

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

[TB388 trade name][†]
Delamanid

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 [TB388 trade name] is and what it is used for
2. What you need to know before you take [TB388 trade name]
3. How to take [TB388 trade name]
4. Possible side effects
5. How to store [TB388 trade name]
6. Contents of the pack and other information

1. What [TB388 trade name] is and what it is used for

[TB388 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 TB in the lungs, when the TB bacteria cannot be killed with more common medicines. Your health care provider has chosen the combination that is right for your condition.

[TB388 trade name] contains the active substance delamanid, which is an antibiotic that kills the bacteria responsible for TB.

2. What you need to know before you take [TB388 trade name]

Do not take [TB388 trade name]:

- if you are allergic to delamanid or any of the other ingredients of this medicine (listed in section 6).
- if you have very low levels of albumin in the blood.
- if you are taking medicines (e.g. carbamazepine), that increase the action of a certain liver enzyme called CYP3A4.

Warnings and precautions

Talk to your health care provider before taking [TB388 trade name].

Before you start taking [TB388 trade name], and during the treatment, your health care provider will check your heart's electrical activity using an ECG (electrocardiogram) machine (electrical recording of the heart). Your health care provider may also perform a blood test to check the levels of some minerals and proteins

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

which are important for the function of your heart.

Tell your health care provider if you know or have been told you have one of the following conditions:

- reduced levels of albumin, potassium, magnesium or calcium in the blood. Your healthcare provider will check your albumin levels
- heart problems, for example a slow heart rhythm (bradycardia) or you have ever had a heart attack (myocardial infarction) or serious heart disease
- an inherited problem of your heart's electrical activity called congenital long QT syndrome, or other problems with heart rhythm
- liver disease or kidney disease
- HIV.

Sometimes, even when the treatment is working, TB symptoms may temporarily get worse. This is called a paradoxical reaction. Do not stop taking your medicine if this happens, as it is often a sign your immune system is responding. Tell your health care provider immediately if you notice any new or worsening symptoms; they can help manage them.

Other medicines and [TB388 trade name]

Tell your health care provider if you are taking, have recently taken or might take any other medicines, including medicines or herbal remedies obtained without prescription, especially:

- if you are taking medicines to treat an abnormal heart rhythm (e.g. *amiodarone, disopyramide, dofetilide, ibutilide, procainamide, quinidine, hydroquinidine, sotalol*).
- if you are taking medicines to treat mental problems (e.g. *chlorpromazine or related medicines called phenothiazines, sertindole, sultopride, haloperidol, mesoridazine, pimozide, or thioridazine*) or medicines for depression.
- if you are taking certain medicines for infections (e.g. *erythromycin, clarithromycin, moxifloxacin, sparfloxacin, bedaquiline, or pentamidine*).
- if you are taking certain antifungal medicines (e.g. *fluconazole, itraconazole, voriconazole*).
- if you are taking certain medicines to treat allergic reactions (e.g. *terfenadine, astemizole, mizolastine*).
- if you are taking certain medicines to treat malaria (e.g. *halofantrine, quinine, chloroquine, artesunate/amodiaquine, dihydroartemisinin/piperaquine*).
- if you are taking any of the following: *droperidol* (used against vomiting and migraine), *domperidone* (used against nausea and vomiting), *diphemanil* (used to treat stomach disorders or excessive sweating), *probucol* (lowers the level of cholesterol in the bloodstream), *levomethadyl* or *methadone* (used for the treatment of drug addiction), *vinca alkaloids* (cancer medicines), or *arsenic trioxide* (used to treat certain types of leukaemia).
- if you are taking HIV-medicines containing *atazanavir/ ritonavir, darunavir/ ritonavir or lopinavir/ritonavir*. You may be more at risk for dangerous changes of heart rhythm.

If your TB medicines also include a medicine called cycloserine, your health care provider will carefully monitor you for side effects that affect your *nerves* or mental function, such as hallucinations (sensing things that aren't really there).

Pregnancy and breastfeeding

Pregnancy

This medicine can be used during pregnancy. However, you may need to be carefully monitored for side effects. If you become pregnant, think you might be, or are planning a pregnancy, tell your health care provider right away for advice.

Breastfeeding

It is not known if delamanid passes into breast milk in humans.

You can breast-feed while taking this medicine.

Driving and using machines

[TB388 trade name] is not likely to affect your ability to drive or operate machinery.

However, make sure you feel well enough to take on any skilled tasks.

[TB388 trade name] contains lactose

Each tablet of [TB388 trade name] contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take [TB388 trade name]

Always take this medicine exactly as your health care provider has told you. Your healthcare provider may watch you take each dose of your medicine.

[TB388 trade name] is always given as part of a combined treatment with other medicines for TB.

The tablets should be taken during or just after a meal. Don't take the tablets along with your other TB medicines; if you can, have a small break of an hour or so between taking this medicine and taking other medicines (talk to your health care provider about the best timing). For instructions on how to take the tablets, see “**Instructions for taking [TB388 trade name] tablets**”, below.

The recommended dose of [TB388 trade name] depends on your weight, as shown in the table below, and is usually taken for 6 months. In some cases, your health care provider may ask you to take this medicine for longer.

Patient's weight	Number of tablets of [TB388 trade name]
3 to less than 5 kg	half* a tablet once a day
5 to less than 10 kg	<i>If aged less than 3 months:</i> half* a tablet once a day
	<i>If aged 3 months or over:</i> half* tablet twice a day
10 to less than 16 kg	half* tablet twice a day
16 to less than 30 kg	1 tablet in the morning , and half* tablet in the evening
30 to less than 46 kg	<i>If aged less than 15 years:</i> 1 tablet twice a day
	<i>If aged 15 years or over:</i> 2 tablets twice a day
46 kg or more	2 tablets twice a day

* When half a tablet is to be given, the tablet should be crushed and dispersed in 10 mL of water. 5 mL of the mixture should then be taken.

If you take more [TB388 trade name] than you should

If you have taken more tablets than your prescribed dose, contact your health care provider or your local hospital. Remember to take the pack with you so that it is clear what medicine you have taken.

If you forget to take [TB388 trade name]

If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, just skip the missed dose.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking [TB388 trade name]

DO NOT stop taking the tablets unless your health care provider tells you to. Stopping too early could allow the bacteria to become resistant to delamanid and make your treatment stop working.

Instructions for taking [TB388 trade name] tablets

Your health care provider will explain how many tablets to use for each dose. The usual number of tablets per dose for children of different weights are given in the tables above but always use the number of tablets your health care provider recommends.

When the dose is a whole number of tablets, they should be swallowed whole with water.

However, in patients who cannot swallow tablets, or when half a tablet is to be taken, each tablet should be crushed and dispersed in 10 mL water.

1. Place the required volume of water in a small, clean cup or bowl and add the required number of tablets.
2. Stir gently until the tablets break up and form a mixture.
3. **If the recommended dose is a half tablet:**
 - a. crush a whole tablet to powder and make a mixture with 10mL of water
 - b. measure out half of the mixture (5 mL) using a suitable measuring device such as a measuring spoon or cup (talk to your health care provider about how to measure the dose).
 - c. Drink the measured half of the mixture immediately.
 - d. Throw away any mixture left in the cup or bowl.
4. **If the recommended dose is a full number of tablets**, drink the entire medicine mixture immediately.
5. The patient may have a little milk/juice/water after taking the medicine, this will help to take away the taste of the medicine.

If you have any further questions on the use of this medicine, ask your health care provider.

4. Possible side effects

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

Side effects **very commonly reported** (may affect more than 1 in 10 people) were:

- Decreased appetite
- Disturbed sleep, including nightmares
- Feeling dizzy
- Feeling sick (nausea)
- Headache
- Stomach irritation (gastritis)
- Vomiting

Side effects **commonly reported** (may affect up to 1 in 10 people) were:

- Chest pain
- Decrease in the thyroid gland activity (hypothyroidism)
- Defect in cardiac rhythm that can cause fainting, dizziness and palpitations (electrocardiogram QT prolonged)
- Depression
- Feeling anxious (anxiety)
- Hallucination (seeing, hearing or feeling things that are not there)
- Heart rhythm disturbance (atrioventricular block first degree)
- Indigestion (dyspepsia)
- Irregular heartbeats (ventricular extrasystoles)

- Muscle weakness
- Muscle spasms
- Numbness, decreased sensation in hands and/or feet (hypoesthesia)
- Pounding heartbeat (palpitations)
- Rise in the level of the hormone cortisol in your blood
- Shakiness (often in the hands; tremor)
- Signs of psychosis: a loss of contact with reality, such as hearing voices or seeing things that are not there
- Throat irritation

Side effects **uncommonly reported** (may affect up to 1 in 100 people) were:

- Lack of energy (lethargy)

Other side effects that occur at an unknown frequency:

- Paradoxical drug reactions (symptoms of tuberculosis that recur or new symptoms that appear after initial improvement during treatment)

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 [TB388 trade name]

Do not store above 30°C. Store in the original package in order to protect from moisture.

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

Do not use this medicine after the expiry date stated on the carton 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 [TB388 trade name] contains

- The active ingredient is delamanid
- The other ingredients of [TB388 trade name] are:
Core tablet: hypromellose phthalate, povidone, all-rac- α -tocopherol, microcrystalline cellulose, colloidal hydrated silica, lactose monohydrate, sodium starch glycolate, carmellose calcium and magnesium stearate
Film coat: hypromellose, macrogol /polyethylene glycol, titanium dioxide, iron oxide yellow (E172), talc

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

What [TB388 trade name] looks like and contents of the pack

[TB388 trade name] is a yellow, round, film-coated tablets. They are biconvex (rounded on top and bottom) with a bevelled edge. The tablets have “DLM” debossed (Stamped into) and “50” debossed (Stamped into) on one side and plain on the other side.

[TB388 trade name] is available in cold form aluminium (Alu /Alu) blisters containing 8 tablets. Such 6 blister cards are packed in a carton (6 x 8).

Supplier and Manufacturer

Supplier

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

Manufacturer

Mylan Laboratories Limited
F-4 & F-12, MIDC, Malegaon
Sinnar, Nashik-422113
Maharashtra, 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>