

SIRTURO[®]

Bedaquiline

100 mg tablets

What is in this leaflet

Please read this leaflet carefully before you start using SIRTURO.

This leaflet answers some common questions about SIRTURO. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using SIRTURO against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What SIRTURO is used for

SIRTURO is used to treat tuberculosis (TB) that affects the lungs when the disease has become resistant to other antibiotics. This is called multi-drug resistant tuberculosis (MDR-TB). SIRTURO is used as part of combination therapy in adults and adolescents (12 years to less than 18 years of age and weighing at least 30 kg).

SIRTURO is a type of antibiotic. Antibiotics are medicines that kill bacteria that cause disease.

SIRTURO must always be taken together with other medicines for treating tuberculosis.

Your doctor may have prescribed SIRTURO for another reason.

Ask your doctor if you have any questions about why SIRTURO has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you use SIRTURO

When you must not use it

Do not take SIRTURO if:

- you are allergic to bedaquiline, or any of the other ingredients listed at the end of this leaflet

If you are not sure whether you should start using SIRTURO, talk to your doctor.

Before you start to use it

Tell your doctor if you have:

- heart problems including heart failure, slow heart rate, abnormal heart rhythm
- a family history of a heart problem called “congenital long QT syndrome”
- decreased thyroid gland function (hypothyroidism)
- liver or kidney problems
- human immunodeficiency virus (HIV) infection

You must tell your doctor if:

- you are or planning to become pregnant
- you are breastfeeding or intend to breastfeed
- you drink alcohol

If you have not told your doctor about any of the above, tell them before you start using SIRTURO.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking SIRTURO.

Some medicines may interfere with SIRTURO. Tell your doctor if you are taking:

- medicines to treat bacterial infections such as rifamycins (rifampin, rifapentine, rifabutin) and fluoroquinolones (gatifloxacin, moxifloxacin, sparfloxacin)
- medicines to treat HIV such as efavirenz, lopinavir, ritonavir and nevirapine

- medicines to treat fungal infections such as ketoconazole
- medicines to treat leprosy such as clofazimine

These medicines may be affected by SIRTURO, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking SIRTURO.

How to use SIRTURO

Always take SIRTURO exactly as your doctor or pharmacist tells you. You must check with your doctor or pharmacist if you are not sure.

SIRTURO must always be taken together with other medicines for treating tuberculosis. Your doctor will decide which other medicines you should take with SIRTURO.

SIRTURO should be taken with food. The food is important to get the right levels of medicine in your body.

How much to take

SIRTURO is for use in adults and adolescents (12 years to less than 18 years of age and weighting at least 30 kg).

Take SIRTURO for a total of 24 weeks. Swallow the tablets whole with water.

Weeks 1 to 2:

- Take 400 mg (4 tablets of 100 mg) once a day with food.

Weeks 3 to 24:

- Take 200 mg (2 tablets of 100 mg) once a day with food for **three days of each 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.

You may need to take your other tuberculosis medicines for longer than 24 weeks. Check with your doctor or pharmacist if you are not sure.

How long to take it

It is important to complete the full course of treatment with SIRTURO. Continue taking SIRTURO until your doctor tells you to stop.

Do not stop taking SIRTURO unless your doctor tells you to.

Do not skip SIRTURO doses.

Skipping doses or not completing the full treatment course may:

- make your treatment ineffective and your tuberculosis could get worse, and
- increase the chance that the bacteria will become resistant to the medicine. This means your disease may not be treatable by SIRTURO or other medicines in the future.

If you forget to take it

During the first 2 weeks of treatment

- Skip the missed dose and take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

From week 3 onwards

- 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 total of 600 mg SIRTURO in a 7-day period.

If you take more SIRTURO than you should, talk to a doctor straight away.

While you are using SIRTURO

Things you must do

Take SIRTURO exactly as prescribed by your doctor.

Complete the full course of treatment with SIRTURO.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking SIRTURO.

Tell your doctor immediately if you become pregnant while you are taking SIRTURO.

Things you must not do

Do not give SIRTURO to anyone else, even if they have the same condition as you.

Do not skip taking any doses of SIRTURO.

Do not stop taking SIRTURO without first checking with your doctor.

Do not drink alcohol while you are taking SIRTURO. Drinking alcohol increases the risk of side effects from SIRTURO.

Things to be careful of

Do not drive or operate machinery until you know how SIRTURO affects you.

SIRTURO may cause dizziness in some people. If this happens, do not drive or operate machinery.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much SIRTURO.

Do this even if there are no signs of discomfort or poisoning.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using SIRTURO.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you/your child experience any of the following and they worry you:

- headache
- feeling or being sick (nausea or vomiting)
- dizziness
- abnormal heart rhythm
- diarrhoea
- increased level of liver enzymes joint pain
- aching or tender muscles, not caused by exercise

SIRTURO can increase 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.

Tell your doctor right away if you have a change in your heartbeat (a fast or irregular heartbeat). SIRTURO can cause a serious heart rhythm problem called “congenital long QT syndrome”. This condition can cause an abnormal heartbeat in people who take SIRTURO and may lead to death. Your doctor should check your heart and perform blood tests before and during treatment with SIRTURO.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

After using SIRTURO

Storage

Keep SIRTURO out of the sight and reach of children

Keep SIRTURO below 30°C. Store SIRTURO in the original container or package in order to protect it from light.

Do not use SIRTURO after the expiry date.

Disposal

If your doctor tells you to stop taking SIRTURO or if it has passed the expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

SIRTURO 100 mg is an uncoated, white to almost white round biconvex tablet with debossing of "T" over "207" on one side and "100" on the other side.

SIRTURO is available in bottles of 188 tablets and in blister packs of 24 tablets.

Ingredients

Active ingredient

bedaquiline 100 mg

Inactive ingredients:

- colloidal anhydrous silica
- maize starch
- croscarmellose sodium
- hypromellose
- lactose monohydrate
- magnesium stearate
- microcrystalline cellulose
- polysorbate 20

SIRTURO tablets contain sugars as lactose. Each tablet contains 145 mg of lactose (as monohydrate).

Sponsor Details

SIRTURO is supplied in New Zealand by:

Janssen-Cilag Pty Ltd
NZ Office: Auckland New Zealand
Telephone: 0800 800 806

Date of Preparation

This leaflet was prepared in July 2022.