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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 a medicine for treating adults with drug-resistant tuberculosis. It is used to treat tuberculosis that is:

- extensively drug-resistant (resistant to at least 4 antibiotics used for treating tuberculosis, including the standard antibiotics isoniazid and rifampicin);
- multi-drug resistant (resistant to isoniazid and rifampicin) and when antibiotics used for this form of tuberculosis do not work or cause unacceptable side effects.

Dovprela is used together with bedaquiline and linezolid.

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. Treatment should be started and monitored by a doctor experienced in managing multi-drug resistant (MDR) tuberculosis.

Dovprela is available as tablets to be taken with food once daily for 6 months, or longer if necessary. It is taken in combination with bedaquiline and linezolid.

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 interfering with the production of one of the cell wall components. Pretomanid is also thought to trigger

[1] Previously known as Pretomanid FGK.

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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 causing tuberculosis in patients with either extensively drug-resistant tuberculosis or MDR tuberculosis when other treatments did not work or cause too many side effects.

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.

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 (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).

Why is Dovprela authorised in the EU?

Dovprela used with bedaquiline and linezolid has been 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. At the time of approval, treatment options were limited for these patients with difficult-to-treat, life-threatening infection.

The safety profile of the combination regimen is 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 Pretomanid Dovprela's benefits are greater than its risks and it can be authorised for use in the EU.

Dovprela was originally given 'conditional authorisation' because there was more evidence to come about the medicine. As the company has supplied the additional information necessary, the authorisation has been switched from conditional to standard authorisation.

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.

This overview was last updated in 12-2023.