NEW ZEALAND CONSUMER MEDICINE INFORMATION

DOVPRELA®

Pretomanid 200 mg Tablet

What is in this leaflet

Please read this leaflet carefully before you start taking DOVPRELA.

This leaflet answers some common questions about DOVPRELA.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking DOVPRELA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What DOVPRELA is used for

DOVPRELA is used in adults (18 years and over) 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 (isoniazid, rifampicin, any fluoroquinolone and any second line injectable antimycobacterial medication), or
- that is resistant to only isoniazid and rifampicin, when you do not respond to or cannot tolerate the standard treatment.

DOVPRELA contains the active ingredient Pretomanid. It belongs to a group of medicines called antibiotic. Antibiotics are medicines used to kill bacteria that cause diseases.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you take DOVPRELA

When you must not take it

Do not take DOVPRELA if you have an allergy to:

- any medicine containing pretomanid, antibiotics of the group called nitroimidazoles
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Pretomanid must be used in combination with other medicines against tuberculosis such as linezolid and bedaquiline. Please make sure that you read the consumer medicine information for these medicines as well.

Do not give this medicine to a child under the age of 18 years. Safety and effectiveness in children younger than 18 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

Tell your doctor if you have or have had any of the following:

- 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.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding. Your doctor can discuss with you the risks and benefits involved. 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. It is not known if pretomanid is passed into human milk. Your doctor has to decide if you should discontinue breastfeeding or avoid treatment with DOVPRELA.

If you have not told your doctor about any of the above, tell them before you start taking DOVPRELA.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking DOVPRELA.

Some medicines may interfere with DOVPRELA. These include:

- other medicines used to treat tuberculosis or certain other infections such as rifampicin, rifamycin, rifapentine, and rifabutin
- medicines to treat HIV infection such as efavirenz, ritonavir and etravirine
- medicines to treat epilepsy and certain pain conditions such as carbamazepine and phenytoin
- St John's wort, a herbal product for depression and anxiety
- methotrexate, a medicine to treat severe joint inflammation, cancer and the skin disease psoriasis
- benzylpenicillin, and ciprofloxacin, medicines used to treat bacterial infections
- indomethacin, a medicine used to treat pain and inflammation

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

These medicines may be affected by DOVPRELA or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Avoid drinking alcohol while being treated with DOVPRELA since this increases the risk of serious liver damage.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take DOVPRELA

Follow all directions given to you by your doctor or pharmacist carefully.
They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

DOVPRELA is used in combination with linezolid and bedaquiline. Please also read the consumer medicine information for these medicines. If you have any questions ask your doctor or pharmacist.

How much to take

The recommended dose is 1 DOVPRELA 200 mg tablet once daily.

How to take it

Take DOVPRELA at the same time as linezolid and bedaquiline. Swallow the tablets with a glass of water and take them with food.

The tablets are taken under observation of a healthcare professional or in accordance with local practice.

How long to take it

The duration of treatment with the combination DOVPRELA, linezolid and bedaquiline is 26 weeks.
Your doctor may decide to expand the period or to interrupt dosing to ensure that the treatment is safe and effective for you.

If you forget to take it

Do not take a double dose to make up for the dose that you missed.
This may increase the chance of you getting an unwanted side effect.

Any missed dose of pretomanid and bedaquiline 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.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking DOVPRELA

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking DOVPRELA.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.
Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take DOVPRELA to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking DOVPRELA or its combination medicines linezolid or bedaquiline 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.

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

Things to be careful of

You may feel dizzy after taking DOVPRELA or you may experience problems with your vision. Do not drive or operate machinery if this happens.

Liver damage

There is a risk of liver damange when you are treated with DOVPRELA, linezolid and bedaquiline. 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, linezolid and bedaquiline 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 you blood cell count is reduced.

Nerve disorders in hand, feet or eyes

Nerve disorders in hands, feet or eyes may occur during treatment. Contact your doctor if you have visual problems, or numbness, ingling 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.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much DOVPRELA. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DOVPRELA.
This medicine helps most people to kill the bacteria, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea, vomiting, indigestion
- acne
- decreased appetite
- nerve problems in the hands, or feet, such as pain, burning, abnormal sensation or numbness
- fungal (including candida, yeast, fungi) infection in the

mouth or throat, which appears as white patches
- sleeping difficulties
- fatigue
- taste disturbance
- dizziness
- headache
- muscle spasm, muscle and skeleton pain, such as joint pain, back pain, muscle pain
- diarrhoea, constipation
- inflammation of stomach lining, pancreas inflammation
- reflux of stomach juices in the oesophagus
- abdominal pain
- hair loss, dry skin, itching skin, rash
- eye swelling
- irritation or pain of the eye, dry eye, vision problems
- optic nerve damage and/or inflammation with swellings and visual disturbances
- abnormal electrical activity of the heart (prolonged electrocardiogram QT interval)
- anxiety, depression
- eye lens disorder
- low blood pressure
- cough, nosebleed
- feeling bloated
- eczema, excessive skin pigmentation
- inability to have or maintain an erection
- womb bleeding at irregular intervals, particularly between the expected menstrual periods
- feeling unwell.

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- feeling tired, weakness, shortness of breath, loss of consciousness and increased thirst
- 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.
- bruising, bleeding or infections
- recurrent nausea or vomiting
- yellowing of the skin, internal organs and/or the whites of the eyes (jaundice)
- optic disc swelling (leading to loss of vision)
- deafness
- feeling of increased heartbeat
- increased heartbeat
- burning tongue, enlargement of the small, nipple-like structures on the upper surface of the tongue
- abnormal presence of the protein albumin in the urine
- vomiting blood

The above list includes serious side effects that may require medical attention.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Some of these side effects (for example, blood pressure, blood sugar, liver enzyme levels, kidney function, magnesium or calcium blood level, red or white blood cell count) can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking DOVPRELA

Storage

Keep your tablets in the bottle until it is time to take them.
If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store DOVPRELA or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.
Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.
A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

White to off-white oval shaped, uncoated tablets debossed with **M** on one side and **P200** on the other side of tablet.

Ingredients

Active ingredient:
Pretomanid contains 200 mg of pretomanid as the active ingredient.

Inactive ingredients:
Pretomanid also contains:

- lactose monohydrate
- microcrystalline cellulose
- sodium starch glycolate
- povidone
- sodium laurilsulfate
- colloidal anhydrous silica
- magnesium stearate.

Contains sulfites and sugars as lactose.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

DOVPRELA is supplied in New Zealand by:

Viatris Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatris.co.nz
Telephone 0800 168 169

Date of Preparation

10 September 2026
(Based on datasheet dated 10 September 2026)

DOVPRELA® is a Viatris company trade mark.