

## Package leaflet: Information for the patient

### SIRTURO 20 mg tablets bedaquiline

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What SIRTURO is and what it is used for
2. What you need to know before you take SIRTURO
3. How to take SIRTURO
4. Possible side effects
5. How to store SIRTURO
6. Contents of the pack and other information

#### 1. What SIRTURO is and what it is used for

SIRTURO contains the active substance bedaquiline.

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

SIRTURO is used to treat tuberculosis that affects the lungs when the disease has become resistant to at least rifampicin and isoniazid, which are also antibiotics.

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

It is used in adults and children (5 years and over, who weigh at least 15 kg).

#### 2. What you need to know before you take SIRTURO

##### Do not take SIRTURO

- if you are allergic to bedaquiline or any of the other ingredients of this medicine (listed in section 6). Do not take SIRTURO if this applies to you. If you are not sure, talk to your doctor or pharmacist before taking SIRTURO.

##### Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking SIRTURO, if:

- you have had an abnormal heart reading on an electrocardiogram (ECG) or heart failure;
- you have a personal or family history of a heart problem called “congenital long QT syndrome”;
- you are taking any other medications, as some may increase the risk of side effects;
- you have a decreased thyroid gland function. This can be seen in a blood test;
- you have liver disease or you drink alcohol on a regular basis;
- you have a low level of potassium in the blood. This can be seen in a blood test;
- you have human immunodeficiency virus (HIV) infection.

If any of the above applies to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking SIRTURO.

### Children and adolescents

In adolescents weighing 30 to 40 kg, the levels of SIRTURO in the blood were predicted to be higher than in adults. This might be associated with an increased risk of abnormal heart reading on an ECG (called QT prolongation) or increased liver enzymes (shown in blood test). Talk to your doctor, pharmacist or nurse before taking SIRTURO.

Do not give this medicine to children under 5 years of age or weighing less than 15 kg because it has not been studied in these patients.

### Other medicines and SIRTURO

Other medicines may affect SIRTURO. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following are examples of medicines patients with pulmonary tuberculosis due to *M. tuberculosis* resistant to at least rifampicin and isoniazid may take and that may potentially interact with SIRTURO:

Medicine (name of the active substance)	Purpose of the medicine
rifampicin, rifapentine, rifabutin	to treat some infections like tuberculosis (antimycobacterial)
efavirenz, etravirine	to treat HIV infection (antiretroviral non-nucleoside reverse transcriptase inhibitors)
carbamazepine, phenytoin	to treat epileptic fits (anticonvulsants)
St. John's wort ( <i>Hypericum perforatum</i> )	an herbal product to relieve anxiety

### SIRTURO with alcohol

You should not drink alcohol while taking SIRTURO.

### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### Driving and using machines

You may feel dizzy after taking SIRTURO. If this happens, do not drive or operate machinery.

## 3. How to take SIRTURO

Always take this medicine exactly as your doctor or pharmacist has told you. 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.

### Use in children (5 years and over and weighing between 15 kg and 20 kg)

#### How much to take

You take SIRTURO for a 24-week course.

##### First 2 weeks:

- Take 160 mg **once a day**.

##### From Week 3 to Week 24:

- Take 80 mg once a day **for 3 days of each week only**.

- There must be at least 48 hours in between each time you take SIRTURO. For example, you may take SIRTURO on Monday, Wednesday and Friday every week from Week 3 onwards.

### **Use in children (5 years and over and weighing between 20 kg and 30 kg)**

#### **How much to take**

You take SIRTURO for a 24-week course.

##### **First 2 weeks:**

- Take 200 mg **once a day**.

##### **From Week 3 to Week 24:**

- Take 100 mg once a day **for 3 days of each week** only.
- There must be at least 48 hours in between each time you take SIRTURO. For example, you may take SIRTURO on Monday, Wednesday and Friday every week from Week 3 onwards.

### **Use in adults and in children (5 years and over and weighing at least 30 kg)**

#### **How much to take**

You take SIRTURO for a 24-week course.

##### **First 2 weeks:**

- Take 400 mg **once a day**.

##### **From Week 3 to Week 24:**

- Take 200 mg once a day **for 3 days of each week** only.
- There must be at least 48 hours in between each time you take SIRTURO. For example, you may take SIRTURO on Monday, Wednesday and Friday every week from Week 3 onwards.

You may need to keep taking your other medicines for tuberculosis for longer than 6 months. Check with your doctor or pharmacist.

#### **Taking this medicine**

- Always take SIRTURO with food. The food is important to get the right levels of medicine in your body.

#### **If you can swallow tablets**

- Swallow the tablets with water – the tablets can be taken whole or split in half.

#### **If you cannot swallow tablets**

- If you are unable to swallow SIRTURO tablets, you may:
  - **Mix with water:** Mix up to 5 tablets per one teaspoon of water until fully mixed.
    - Swallow the mixture straight away, **or**
    - To help with taking SIRTURO you may add at least one extra teaspoon of water (or another drink) or soft food and mix.
    - You can use the following drinks for mixing: water, milk product, apple juice, orange juice, cranberry juice or carbonated drinks. You can use the following soft foods for mixing: yoghurt, apple sauce, mashed bananas or porridge.
    - Swallow the mixture straight away.
    - Repeat with more tablets until you have taken all the dose.
    - Make sure no bits of the tablet are left in the container, rinse with more of your drink or soft food and swallow the mixture straight away.
  - **Crush tablets and mix with soft food:** You can use soft food such as yoghurt, apple sauce, mashed bananas or porridge. Swallow the mixture straight away. Make sure no bits of the tablet are left in the container - add more soft food and swallow the mixture straight away.

- **Feeding tube:** SIRTURO 20 mg tablets may also be given through certain feeding tubes. Ask your healthcare provider for specific instructions on how to properly take the tablets through a feeding tube.

### **If you take more SIRTURO than you should**

If you take more SIRTURO than you should, talk to a doctor straight away. Take the medicine pack with you.

### **If you forget to take SIRTURO**

#### **During the first 2 weeks**

- 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.
- Resume the three 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 have missed a dose and you are not sure what to do, talk to your doctor or pharmacist.

### **If you stop taking SIRTURO**

Do not stop taking SIRTURO without first talking to your doctor.

Skipping doses or not completing the full course of therapy 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 have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Very common** (may affect more than 1 in 10 people):

- abnormal reading on an ECG called “QT prolongation”. Tell your doctor right away if you faint
- increased liver enzymes (shown in blood tests)
- headache
- joint pain
- feeling dizzy
- feeling of or being sick (nausea or vomiting).

**Common** (may affect up to 1 in 10 people):

- diarrhoea
- aching or tender muscles, not caused by exercise.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store SIRTURO**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

Store in the original container and keep the container tightly closed in order to protect from light and moisture. Do not remove desiccant (pouch containing drying agent).

This medicine may pose a risk to the environment. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What SIRTURO contains**

- The active substance is bedaquiline. Each tablet contains bedaquiline fumarate equivalent to 20 mg of bedaquiline.
- The other ingredients are: microcrystalline cellulose, crospovidone, colloidal anhydrous silica, hypromellose, polysorbate 20, sodium stearyl fumarate.

### **What SIRTURO looks like and contents of the pack**

Uncoated, white to almost white oblong tablet with score line on both sides, debossed with “2” and “0” on one side and plain on other side.

A plastic bottle containing 60 tablets

### **Marketing Authorisation Holder**

Janssen-Cilag Limited  
50-100 Holmers Farm Way  
High Wycombe  
Buckinghamshire  
HP12 4EG  
UK

### **Manufacturer**

Janssen Pharmaceutica NV  
Turnhoutseweg 30  
B-2340 Beerse  
Belgium

**For information in large print, tape, CD or Braille, telephone 0800 7318450**

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