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What Deltalba is used for

Deltalba 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. It must always be taken together with other medicines for treating tuberculosis.

Deltalba is used in adults, adolescents and children who are weighing at least 30 kg.

How Deltalba works

Delamanid inhibits the synthesis of mycobacterial cell wall components, methoxy-mycolic and keto-mycolic acid in *Mycobacterium tuberculosis*.

Before you use Deltalba

-When you must not use it

Do not take Deltalba if:

- you are allergic to delamanid or any of the other ingredients of this medicine (see *Product description*)
- you have very low levels of albumin in the blood
- you are taking medicines that strongly increase the activity of a certain liver enzyme called 'CYP450 3A4' (e.g. carbamazepine, a medicine used to treat epilepsy and prevent seizures)

-Before you start to use it

Before you start taking Deltalba, and during the treatment, your doctor may check your heart's electrical activity using an electrocardiogram (ECG) machine. 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.

Talk to your doctor or pharmacist before taking Deltalba if you have one of the following conditions:

- you have reduced levels of albumin, potassium, magnesium, or calcium in 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 severe kidney disease

-Taking other medicines

Tell your doctor or pharmacist if

- you are taking, have recently taken or might take any other medicines.
- you are taking medicines to treat an abnormal heart rhythm (e.g. amiodarone, disopyramide, dofetilide, ibutilide, procainamide, quinidine, hydroquinidine, sotalol).
- you are taking medicines to treat psychosis (e.g. phenothiazines, sertindole, sultopride, chlorpromazine, haloperidol, mesoridazine, pimozide, or thioridazine) or depression.
- you are taking certain antimicrobial medicines (e.g. erythromycin, clarithromycin, moxifloxacin, sparfloxacin, bedaquiline, or pentamidine).
- you are taking triazole antifungal medicines (e.g. fluconazole, itraconazole, voriconazole).
- you are taking certain medicines to treat allergic reactions (e.g. terfenadine, astemizole, mizolastine).
- you are taking certain medicines to treat malaria (e.g. halofantrine, quinine, chloroquine, artesunate / amodiaquine, dihydroartemisinin / piperaquine).
- 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).

- you are taking HIV-medicines containing lopinavir/ritonavir, or saquinavir.

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

-Pregnancy and breastfeeding

Deltalba 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 Deltalba whilst you are pregnant.

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

-Deltalba contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

How to use Deltalba

-How much to use

The recommended dose as advised by your doctor is:

Adults, adolescents and children with a body weight of 50 kg or more:

Two 50 mg film-coated tablets taken twice a day (morning and evening) for 24 weeks.

Children with a body weight of 30 kg or more and less than 50 kg:

One 50 mg film-coated tablet taken twice daily for 24 weeks.

-When to use it

The film-coated tablets must be taken during or just after a meal. Swallow the tablets with water.

-How long to use it

Always take Delyba exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Your doctor may decide to prescribe the 50 mg film-coated tablets for longer than 24 weeks.

-If you forget to use it

If you forget to take your medicine, you should take the dose 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 use too much (overdose)

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

While you are using it-Things you must do

Delyba treatment should be started and monitored under the supervision of your doctor with expertise in managing multidrug resistant *Mycobacterium tuberculosis*. You should always take Delyba together with other medicines for treating tuberculosis.

-Things you must not do

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.

-Things to be careful of

Delyba may cause abnormal heart rhythm. Consult your doctor if you develop sensations or irregular and/or forceful beating of the heart.

To check for any changes in your heart, your doctor may check your heart's electrical activity using an ECG 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.

Delyba is expected to have a moderate 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.

Side effects

Very common (may affect more than 1 in 10 people)

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

*Cases were mostly reported in children.

Common (may affect up to 1 in 10 people)

- Chest pain
- Decrease in the thyroid gland activity (hypothyroidism)
- Defect in cardiac rhythm that predisposes to 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)
- Muscular weakness
- Muscle spasms
- Numbness, decreased sensation in hands and/or feet (hypoesthesia)
- Pounding heartbeat (palpitations)
- Rise in the level of 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

*Cases were mostly reported in children.

Uncommon (may affect up to 1 in 100 people)

- Lack of energy (lethargy)

Other side effects that have been reported with Delyba use (frequency cannot be estimated from the available data)

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

If you experience any of the side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Delyba-Storage

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 which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

-Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer require. These measures will help protect the environment.

Product Description-What it looks like

Delyba is a round, yellow, film-coated tablet, 11.7mm in diameter, debossed with "DLM" and "50" on one side.

Delyba is supplied in packs of 48 film-

coated tablets in aluminium /
aluminium foil blisters.

- Ingredients:

- Active ingredient:

The active substance of Delyba is delamanid.

One film-coated tablet contains 50mg of the active substance delamanid.

-Inactive ingredients:

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 yellow (E172).

- MAL number(s):

MAL24086003ARZ

Manufacturer(s)

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