Deltyba

delamanid

This is a summary of the European public assessment report (EPAR) for Deltyba. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Deltyba.

For practical information about using Deltyba, patients should read the package leaflet or contact their doctor or pharmacist.

What is Deltyba and what is it used for?

Deltyba is a tuberculosis medicine that contains the active substance delamanid. Tuberculosis is an infection caused by the bacterium *Mycobacterium tuberculosis* (*M. tuberculosis*). Deltyba is used in adults with tuberculosis that is affecting the lung and that is multi-drug resistant (resistant to at least isoniazid and rifampicin, two standard anti-tuberculosis medicines). It is used together with other standard medicines and when other combinations without this medicine cannot be used either because the disease is resistant to them or because of their side effects.

Because the number of patients with tuberculosis is low in the EU, the disease is considered ‘rare’, and Deltyba was designated an ‘orphan medicine’ (a medicine used in rare diseases) on 1 February 2008.

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.

The medicine is available as tablets (50 mg) and the recommended dose is two tablets twice a day taken together with food. Deltyba is given for 6 months together with other standard medicines. Treatment with these standard medicines should continue as recommended by official guidelines after completion of Deltyba treatment. For further information, see the package leaflet.
How does Deltyba work?

The active substance in Deltyba, delamanid, is an antibiotic active against *M. tuberculosis*. Although the precise mode of action is unclear, delamanid is known to block the production of methoxy-mycolic and keto-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.

What are the risks associated with Deltyba?

The most common side effects with Deltyba (which may affect around a third of patients) are nausea, vomiting and dizziness. The most serious side effect is QT prolongation (an alteration of the electrical activity of the heart which can cause a life-threatening abnormality of heart rhythm). Other important side effects are anxiety, paraesthesia (unusual sensations like pins and needles) and tremor (shaking). For the full list of all side effects reported with 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 approved?

The Agency’s Committee for Medicinal Products for Human Use (CHMP) decided that Deltyba’s benefits are greater than its risks and recommended that it be approved for use in the EU. The Committee 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 CHMP took the view that the effects shown after the initial 2 months of treatment are likely to be sustained for the full treatment duration. The CHMP noted that an on-going clinical study will provide confirmation on the long-term effectiveness. In addition, the CHMP required that an additional study should be carried out to confirm that the current recommended dose is the most appropriate dose.

Regarding the safety of Deltyba, 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 Committee highlighted the medical need for new agents to treat multi-drug resistant tuberculosis.
Deltyba has been given ‘conditional approval’. 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 summary will be updated as necessary.

**What information is still awaited for Deltyba?**

Since Deltyba has been granted a conditional approval, the company that markets Deltyba will carry out further studies to confirm the long-term effectiveness and safety of Deltyba. A further study will also be carried out to confirm the most appropriate dose.

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

A risk management plan has been developed to ensure that Deltyba is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Deltyba, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Deltyba will provide educational material for healthcare professionals, explaining how to use the medicine safely in order 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.

**Other information about Deltyba**

The European Commission granted a marketing authorisation valid throughout the European Union for Deltyba on 28 April 2014.

The full EPAR for Deltyba can be found on the Agency’s website: [ema.europa.eu/Find medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find%20medicine/Human%20medicines/European%20public%20assessment%20reports). For more information about treatment with Deltyba, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Deltyba can be found on the Agency’s website: [ema.europa.eu/Find medicine/Human medicines/Rare disease designation](http://ema.europa.eu/Find%20medicine/Human%20medicines/Rare%20disease%20designation).

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