Dovprela 200 mg tablets

Pretomanid (200mg)

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What Dovprela is used for

Dovprela is used in adults (18 years and over) in combination with three other medicines called linezolid, bedaquiline and moxifloxacin, to treat tuberculosis that affects the lungs that is resistant to another antibiotic, rifampicin, and may also be resistant to isoniazid.

Dovprela is also used in adults in combination with two other medicines called linezolid and bedaquiline to treat tuberculosis that affects the lungs that is resistant to multiple other classes of antibiotics (rifampicin, any fluoroquinolone) and may also be resistant to isoniazid.

How Dovprela works

Dovprela contains the active substance pretomanid, a type of antibiotic. Antibiotics are medicines used to kill bacteria that cause diseases.

Before you use Dovprela

- *When you must not use it*

Do not take this medicine if:

• if you are allergic to pretomanid, antibiotics of the group called nitroimidazoles, or any of the other ingredients of this medicine

Since pretomanid must be used in combination with other medicines against tuberculosis – linezolid and bedaquiline – please make sure that you read the "Do not take" section of the package leaflets for these medicines as well. If you are unsure of any information in the package leaflets, please contact your doctor or pharmacist.

- *Before you start to use it*

Check with your doctor or pharmacist before taking Dovprela if you:

• have reduced liver function
• drink alcohol on a regular basis
• have reduced kidney function
• have or have had disturbances of the heart rhythm, or if someone in your family has a heart rhythm problem
• have heart failure
• have or have had an underactive thyroid
• have reduced blood levels of calcium, magnesium or potassium

Liver damage

There is a risk of liver damage when you are treated with Dovprela in combination with other medicines against tuberculosis. Your doctor will therefore monitor you for signs of liver damage and take blood samples before the start of treatment and regularly during treatment. Tell your doctor if you experience symptoms such as:
• fatigue
• lack or loss of appetite
• nausea
• yellowing of the skin and eyes
• dark urine
• abdominal pain

The doctor will adjust your treatment if your liver is affected.

Reduced number of blood cells

Treatment with Dovprela in combination with other medicines against tuberculosis can severely reduce the number of blood cells, such as blood platelets, red blood cells and white blood cells called neutrophils. Contact your doctor immediately about any signs of bruising, bleeding or infections.
Your doctor will monitor complete blood counts before the start of treatment and regularly during treatment. The doctor will adjust your treatment if your blood cell count is reduced.

Nerve disorders in hands, feet or eyes

Nerve disorders in hands, feet or eyes may occur during treatment. Contact your doctor if you have visual problems, or numbness, tingling or burning in your hands or feet during treatment. Your doctor will adjust your treatment in these cases. If visual problems occur contact a doctor for a prompt eye examination.

Increased blood level of lactic acid

A disorder of blood over-acidification called lactic acidosis may occur during treatment. Contact your doctor if you have recurrent nausea or vomiting. Your doctor may adjust your treatment in these cases.

Heart problems

A certain heartbeat abnormality known as QT prolongation may occur during treatment. Your doctor will therefore perform an ECG before the start of treatment and regularly during treatment. Your treatment will be adjusted if heartbeat abnormalities occur. In addition, potassium, calcium and magnesium levels will be monitored and corrected if abnormal.

The safety and efficacy of Dovprela has not been studied in combination with medicines other than linezolid and bedaquiline and therefore it should not be used as part of any other treatment combination.

Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

•Pregnancy

Very limited knowledge exists about the use of Dovprela during pregnancy. Therefore, Dovprela is used during pregnancy only if the benefit to the patient outweighs the potential risk to the foetus. Your doctor will decide whether you should be treated with Dovprela.

•Breast-feeding

It is not known if pretomanid is passed into human milk. Your doctor has to decide if you should discontinue breast-

feeding or avoid treatment with Dovprela.

Children and adolescents
This medicine is not recommended for children and adolescents under 18 years. This is because it has not been studied in this age group.

- *Taking other medicines*
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including herbal therapies. These may affect the way Dovprela works or increase the risk of side effects.
Avoid treatment with Dovprela and any of the following medicines at the same time. These may lower the effect of Dovprela so your treatment may not work; therefore, inform your doctor immediately about these:
• rifampicin, rifamycin, rifapentine, rifabutin: other medicines to treat tuberculosis or certain other infections
• efavirenz, etravirine: medicines to treat HIV infection
• carbamazepine, phenytoin: medicines to treat epilepsy and certain pain conditions
• St John's wort: a herbal medicine to treat depression and anxiety

You should also avoid the use of medicines that may have a damaging effect on your liver (other than bedaquiline and linezolid). Talk to you doctor who will be able to tell you which medicines this applies to.

Inform your doctor if you are using:
• methotrexate: a medicine to treat severe joint inflammation, cancer and the skin disease psoriasis
• benzylpenicillin, ciprofloxacin: medicines to treat bacterial infections
• indomethacin: a medicine to treat pain and inflammation
• ritonavir: a medicine to treat HIV infection

How to use Dovprela
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Dovprela is used in combination with linezolid, bedaquiline and moxifloxacin. Please also read the package leaflets from these medicines. If you have any questions ask your doctor or pharmacist.

- *How much to use*
The recommended dose is
• Dovprela: 1 tablet once daily
• linezolid: 600 mg daily
• bedaquiline: 400 mg once daily for 2 weeks, followed by 200 mg 3 times per week (with at least 48 hours between doses). For example you may take bedaquiline on Monday, Wednesday and Friday every week from week 3 onwards

If you have been told by your doctor that you will have moxifloxacin as well as Dovprela, linezolid and bedaquiline, the recommended dose is
• moxifloxacin: 400 mg once daily.

- *When to use it*
Take Dovprela at the same time as linezolid, bedaquiline and moxifloxacin. Swallow the tablets with a glass of water and take them with food. If you have trouble swallowing a whole tablet, crushing the tablets and mixing with water for administration may be an acceptable alternative. You should take the tablets immediately after crushing and mixing with water.
The tablets are taken under direct observation of a healthcare professional or in accordance with local practice

- *How long to use it*
The duration of treatment with the combination Dovprela, linezolid and bedaquiline is 26 weeks. Your doctor may decide to expand this period or to interrupt dosing to ensure that the treatment is safe and effective for you.

- *If you forget to use it*
Do not take a double dose to make up for a forgotten dose. Any missed dose of pretomanid, bedaquiline, or moxifloxacin is recommended to be made up at the end of treatment. Doses of linezolid missed due to linezolid adverse reactions are not recommended to be made up. Talk to your doctor or pharmacist if you have missed a dose and you are not sure what to do

- *If you use too much (overdose)*
Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Dovprela
- *Things you must do*
Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Dovprela.

Tell your doctor immediately if you become pregnant while using this medication.

Take Dovprela only with a doctor's prescription.

- *Things you must not do*
Do not stop taking Dovprela or its combination medicines linezolid, bedaquiline, or moxifloxacin without your doctor's permission. Skipping doses or not completing the full course of therapy may make treatment ineffective and your tuberculosis could get worse. In addition, this would increase the chance that bacteria become resistant to these medicines.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Dovprela to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*
Driving and using machines
You may feel dizzy after taking Dovprela or you may experience problems with your vision. Do not drive or operate machinery if this happens.

Dovprela contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium- free'.

Dovprela with alcohol
Avoid drinking alcohol while being treated with Dovprela since this

increases the risk of serious liver damage.

Side effects

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

When Dovprela is used together with linezolid and bedaquiline the following side effects have been reported:

Contact your doctor immediately if you experience any of the following:

Very common (may affect more than 1 in 10 people)
• reduced number of red blood cells
Possible signs are feeling tired, weakness, shortness of breath, loss of consciousness and increased thirst.
• reduced number of white blood cells
Possible signs are infections.
• increased blood levels of liver enzymes called transaminase such as ALT, AST
Tell your doctor if you experience symptoms such as fatigue, lack or loss of appetite, nausea, yellowing of the skin and eyes, dark urine or abdominal pain.

Common (may affect up to 1 in 10 people)
• reduced number of white blood cells or platelets Possible signs are bruising, bleeding or infections.
• increased blood levels of a liver enzyme called gamma GT (indicating how well your liver is working)
• increased blood level of lactic acid
Contact your doctor if you have recurrent nausea or vomiting.

Other side effects may occur with following frequencies:
Very common (may affect more than 1 in 10 people)
• nausea, vomiting
• Rash
• nerve problems in the hands or feet, such as pain, burning, abnormal sensation or numbness
• abnormal electrical activity of the heart (prolonged electrocardiogram QT interval)

Common (may affect up to 1 in 10 people)
• fungal (including candida, yeast, fungi) infection in the mouth or throat, which appears as white patches
• fungal (including candida, yeast, fungi) infection in the vagina, which may cause itching, soreness, burning and redness
• sleeping difficulties, depression
• fatigue
• decreased appetite
• taste disturbance
• dizziness
• tremor
• muscle spasm
• diarrhoea, constipation, indigestion
• inflammation of stomach lining, pancreas inflammation
• abdominal pain
• dry skin, itching skin, hives, acne
• vision problems
• deafness
• feeling of increased heartbeat, chest pain
• high blood pressure
• coughing up blood, nosebleed
• increased number of white blood cells
• increased blood levels:
  - amylase
  -bilirubin, which is the yellow breakdown substance of the blood pigment
  - lipase
  - alkaline phosphatase
  - creatinine
  - blood sugar
  - urea
  - sodium
  - potassium
• decreased blood level
  - blood sugar
  - sodium
  - calcium
  - albumin
  - potassium
  - magnesium
• decreased elimination of the muscle tissue breakdown product creatinine through kidneys

Uncommon (may affect up to 1 in 100 people)
• too much fluid loss, reduced body fluid volume
• anxiety
• enlarged liver
• yellowing of the skin, internal organs and/or the whites of the eyes (jaundice)
• eye lens disorder
• worsening ability to focus clearly on close objects
• eye itching, eye swelling, irritation or pain of the eye
• optic nerve damage and/or inflammation with swellings and visual disturbances
• optic disc swelling (leading to loss of vision)
• clouding of the eye lens (cataracts)
• increased or decreased heartbeat
• low blood pressure
• cough
• feeling bloated, burping
• burning tongue, enlargement of the small, nipple-like structures on the upper surface of the tongue
• reflux of stomach juices in the oesophagus
• swelling and pain (arthritis) in several joints
• allergic reaction
• eczema, excessive skin pigmentation, skin redness, hair loss
• abnormal presence of the protein albumin in the urine
• vomiting blood
• lack of white and red blood cells, and blood platelets
• increased blood levels:
  - creatine phosphokinase isoenzyme (MB)
  - uric acid
  - creatine phosphokinase

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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

Storage and Disposal of Dovprela

- *Storage*

Keep out of the reach and sight of children.
Do not store above 30°C. Store in the original container. Discard the medicine after 60 days from the day of first opening.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

Dovprela is a white to off-white oval tablet with “M” debossed on one side and “P200” on the other side. Tablet dimensions: 18 × 9 mm.

The tablets are provided in plastic bottles containing 26 tablets

- *Ingredients*
- Active ingredient

Each tablet contains 200 mg pretomanid.

- Inactive ingredients

lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, silica colloidal, sodium lauryl sulphate, povidone

- *MAL number:*

MAL26066008AZ

Manufacturer

Mylan Laboratories Limited,
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Chhatrapati Sambhajinagar,
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Product Registration Holder

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