

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Deltyba 50 mg film-coated tablets delamanid

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report 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 any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Deltyba is and what it is used for

Deltyba contains the active substance delamanid, an antibiotic for the treatment of tuberculosis in the lung caused by bacteria that are not killed by the most commonly used antibiotics to treat tuberculosis.

2. What you need to know before you take Deltyba

Do not take Deltyba:

- 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 that strongly induce a certain liver enzyme called “CYP450 3A4” (e.g. carbamazepine).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Deltyba.

Before you start taking Deltyba, and during the treatment, your doctor may check your heart's electrical activity using an ECG (electrocardiogram) machine (electrical recording of the heart). Your doctor may also perform a blood test to check the concentration of some minerals and proteins which are important for the function of your heart.

Tell your doctor if you have one of the following conditions:

- you have reduced levels of albumin, potassium, magnesium or calcium in the blood
- you have been told that you have heart problems, for example a slow heart rhythm (bradycardia) or have a history of heart attack (myocardial infarction)
- if you have a condition called congenital long QT syndrome or have a serious heart disease or problems with heart rhythm.
- you have liver disease or kidney disease.
- you have HIV.

Children

Deltyba is not suitable for children under age 18.

Other medicines and Deltyba

Tell your doctor...

- if you are taking, have recently taken or might take any other medicines, including medicines or herbal remedies obtained without prescription,
- 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 psychoses (e.g. phenothiazines, sertindole, sultopride, chlorpromazine, haloperidol, mesoridazine, pimozide, or thioridazine) or depression
- if you are taking certain antimicrobial medicines (e.g. erythromycin, clarithromycin, moxifloxacin, sparfloracin, pentamidine, or saquinavir).
- if you are taking triazole 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 any of the following: cisapride (used to treat stomach disorders), 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 opiate addiction), vinca alkaloids (anti-cancer medicines), or arsenic trioxide (used to treat certain types of leukaemia).
- if you are taking HIV-medicines containing lopinavir/ritonavir.

You may be more at risk for dangerous changes of the heart rhythm.

Pregnancy and breast-feeding

Deltyba may cause harm to an unborn baby. It is not usually recommended for use during pregnancy.

It is important to tell your doctor if you are pregnant, think you may be pregnant, or are planning to get pregnant. Your doctor will weigh up the benefits to you against the risks to your baby of taking Deltyba whilst you are pregnant.

It is not known if delamanid passes into breast milk in humans. Breast-feeding is not recommended during treatment with Deltyba.

Driving and using machines

Deltyba is not expected to have an influence on your ability to drive and use machines. If you experience side effects that might affect your ability to concentrate and react, do not drive or use machines.

Deltyba contains lactose monohydrate.

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 Deltyba

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is two 50 mg tablets taken twice a day (morning and evening) as advised by your doctor. The tablets should be taken during or just after a meal. Swallow the tablets with water.

If you take more Deltyba than you should

If you have taken more tablets than your prescribed dose, contact your doctor 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 Deltyba

If you forget a dose, take it as soon as you remember it. 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 Delyba

DO NOT stop taking the tablets unless your doctor tells you to. Stopping too early could allow the bacteria to recover and to become resistant to delamanid.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

The frequency of the side effects listed below is defined using the following definitions:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Side effects very commonly reported in clinical studies with Delyba were:

- Sensations of irregular and/or forceful beating of the heart
- Vomiting
- Nausea
- Diarrhoea
- Stomach pain
- Headache
- A tingling, burning or pricking sensation or numbness of the skin (paresthesia)
- Shaking (tremor)
- Decreased appetite
- Dizziness
- Hearing a persistent sound in your ear when no sound exists (tinnitus)
- Intense lack of energy
- Joint or muscle pain
- Difficulties with falling or staying asleep
- Increase in immature red blood cells
- Low blood potassium level
- Increased blood uric acid level
- Coughing up blood
- Changes found in investigations (electrocardiogram, ECG) of the heart

Side effects commonly reported in clinical studies with Delyba were:

- Anaemia
- Increase of certain white blood cells (eosinophilia)
- Increased blood tryglycerides
- Psychotic disorder
- Agitation
- Anxiety
- Depression
- Restlessness
- Nerve damage causing numbness or pain (burning) or tingling feeling in hands or feet
- Drowsiness
- Reduced sensation
- Dry eye
- Decreased tolerability of the eyes for bright light
- Ear pain
- Increase of blood pressure (hypertension)

- Decrease of blood pressure (hypotension)
- Bruising
- Hot flushes
- Shortness of breath
- Cough
- Pain in the mouth or throat
- Throat irritation
- Dry throat
- Runny nose
- Chest pain
- Gastritis
- Constipation
- Indigestion
- Dermatitis
- Hives
- Itching
- Papules (small skin elevations)
- Rash
- Acne
- Increased sweating
- A bone disease called osteochondrosis
- Muscular weakness
- Pain in bones
- Flank pain
- Pain in arms or legs
- Blood in urine
- Fever
- Chest pain
- Feeling unwell
- Chest discomfort
- Foot, leg or ankle swelling
- Increased values for blood investigations for the hormone cortisol

Side effects uncommonly reported in clinical studies with Delytyba were:

- Shingles
- Oral thrush
- Yeast infection of the skin (tinea versicolor)
- Low white blood cell count (leukopenia)
- Low blood platelets count (thrombocytopaenia)
- Dehydration
- Low blood calcium level
- High blood cholesterol level
- Aggression
- Paranoia
- Panic attacks
- Adjustment disorder with depressed mood
- Neurosis
- Feeling of emotional and mental discomfort
- Mental aberration
- Problems with sleeping
- Increase of libido
- Lethargy
- Balance disorder
- Regional pain

- Allergic conjunctivitis
- Heart rhythm problems
- Swallowing problems
- Abnormal feeling in the mouth
- Tenderness in the abdomen
- Hair loss
- Itchy or red skin including around the hair roots.
- Urine retention
- Painful urination
- Increased need to urinate at night
- Feeling hot
- Abnormal values for blood investigations related to coagulation (prolonged APPT)
- Abnormal blood values related to the function of the liver, biliary system or pancreas
- Decreased values for blood investigations for the hormone cortisol
- Increased blood pressure

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Delyba

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

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

Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist 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 Delyba contains

- One film-coated tablet contains 50 mg of the active substance delamanid.
- The other ingredients are hypromellose phthalate, povidone, all-rac- α -tocopherol, microcrystalline cellulose, sodium starch glycolate, carmellose calcium, colloidal hydrated silica, magnesium stearate, lactose monohydrate, hypromellose, macrogol 8000, titanium dioxide, talc, iron oxide (E172).

What Delyba looks like and contents of the pack

Delyba 50 mg film-coated tablets are round, and yellow.

Delyba is supplied in packs of 48 film-coated tablets in aluminium/aluminium blisters.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in <{MM/YYYY}>.

This medicine has been given ‘conditional approval’. This means that there is more evidence to come about this medicine.

The European Medicines Agency will review new information on this medicine at least every year and this leaflet will be updated as necessary.

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>. There are also links to other websites about rare diseases and treatments.