



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Deltyba (*delamanid*)

An overview of Deltyba and why it is authorised in the EU

### What is Deltyba and what is it used for?

Deltyba is a medicine that is used in adults, adolescents, children and infants weighing at least 10 kg who have tuberculosis affecting the lung and that is multi-drug resistant (resistant to at least isoniazid and rifampicin, the two standard tuberculosis medicines).

It is used together with other tuberculosis medicines and only when other standard medicine cannot be used either because the disease is resistant to them or because of their side effects.

Deltyba contains the active substance delamanid.

Tuberculosis is rare in the EU, and Deltyba was designated an 'orphan medicine' (a medicine used in rare diseases) on 1 February 2008. Further information on the orphan designation can be found here: [ema.europa.eu/en/medicines/human/orphan-designations/eu307524](http://ema.europa.eu/en/medicines/human/orphan-designations/eu307524)

### How is Deltyba used?

Deltyba can only be obtained with a prescription and treatment should be started and monitored by a doctor who is experienced in the treatment of multi-drug resistant tuberculosis. It should be used according to official guidelines on treating multi-drug resistant tuberculosis.

The medicine is available as 50 mg tablets and 25 mg dispersible tablets which are taken with food. The 25 mg dispersible tablets are only for children and infants weighing between 10 and 30 kg. The recommended dose for adults is 100 mg twice a day, while the dose for children and infants depends on the patient's body weight.

Deltyba is given for 6 months together with other tuberculosis medicines. Treatment with these medicines should continue after Deltyba treatment, as recommended by official guidelines. For more information about using Deltyba, see the package leaflet or contact a doctor or pharmacist.

### How does Deltyba work?

Tuberculosis is an infection caused by the bacterium *Mycobacterium tuberculosis* (*M. tuberculosis*). The active substance in Deltyba, delamanid, is an antibiotic active against *M. tuberculosis*. Although the way it works is unclear, delamanid is known to block the production of methoxy-mycolic and keto-

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mycolic acids, two essential components of the cell walls of *M. tuberculosis*, which will cause the bacteria to die.

## **What benefits of Deltyba have been shown in studies?**

The effects of Deltyba have been looked at in one main study involving 481 adults with tuberculosis resistant to standard treatments. Patients in the study were given Deltyba or placebo (a dummy treatment) for 2 months in addition to their other treatments. The main measure of effectiveness was the proportion of patients who no longer had the bacteria in their sputum (phlegm). After 2 months of treatment more than 40% of the patients who were taking Deltyba no longer had the bacteria in their sputum compared with 30% of the patients who were taking placebo.

After the main study had finished, patients had the option to receive treatment with Deltyba for 6 months in an extension study. In addition, a majority of patients who entered the main study were followed up for up to 24 months afterwards. Looking at the results of these follow-up studies together, 2 years after starting treatment 75% of patients who received Deltyba for 6 months or more had no bacteria in their sputum compared with 55% of patients who received Deltyba for 2 months or less.

Additional data indicate that the medicine will be as effective in children, including infants, as it is in adults.

## **What are the risks associated with Deltyba?**

The most common side effects with Deltyba (which may affect more than 1 patient in 10) are nausea, vomiting, headache, insomnia (sleeping problems), dizziness, tinnitus (ringing or buzzing in the ears), blood tests showing low potassium levels in the blood, gastritis (inflammation of the stomach lining), decreased appetite and weakness. For the full list of side effects of Deltyba, see the package leaflet.

Deltyba must not be used in patients who have low levels of albumin (a blood protein). It must also not be used in patients who are taking certain other medicines that affect the way Deltyba is broken down in the body. For the full list of restrictions, see the package leaflet.

## **Why is Deltyba authorised in the EU?**

The European Medicines Agency decided that Deltyba's benefits are greater than its risks and it can be authorised for use in the EU. The Agency considered that the benefits of Deltyba had been shown for patients with multi-drug resistant tuberculosis affecting the lung. Although the main study was of short duration and the follow-up studies had shortcomings, the Agency considered that the effects shown after the initial 2 months of treatment are likely to be sustained for the full treatment duration. The Agency noted that an on-going clinical study will provide confirmation on the long-term effectiveness.

The safety profile was considered manageable and several measures were introduced to minimise the risks, including a study to confirm the long-term safety. Furthermore, the medical need for new agents to treat multi-drug resistant tuberculosis was highlighted.

Deltyba has been given 'conditional authorisation'. This means that there is more evidence to come about the medicine, which the company is required to provide. Every year, the European Medicines Agency will review any new information that becomes available and this overview will be updated as necessary.

## **What information is still awaited for Delyba?**

Since Delyba has been given conditional authorisation, the company that markets Delyba will carry out further studies to confirm the long-term effectiveness and safety of Delyba.

## **What measures are being taken to ensure the safe and effective use of Delyba?**

The company that markets Delyba will provide educational material for healthcare professionals, explaining how to use the medicine safely to avoid problems such as the development of resistance and side effects on the heart, as well as the risks in pregnancy or women who are breast-feeding.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Delyba have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Delyba are continuously monitored. Side effects reported with Delyba are carefully evaluated and any necessary action taken to protect patients.

## **Other information about Delyba**

Delyba received a marketing authorisation valid throughout the European Union on 28 April 2014.

Further information on Delyba can be found on the Agency's website:  
[ema.europa.eu/medicines/human/EPAR/delyba](http://ema.europa.eu/medicines/human/EPAR/delyba).

This overview was last updated in 08-2021.