moisture. Take Sirturo® Tablets immediately after removing them from the blister pack.
- Keep Sirturo® Tablets out of reach of children.



Information that you should know before you start taking Sirturo[®] Tablets

Sirturo[®] Tablets may not be suitable for the following patients. Be sure to tell your doctor if you:

- have heart problems, especially “QT prolongation” (see the last page).
- are susceptible to QT prolongation (for example, if you have heart problems such as heart failure and arrhythmia or if anyone in your family has QT prolongation).
- are taking any medicines that are known to prolong the QT interval (see the last page).

Tell your doctor or pharmacist if you are taking any other medicines.

- Some medicines (rifabutin, efavirenz etc.) may decrease the effectiveness of Sirturo[®] Tablets or increase the risk of side effects when taken with Sirturo[®] Tablets. Tell your healthcare provider about all the medicines you take.

In addition, patients who have previously experienced hypersensitivity to any of the ingredients contained in Sirturo[®] Tablets cannot receive Sirturo[®] Tablets.

How should I take Sirturo® Tablets?

To complete the full course of treatment, you must take Sirturo® Tablets exactly as your doctor tells you to.

» How to take Sirturo® Tablets

During the first 2 weeks (14 doses):

Take 4 Sirturo® Tablets (400mg) once a day, immediately after meals, with a glass of water or lukewarm water.

From week 3 onwards:

Take 2 Sirturo® Tablets (200mg) three times a week, immediately after meals, with a glass of water or lukewarm water.

Take the first Week 3 dose at least 48 hours after the last dose during the first 2 weeks. Similarly, the second Week 3 and subsequent doses must be taken at least 48 hours apart.

Talk with your doctor about the treatment schedule for Week 3 onwards. It is recommended that you take Sirturo® Tablets at about the same time on the same day of every week. For example, you may take Sirturo® Tablets on Monday, Wednesday and Friday every week, immediately after breakfast.

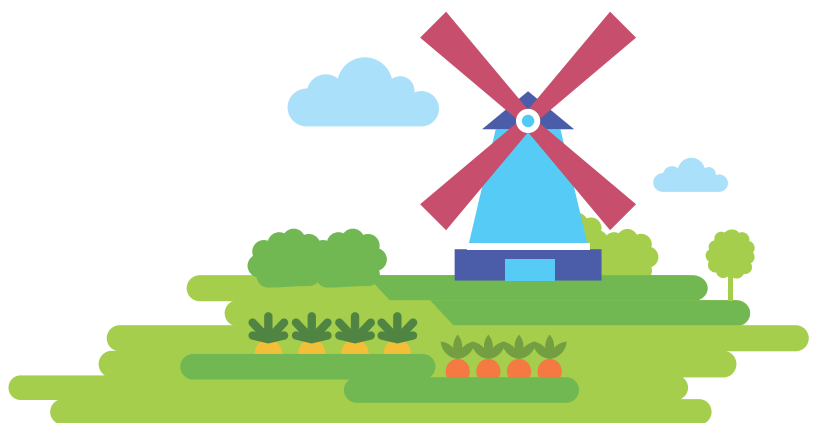
* Sirturo® Tablets must always be taken with other anti-tuberculosis drugs.

» If you miss a dose:

If you find you have missed a dose during the first 2 weeks (14 doses), contact your doctor or pharmacist right away and take Sirturo® Tablets as they tell you to do. If you find you have missed a dose during or after Week 3, take the missed dose immediately after your next meal, and then resume the 3 times a week schedule with at least 48 hours between doses.

Information that you should keep in mind while taking Sirturo® Tablets

- Sirturo® Tablets must only be taken with at least 3 drugs to which the tuberculosis bacteria collected from you have been shown to be sensitive (susceptible).
- The standard duration of treatment with Sirturo® Tablets is 6 months. However, you may need to take Sirturo® Tablets for longer than 6 months if determined necessary by your doctor.
- If you skip doses, resistant bacteria (bacteria that do not respond to drugs) may develop, making Sirturo® Tablets ineffective. It is very important to complete the full course of treatment with Sirturo® Tablets as your doctor tells you to.



What are the most common side effects of Sirturo[®] Tablets?

Talk to your doctor if you experience any of the following side effects while taking Sirturo[®] Tablets.

- **QT prolongation (see the last page)**

During treatment with Sirturo[®] Tablets, electrocardiograms will be regularly monitored to check if you have abnormalities such as QT prolongation. However, tell your doctor right away if you have any subjective symptoms (chest discomfort, palpitations and dizziness).

- **Liver problems**

To detect liver problems early, regular blood tests will be conducted. In addition to abnormal laboratory test data, possible signs of liver problems include nausea or vomiting, stomach pain, fever, weakness, itching, tiredness, loss of appetite, light colored stool, dark colored urine, and yellowing of your skin or the whites of your eyes. Contact your doctor right away if you have any of these symptoms.

- Besides the above symptoms, side effects such as acne, nausea, joint pain, headache, vomiting have been reported.



Supplementary
information

What is QT prolongation?

What is QT prolongation?

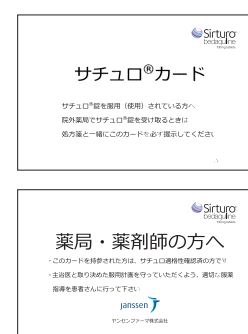
QT prolongation is an abnormal heart rhythm detected on an electrocardiogram. If it is mild, you have no subjective symptoms. However, severe QT prolongation causes symptoms such as palpitations, dizziness, light-headed feeling and fainting, and may occasionally lead to sudden death. There are two types of QT prolongation: one is congenital QT prolongation caused by, for example, genetic inheritance, and the other is caused by side effects of drugs, etc. Keep in mind that taking Sirturo® Tablets with medicines that may prolong the QT interval may increase the risk of QT prolongation.

Major medicines that may cause QT prolongation

Drugs for arrhythmia	quinidine, procainamide, disopyramide, amiodarone, sotalol, nifekalant, etc.
Drugs for Psychiatric disorders	chlorpromazine, tricyclic antidepressants, etc.
Antibiotics	erythromycin, moxifloxacin, delamanid, etc.
Drugs for gastric ulcer	cimetidine, etc.
Drugs for dyslipidemia	probucol, etc.

If you are to have an external pharmacy (a dispensing pharmacy outside the hospital) fill your prescription for Sirturo® Tablets:

- If you are to have an external pharmacy fill your prescription for Sirturo® Tablets, your doctor will provide you with the Sirturo card. The Sirturo card must be presented to the pharmacy together with your prescription.
- Keep the Sirturo card in a safe place because it is required for the prescription of Sirturo® Tablets. Should you lose it, talk to your doctor.
- After the prescription of Sirturo® Tablets is completed, return the Sirturo card to your doctor.



(Image)