

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.

* https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[TB408 trade name][†]
Bedaquiline (fumarate)

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

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 [TB408 trade name] is and what it is used for
2. What you need to know before you take [TB408 trade name]
3. How to take [TB408 trade name]
4. Possible side effects
5. How to store [TB408 trade name]
6. Contents of the pack and other information

1. What [TB408 trade name] is and what it is used for

[TB408 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.

[TB408 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 [TB408 trade name]

Do not take [TB408 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 [TB408 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 [TB408 trade name].

Taking other medicines with [TB408 trade name]

Other medicines may affect [TB408 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 [TB408 trade name] (but the list is not complete):

Medicine (name of the active substance)	Purpose of the medicine
rifampicin, rifapentine, rifabutin	to treat tuberculosis
efavirenz, etravirine	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

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 [TB408 trade name]. If this happens, do not drive or operate machinery.

[TB408 trade name] with alcohol

You should not drink alcohol while taking [TB408 trade name].

Excipients with known effects

[TB408 trade name] contains lactose monohydrate. Lactose is a source of glucose and galactose. The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance. 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 [TB408 trade name]

You must always take [TB408 trade name] together with other medicines for treating tuberculosis.

Always take [TB408 trade name] exactly as your health care provider has told you. Check with your health care provider if you are not sure.

Take [TB408 trade name] with food. Taking it with food increases the amount of medicine that enters your body and so helps it to work better.

You should swallow the tablets whole with water. If you cannot swallow tablets, or for children weighing less than 16 kg, tablets may be crushed and mixed with drinking water.

Your health care provider will work out the right dose for you and tell you for how long you should take [TB408 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.

The usual doses are described in the tables below.

Adults and adolescents weighing at least 30 kg

First 2 weeks	4 tablets of [TB408 trade name] once daily
Week 3 onwards	2 tablets of [TB408 trade name] once daily for 3 days each week (for example, on Mondays, Wednesdays, and Fridays)

Alternative doses for adults and adolescents at least 14 years old

First 8 weeks	2 tablets of [TB408 trade name] once daily
Week 9 onwards	1 tablet of [TB408 trade name] once daily

Children and adolescents weighing 16–30 kg

First 2 weeks	bedaquiline 200 mg (2 tablets of [TB408 trade name]) once daily
Week 3 onwards	bedaquiline 100 mg (1 tablet of [TB408 trade name]) once daily for 3 days each week (for example, on Mondays, Wednesdays, and Fridays)

Children and adolescents weighing less than 16 kg on a longer course

For children weighing less than 16 kg, medicines containing a smaller amount of bedaquiline are preferred. However, [TB408 trade name] can be used in children who weigh less than 16 kg if a more suitable medicine is not available. Your health care provider will explain how much of the medicine to give and how to give it if this is the case.

If [TB408 trade name] must be used in a child weighing less than 16 kg, a tablet should be crushed and made into a mixture with 10 mL of water (see *How to prepare the mixture*, below) and a proportion of the mixture is given according to the child's weight and age. The recommended amounts are:

Child's weight	Child's age	How much mixture to give	For how long
3 to less than 7 kg	0 to less than 3 months	3 mL once daily	First 2 weeks
		1 mL once daily for 3 days each week (for example, on Mondays, Wednesdays, and Fridays)	Week 3 onwards
	at least 3 months	6 mL once daily	First 2 weeks
		2 mL once daily for 3 days each week (for example, on Mondays, Wednesdays, and Fridays)	Week 3 onwards
7 to less than 10 kg	0 to less than 3 months	3 mL once daily	First 2 weeks
		1 mL once daily for 3 days each week (for example, on Mondays, Wednesdays, and Fridays)	Week 3 onwards
	3 to less than 6 months	6 mL once daily	First 2 weeks
		2 mL once daily for 3 days each week (for example, on Mondays, Wednesdays, and Fridays)	Week 3 onwards
	at least 6 months	8 mL once daily	First 2 weeks
		4 mL once daily for 3 days each week (for example, on Mondays, Wednesdays, and Fridays)	Week 3 onwards

10 to less than 16 kg	3 to less than 6 months	6 mL once daily	First 2 weeks
		2 mL once daily for 3 days each week (for example, on Mondays, Wednesdays, and Fridays)	Week 3 onwards
	at least 6 months	12 mL ¹ once daily	First 2 weeks
		6 mL once daily for 3 days each week (for example, on Mondays, Wednesdays, and Fridays)	Week 3 onwards

¹ To make up this dose, 2 tablets of [TB408 trade name] should be dispersed in 20 mL of water.

How to prepare the mixture

For preparing the liquid mixture for children weighing less than 16 kg you need:

- Two small cups
- a teaspoon
- drinking water
- a 10-mL oral syringe, showing measurements of 1.0 mL.

The following steps should be followed:

1. Crush one bedaquiline 100-mg tablet in the first small cup.
2. Measure out 10 mL drinking water using the syringe and add it to the first cup.
3. Stir well until all the crushed tablet is fully mixed, taking care not to spill any of the mixture.
4. Look up the patient's weight and age in the above table (first 2 columns).
5. Then look under 'How much mixture to give', to find the right dose for the child.
6. Use the syringe to draw up the correct amount of liquid mixture from the first cup and make sure there are no bubbles in the mixture you have drawn up.
7. Transfer the mixture to the second cup (or a bottle for an infant) and give it to the child straight away.
8. If there is anything left in the second cup, rinse the cup with a small amount of water and get the child to drink it all. Use a spoon (or a bottle for an infant) to give the child the remaining mixture. This is to make sure that the child gets the full dose.
9. Give the child something to drink after taking the medicine.
10. Throw away any liquid left in the first cup.

Repeat these steps every time you need to give the medicine.

If you take more [TB408 trade name] than you should

If you take more [TB408 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 [TB408 trade name]

If you are taking [TB408 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 missed dose.

If you are taking [TB408 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. When restarting treatment, your health care provider will tell you how to make up for the missed doses to complete the full course, or what dose to take. Rarely, your health care provider may decide that a different treatment is more suitable for you.

If you stop taking [TB408 trade name]

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

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, [TB408 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)

- blood tests showing raised liver enzyme values (a sign of liver problems)
- headache
- heart test (ECG) showing abnormal heart activity. Tell your health care provider right away if you faint or feel lightheaded.
- joint pain
- feeling dizzy
- feeling or being sick (nausea or vomiting)

Common (may affect between 1 in 10 and 1 in 100 people)

- diarrhoea
- muscle pain

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 [TB408 trade name]

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

Do not store above 30°C. Store in the original container. Avoid excursions above 30°C.

Discard the product 180 days after initial opening. (*Applicable to HDPE bottles*)

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

Do not use this medicine if you notice description of the visible signs of deterioration 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 [TB408 trade name] contains

- The active ingredient is bedaquiline. Each tablet contains bedaquiline fumarate equivalent to 100 mg of bedaquiline.
- The other ingredients of [TB408 trade name] are lactose monohydrate, corn starch, hypromellose, polysorbate, microcrystalline cellulose, croscarmellose sodium, 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 [TB408 trade name] looks like and contents of the pack

[TB408 trade name] is a white to off white, round, uncoated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have ‘V’ debossed (stamped into) one side and ‘BA’ on the other side.

Blister pack

[TB408 trade name] is provided in aluminium foil on aluminium foil cold form blister cards, each containing 6 or 10 tablets. Available in boxes of 4x6 or 10x10 tablets.

HDPE bottle

[TB408 trade name] is also provided in round, opaque white plastic (HDPE) bottle containing 188 tablets. It also contains a piece of cotton wool to keep the tablets in place. The bottle has an aluminium foil seal and a white opaque childproof plastic (polypropylene) screw cap.

Supplier and Manufacturer

Supplier

Mylan Laboratories Limited
Plot No.564/A/22, Road No. 92, Jubilee Hills
Hyderabad – 500096, Telangana
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Email: ProductSafety@viatris.com

Manufacturer

Mylan Laboratories Limited
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Chhatrapati Sambhajnagar - 431136
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India.

For any information about this medicine, contact the local representative of the supplier.

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Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>