

**Package leaflet: Information for the
patient**

BEDAQUILINE 100 mg tablets

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 BEDAQUILINE is and what it is used for
2. What you need to know before you take BEDAQUILINE 100 mg Tablets
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1. What BEDAQUILINE is and what it is used for

BEDAQUILINE 100 mg Tablets contains the active substance bedaquiline.

BEDAQUILINE is a type of antibiotic. Antibiotics are medicines that kill bacteria that cause disease. BEDAQUILINE is used to treat tuberculosis that affects the lungs when the disease has become resistant to other antibiotics. This is called multi-drug resistant pulmonary tuberculosis.

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

It is used in adults and adolescents (12 years to less than 18 years of age and weighing at least 30 kg).

2. What you need to know before you take BEDAQUILINE 100 mg Tablets

Do not take BEDAQUILINE 100 mg Tablets if:

- you are allergic to bedaquiline or any of the other ingredients of this medicine (listed in section 6). Do not take BEDAQUILINE 100 mg Tablets if this applies to you. If you are not sure, talk to your doctor or pharmacist before taking BEDAQUILINE 100 mg Tablets.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking BEDAQUILINE 100 mg Tablets, if:

- you have had an abnormal heart reading (ECG) or heart failure;
- you have a personal or family history of a heart problem called “congenital long QT syndrome”;
- 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 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 BEDAQUILINE.

Children and adolescents

Do not give this medicine to children under 12 years of age or weighing less than 30 kg because it has not been studied in these patients.

In adolescents weighing 30 to 40 kg, the levels of BEDAQUILINE 100 mg Tablets in the blood were predicted to be higher than in adults. This might be associated with an increased risk of abnormal reading on the electrocardiogram (QT prolongation) or increased liver enzymes (shown in blood test).

Other medicines and BEDAQUILINE 100 mg Tablets

Other medicines may affect BEDAQUILINE 100 mg Tablets. 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 multi-drug resistant tuberculosis may take and which may potentially interact with BEDAQUILINE 100 mg Tablets:

Medicine (name of the active substance)	Purpose of the medicine
rifampicin, rifapentine, rifabutin	to treat some infections like tuberculosis (antimycobacterial)
ketoconazole, fluconazole	to treat fungal infections (antifungals)
efavirenz, clofazimine	to treat HIV infection (antiretroviral non-nucleoside)
carbamazepine, phenytoin	to treat some infections like epileptic fits (anticonvulsants)
St. John's wort (<i>Hypericum perforatum</i>)	an herbal product to relieve anxiety
ciprofloxacin, erythromycin, clarithromycin	to treat bacterial infections (antibacterials)

BEDAQUILINE 100 mg Tablets with alcohol

You should not drink alcohol while taking BEDAQUILINE 100 mg Tablets.

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 BEDAQUILINE 100 mg Tablets. If this happens, do not drive or operate machinery.

BEDAQUILINE 100 mg Tablets contains lactose monohydrate

BEDAQUILINE 100 mg Tablets contains "lactose" (a type of sugar). If you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

3. How to take BEDAQUILINE 100 mg Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

BEDAQUILINE 100 mg Tablets must always be taken together with other medicines for treating tuberculosis. Your doctor will decide which other medicines you should take with BEDAQUILINE 100 mg Tablets.

Use in adults and in adolescents (12 years of age and older and weighing at least 30 kg) How much to take

You take BEDAQUILINE 100 mg Tablets for a 24-week course.

First 2 weeks:

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

From week 3 to week 24:

- Take 200 mg (2 tablets of 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 BEDAQUILINE. For example, you may take BEDAQUILINE 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

- Take BEDAQUILINE 100 mg Tablets with food. The food is important to get the right levels of medicine in your body.
- Swallow the tablets whole with water.

If you take more BEDAQUILINE 100 mg Tablets than you should

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

If you forget to take BEDAQUILINE 100 mg Tablets

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 of 200 mg as soon as possible.
- Resume the three times a week schedule.

If you have missed a dose and you are not sure what to do, talk to your doctor or pharmacist.

If you stop taking BEDAQUILINE 100 mg Tablets

Do not stop taking BEDAQUILINE 100 mg Tablets 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 BEDAQUILINE 100 mg Tablets 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):

- headache
- joint pain
- feeling dizzy
- feeling or being sick (nausea or vomiting).

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

- diarrhoea
- increased liver enzymes (shown in blood tests)
- aching or tender muscles, not caused by exercise
- abnormal reading on the electrocardiogram called “QT prolongation”. Tell your doctor right away if you faint.

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.

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

5. How to store BEDAQUILINE 100 mg Tablets

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 BEDAQUILINE 100 mg Tablets in the original container or package in order to protect it from light.

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 BEDAQUILINE 100 mg tablets contains:

Active substance: Bedaquiline fumarate equivalent to 100 mg of Bedaquiline.

The other Excipients : Corn Starch, Croscarmellose sodium, Microcrystalline cellulose, Lactose monohydrate, Polysorbate 20, Hypromellose, Colloidal Silicon Dioxide, Croscarmellose sodium, Magnesium stearate (Veg grade)

What BEDAQUILINE 100 mg tablets like and contents of the pack:

White to off white uncoated round biconvex tablets plain on both side.

What BEDAQUILINE 100 mg Tablets looks like and contents of the pack

1. HDPE pack of 188 tablets
2. HDPE pack of 24 tablet
3. 11 x 12's Tablets
4. 8 x 12's tablets
5. 10 x 10's tablets
6. 4 x 14's

Marketing Authorization

Holder

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