PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed with a doctor's prescription only

SIRTURO® tablets, 100 mg

Each tablet contains bedaquiline (as fumarate) equivalent to 100 mg of bedaquiline.

For inactive and allergenic ingredients in the preparation - see section 6 - "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

SIRTURO is intended for the treatment of multidrug-resistant pulmonary tuberculosis in adults, as part of combined treatment with other medicines, when there is no other effective treatment regimen due to resistance or lack of tolerability.

Therapeutic group: Antimycobacterials, medicines to treat tuberculosis.

2. BEFORE USING THE MEDICINE:

☒ Do not use the medicine if:
- You are allergic to bedaquiline or any of the additional ingredients contained in the medicine (as detailed in section 6). If you are uncertain, consult with a doctor or pharmacist before using the medicine.

❗ Special warnings regarding use of the medicine:

❗ Before beginning treatment with SIRTURO, tell the doctor if:
- You have suffered or suffer from an abnormal ECG (recording of the heart's electrical activity) or from heart failure.
- You or a family member have a history of a heart problem called congenital long QT syndrome.
- You suffer from decreased thyroid gland function. This can be seen in blood tests.
- You suffer from liver disease or you consume alcohol on a regular basis.
- You are suffering from the human immunodeficiency virus (HIV).

If any of the sections above is relevant to you or you are unsure, consult with a doctor, pharmacist or nurse before using the medicine.

❗ Use in children and adolescents:
Do not give the medicine to children or adolescents (under the age of 18), as the medicine has not been studied in this age group.

❗ Drug interactions:
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular if you are taking:

The following medicines are examples of medicines that patients with multidrug-resistant tuberculosis may take and that could cause interactions with SIRTURO:

Name of the medicine (active ingredient)	Purpose of use
rifampicin, rifapentine, rifabutin	to treat certain infections such as tuberculosis (antimycobacterials)
ketoconazole, fluconazole	to treat fungal infections (antifungals)
efavirenz, etravirine, lopinavir/ritonavir	to treat HIV infection (antiretroviral non-nucleotide reverse transcriptase inhibitors, antiretroviral protease inhibitors)
clofazimine	to treat certain infections such as leprosy (antimycobacterial)
carbamazepine, phenytoin	to treat epileptic fits (anticonvulsants)
St. John's wort (*Hypericum perforatum*)	herbal preparation to relieve anxiety and an antidepressant
ciprofloxacin, erythromycin, clarithromycin	to treat bacterial infections (antibacterials)

❗ Use of the medicine and food:
Take SIRTURO with food.

❗ Use of the medicine and alcohol consumption:
Do not consume alcohol during treatment with SIRTURO.

❗ Pregnancy and breastfeeding:
If you are pregnant or breastfeeding, think you may be pregnant or are planning a pregnancy, speak with the doctor or pharmacist before taking the medicine.

❗ Driving and operating machinery:
You may feel dizzy after taking SIRTURO. If this happens to you, do not drive or operate machinery.

❗ Important information about some of the ingredients of the medicine:
The medicine contains lactose (a type of sugar). If you have an intolerance to or are unable to digest certain sugars, talk to the doctor before taking the medicine.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the medicine according to the doctor's instructions.
Check with the doctor or pharmacist if you are not sure about the dosage and treatment regimen of the preparation.
SIRTURO must always be taken with other medicines for treating tuberculosis. Your doctor will decide which additional medicines you should take with SIRTURO.
The dosage and treatment regimen will be determined by the doctor only. The usual dosage is:
Treatment with the medicine is for 24 weeks.

In the first 2 weeks:
- 400 mg (4 tablets of 100 mg) once a day.

From week 3 to week 24:
- 200 mg (2 tablets of 100 mg) once a day, 3 times a week only.
- Be careful to allow a minimum interval of 48 hours between doses of SIRTURO. For example, you may take SIRTURO on Monday, Wednesday and Friday every week, starting from week 3 of the treatment.

You may need to take your other medicines to treat tuberculosis for a period longer than 6 months. This should be checked with your doctor or pharmacist.

Taking SIRTURO:
- Take SIRTURO with food. The food will help achieve the right levels of the medicine in your body.
- Swallow the tablets whole with water.
- There is no information regarding halving or crushing the tablet.

Do not exceed the recommended dose

If you accidentally take too high a dosage:
If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forget to take the medicine:
In the first 2 weeks:
- Skip the forgotten dose and take the next dose as usual.
- Do not take a double dose to make up for the forgotten dose.

From week 3 and onwards:
- Take the forgotten dose of 200 mg as soon as possible.
- Resume the 3 times a week schedule.

If you forgot to take the medicine and you are not sure what to do, refer to the doctor or pharmacist.

Adhere to the treatment regimen as recommended by the doctor.

If you stop treatment with the medicine:
Do not stop treatment with the medicine without consulting the doctor.
Skipping doses of medicine or not completing the full course of therapy may:
- Make the treatment ineffective and bring about a worsening of the tuberculosis.
- Increase the chance that the bacteria will become resistant to the medicine. This means your disease will not be treatable by SIRTURO or other medicines in the future.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of SIRTURO may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Very common side effects (occur in more than 1 user in 10)
- Headache
- Joint pain
- Feeling dizzy
- Nausea or vomiting

Common side effects (occur in 1-10 in 100 users)
- Diarrhea
- Increased liver enzymes (can be seen in blood tests)
- Muscle pain or muscle weakness, not caused by exercise
- Abnormal ECG (recording of the heart's electrical activity) called "QT prolongation". Tell your doctor right away if you faint.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- There are no special storage requirements. It is recommended to store at room temperature.
- Store the medicine in the original packaging in order to protect it from light.
- This medicine may pose a risk to the environment. Do not dispose of the medicine via wastewater or household waste. Ask your pharmacist how to throw away unused medicines. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Lactose monohydrate, Microcrystalline cellulose, Maize starch, Croscarmellose sodium, Hypromellose, Magnesium stearate, Silica, colloidal anhydrous, Polysorbate 20

What the medicine looks like and the contents of the package:
A plastic bottle containing 188 tablets.
White to almost white, round, convex, uncoated tablets, 11 mm in diameter, imprinted with "T" and "207" on one side and "100" on the other.

Registration holder and address: J-C Healthcare Ltd., Kibbutz Shefayim, 6099000, Israel.

Manufacturer: Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

This leaflet was checked and approved by the Ministry of Health in: 11/19.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 162-85-35758