

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

Information for the patient

[TB396 trade name][†]
Bedaquiline fumarate

*The warnings and instructions in this leaflet are intended for the person taking the medicine.
If you are a parent or carer responsible for giving the medicine to someone else such as a child,
you will need to apply the instructions accordingly.*

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 questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [TB396 trade name] is and what it is used for
2. What you need to know before you take [TB396 trade name]
3. How to take [TB396 trade name]
4. Possible side effects
5. How to store [TB396 trade name]
6. Contents of the pack and other information

1. What [TB396 trade name] is and what it is used for

[TB396 trade name] is a medicine used to treat tuberculosis (TB), an infection caused by bacteria called *Mycobacterium tuberculosis*.

It is always given together with other medicines to treat tuberculosis. Your health care provider has chosen the combination that is right for your condition.

[TB396 trade name] contains the active substance bedaquiline which kills bacteria. It prevents the tuberculosis bacteria from producing the energy they need to survive and reproduce.

2. What you need to know before you take [TB396 trade name]

Do not take [TB396 trade name] if:

- you are allergic (hypersensitive) to bedaquiline or to any other ingredients of this medicine (see section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat, or tongue.

Take special care with [TB396 trade name] if:

- you have had an abnormal ECG (a test of your heart's electrical activity) or you have heart failure
- you or anyone in your family has had a heart condition called congenital long QT syndrome
- tests have shown you have low levels of potassium in your blood
- you have an underactive thyroid gland
- you have liver disease or drink alcohol on a regular basis

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

If any of the above apply to you, or if you are not sure, talk to your healthcare provider before taking [TB396 trade name].

Taking other medicines with [TB396 trade name]

Other medicines may affect [TB396 trade name]. Tell your healthcare provider if you are taking, have recently taken, or might take any other medicines, including medicines or supplements that you may have bought.

The following are examples of medicines patients may take and which may affect treatment with [TB396 trade name] (but the list is not complete):

Medicine (name of the active substance)	Purpose of the medicine
ciprofloxacin, clarithromycin, erythromycin, rifampicin, rifapentine, rifabutin	to treat bacterial infections, including tuberculosis
ketokonazole, fluconazole	to treat fungal infections
efavirenz, etravirine, lopinavir/ritonavir	to treat HIV infection
clofazimine	to treat some infections like leprosy
carbamazepine, phenytoin	to prevent fits or convulsions in epilepsy
St John's wort (<i>Hypericum perforatum</i>)	herbal remedy used for anxiety or depression

Children and adolescents

[TB396 trade name] should not be given to children aged less than 5 years, or weighing less than 15 kg, because it has not been tested in these patients.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your health care provider for advice before taking this medicine.

Driving and using machines

You may feel dizzy after taking [TB396 trade name]. If this happens, do not drive or operate machinery.

[TB396 trade name] with alcohol

You should not drink alcohol while taking [TB396 trade name].

Other ingredients of [TB396 trade name]

[TB396 trade name] contains **lactose**. Lactose is a source of glucose and galactose. The small amount of lactose in a dose may cause symptoms of lactose intolerance in some patients. If, however, you have one of the rare genetic disorders galactosaemia, glucose-galactose intolerance or congenital lactase deficiency you must talk to your health care provider before taking this medicine.

3. How to take [TB396 trade name]

You must always take [TB396 trade name] together with other medicines for treating tuberculosis. Your health care provider has chosen the right doses and combination of medicines to treat your tuberculosis.

Always take [TB396 trade name] exactly as your health care provider has told you. Check with your health care provider if you are not sure.

Your health care provider will tell you how long you should take [TB396 trade name]. This is usually 6 months but might be longer in some cases. Do not change the dose unless your health care provider tells you to. It is important to take the full course of treatment, even if you feel better.

You may need to keep taking your other tuberculosis medicines for longer than 6 months. Check with your health care provider.

How to take this medicine

- Take [TB396 trade name] with food. Taking it with food increases the amount of medicine that enters your body and so helps it to work better.
- Swallow the tablets whole with water.

If you cannot swallow the tablet whole, crush it in a small clean cup and mix it thoroughly with a small amount of water. Swallow this mixture. Rinse the cup with some more water and drink that too to make sure you have taken the full dose.

If you take more [TB396 trade name] than you should

If you take more [TB396 trade name] than you should, contact a health care provider straight away. Show your medicine pack to the health care provider.

If you forget to take [TB396 trade name]

If you are taking [TB396 trade name] **once daily** and miss a dose:

- you should skip the missed dose and take the next dose at your normal time
- you should not take a double dose to make up for a forgotten or missed dose.

If you are taking [TB396 trade name] **3 times a week** and miss a dose, ask your health care provider about what to do. Usually:

- you should take a dose straightaway
- you should take the next dose after 2 days
- you should then take the next dose on the usual day you take it.

Talk to your health care provider if you have missed a dose and you are not sure what to do.

If your health care provider temporarily stops your treatment

If you get certain side effects, your health care provider may stop your treatment for a short time. Your health care provider will tell you how to make up for the missed doses to complete the full course. Rarely, your health care provider may decide that a different treatment is more suitable for you.

If you stop taking [TB396 trade name]

Keep taking the medicine regularly for as long as your health care provider has told you. If you stop the medicine too soon, your infection may not be cured. Also, the medicine may stop working because the bacteria become resistant to these medicines.

You should not stop treatment unless your health care provider tells you to.

If you have any questions about this medicine, ask your health care provider.

4. Possible side effects

Like all medicines, [TB396 trade name] can cause side effects, but not everybody gets them. Tell your health care provider about any change in your health.

Very serious side effects

All medicines can cause allergic reactions, but serious allergic reactions are very rare. If you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body), contact your health care provider or your nearest hospital casualty department at once.

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 between 1 in 10 and 1 in 100 people)

- diarrhoea
- blood tests showing increased liver enzymes (a sign of liver problems)
- muscle pain
- heart test (ECG) showing abnormal heart activity. Tell your health care provider right away if you faint or feel lightheaded.

Other side effects

- coughing up blood
- chest pain
- loss of appetite
- rash

If you get any side effects, talk to your health care provider. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [TB396 trade name]

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

Do not store above 30°C. Store in the original container or package to protect from light. Avoid excursions above 30°C.

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

Do not use this medicine if you notice visible signs of deterioration or that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider 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 [TB396 trade name] contains

- The active ingredient is 100 mg of bedaquiline.
- The other ingredients of [TB396 trade name] are corn starch, croscarmellose sodium, microcrystalline cellulose, lactose monohydrate, polysorbate 20, hypromellose, colloidal silicon dioxide and magnesium stearate.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [TB396 trade name] looks like and contents of the pack

White to off-white, round, uncoated tablets. They are biconvex (rounded on top and bottom). The tablets are plain on both sides.

[TB396 trade name] is available in:

Plastic (HDPE) bottles

Round, opaque, white plastic (HDPE) bottle containing 24 or 188 tablets. The bottle has an aluminium/plastic foil seal and a white, childproof plastic (polypropylene) screw cap.

Bedaquiline (as fumarate) 100mg
tablets
(Lupin Ltd), TB396

WHOPAR Part 3

December 2023

Blister packs

Aluminium foil on aluminium foil blister cards, each containing 12 or 14 tablets. Available in cartons of 8 x 12, 11 x 12 or 4 x 14 tablets.

Strip pack

Aluminium foil strip packs, each containing 10 or 14 tablets. Available in boxes of 10 x 10 or 4x14 tablets.

Supplier

Lupin Limited
Kalpataru Inspire
3rd Floor, Off Western Express Highway
Santacruz (East), Mumbai 400055
India

Tel. No.: 91-22-66402370, 66402372

Fax No.: 91-22-266408128

E-mail: globaltb@lupin.com

dsrcm@lupin.com

Manufacturer

Lupin Limited
A-28/1, MIDC Area
Chikalthana,
Aurangabad-431210
Maharashtra State
India

Tel. No.: +91 240 6612444

For any information about this medicine, contact t the supplier.

This leaflet was last revised in December 2023.

Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/pqweb/medicines>