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Dovprela[1] (*pretomanid*)

An overview of Dovprela and why it is authorised in the EU

What is Dovprela and what is it used for?

Dovprela is an antibiotic for treating adults with drug-resistant tuberculosis. It is used together with:

- bedaquiline (another tuberculosis medicine), linezolid and moxifloxacin (other antibiotics) to treat tuberculosis that is resistant to the antibiotic rifampicin, with or without resistance to isoniazid (another antibiotic);
- bedaquiline and linezolid to treat tuberculosis that is resistant to rifampicin and a fluoroquinolone antibiotic, with or without resistance to isoniazid;

Tuberculosis is rare in the EU, and Dovprela was designated an 'orphan medicine' (a medicine used in rare diseases) on 29 November 2007. Further information on the orphan designation can be found on the EMA website: ema.europa.eu/medicines/human/orphan-designations/eu 307513.

Dovprela contains the active substance pretomanid.

How is Dovprela used?

The medicine can only be obtained with a prescription and prescribers should take into account official guidance on the use of antibiotics. Treatment should be started and monitored by a doctor experienced in managing drug-resistant tuberculosis.

Dovprela is available as tablets to be taken with food once daily for 26 weeks. When taken in combination with bedaquiline and linezolid (without moxifloxacin), treatment can be extended to a total of 39 weeks, if necessary.

For more information about using Dovprela, see the package leaflet or contact your doctor or pharmacist.

How does Dovprela work?

The way the active substance in Dovprela works is not fully understood. It is thought to block the building of the cell walls of the bacteria that cause tuberculosis (*Mycobacterium tuberculosis*) by

[1] Previously known as Pretomanid FGK.

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interfering with the production of one of the cell wall components. Pretomanid is also thought to trigger the production of substances that are toxic for the bacteria (reactive nitrogen species). These actions are expected to kill the bacteria.

What benefits of Dovprela have been shown in studies?

A main study showed that Dovprela taken with bedaquiline and linezolid for 6 months is effective at clearing the bacteria that cause tuberculosis in patients with either extensively drug-resistant tuberculosis or multidrug-resistant (MDR) tuberculosis when other treatments did not work or caused too many side effects.

At the time of the study, extensively drug-resistant tuberculosis was defined as tuberculosis caused by bacteria that are resistant to isoniazid, rifampicin, a fluoroquinolone and an injectable aminoglycoside (another class of antibiotics). MDR tuberculosis was defined as being caused by bacteria resistant to isoniazid and rifampicin.

In this study, 90% of patients with extensively drug-resistant tuberculosis (63 out of 70) and 95% of patients with MDR tuberculosis (35 out of 37) were cleared of the infection and did not get re-infected in the 6 months after the end of the treatment.

A second main study showed that Dovprela taken with bedaquiline, linezolid and moxifloxacin for 6 months was at least as effective as standard treatment given for 9 to 24 months in treating people with rifampicin-resistant tuberculosis. The study looked at how many people had an unfavourable outcome (treatment stopped, treatment not working, infection returned, or patient died). In this study, 12% (16 out of 138) of people treated with Dovprela plus bedaquiline, linezolid and moxifloxacin had an unfavourable outcome compared with 41% (56 out of 137) of those receiving standard treatment.

What are the risks associated with Dovprela?

For the full list of side effects and restrictions with Dovprela, see the package leaflet.

The most common side effects with Dovprela when used together with bedaquiline and linezolid (which may affect more than 1 in 10 people) include nausea (feeling sick), vomiting and blood tests showing raised levels of liver enzymes (a sign of liver stress).

The most common side effects with Dovprela when used together with bedaquiline, linezolid and moxifloxacin (which may affect more than 1 in 10 people) include increased blood levels of liver enzymes and QT prolongation (abnormal electrical activity of the heart seen on an electrocardiogram [ECG]).

Why is Dovprela authorised in the EU?

At the time of approval, treatment options were limited for patients with difficult-to-treat, life-threatening tuberculosis. Dovprela used with bedaquiline and linezolid was shown to be effective at treating difficult-to-treat tuberculosis. Although the number of patients included in the main study was small and the effects of the combination were not compared with those of other treatments, the European Medicines Agency considered that the high cure rate in the study, the shorter treatment duration and simplification of treatment compared to existing therapies are significant benefits.

Since the initial approval, Dovprela used with bedaquiline, linezolid and moxifloxacin for 6 months has been shown to be effective in treating rifampicin-resistant tuberculosis. In 2022, this combination was recommended by the World Health Organization as the standard treatment for rifampicin-resistant

tuberculosis because it is better tolerated than the previous standard treatment and easier to follow due to its shorter treatment duration.

The safety profiles of the combination regimens with Dovprela are considered acceptable and the side effects manageable, provided that close monitoring and surveillance of the patients during and after treatment are in place.

The European Medicines Agency decided that Dovprela's benefits are greater than its risks and it can be authorised for use in the EU.

Dovprela was originally given 'conditional authorisation'. The authorisation was then switched to standard authorisation as the company has provided additional data requested by the Agency.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Dovprela have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Dovprela are continuously monitored. Side effects reported with Dovprela are carefully evaluated and any necessary action taken to protect patients.

Other information about Dovprela

Pretomanid FGK received a conditional marketing authorisation valid throughout the EU on 31 July 2020. The name of the medicine was changed to Dovprela on 11 January 2021.

The conditional marketing authorisation was switched to a standard marketing authorisation on 15 November 2023.

Further information on Dovprela can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/dovprela.

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