11 December 2025
EMADOC-1700519818-2699355
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Dovprela

pretomanid

On 11 December 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Dovprela. The marketing authorisation holder for this medicinal product is Mylan IRE Healthcare Limited.

The CHMP adopted extensions to the existing indications as follows:[2]

Dovprela is indicated in combination with bedaquiline, linezolid and moxifloxacin for the treatment of

- **adults with pulmonary tuberculosis (TB) due to *Mycobacterium tuberculosis* resistant to rifampicin, with or without resistance to isoniazid.**

Dovprela is indicated in combination with bedaquiline and linezolid for the treatment of

- adults with pulmonary ~~tuberculosis (~~TB~~)~~ due to *M.*~~ycobacterium~~ *tuberculosis* resistant to ~~all of isoniazid,~~ rifampicin **and**~~,~~ a fluroquinolone, ~~and~~ **with or without resistance to isoniazid** ~~a second line injectable antibacterial drug and~~
- ~~adults with pulmonary TB due to *M. tuberculosis* resistant to both isoniazid and rifampicin, who are treatment intolerant or nonresponsive to standard therapy~~ (see sections 4.2, 4.4 and 5.1).

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

For information, the full indications for Dovprela will be as follows:

Dovprela is indicated in combination with bedaquiline, linezolid and moxifloxacin for the treatment of

- adults with pulmonary tuberculosis (TB) due to *Mycobacterium tuberculosis* resistant to rifampicin, with or without resistance to isoniazid.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold, removed text as strikethrough

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Dovprela is indicated in combination with bedaquiline and linezolid for the treatment of

- adults with pulmonary TB due to *M. tuberculosis* resistant to rifampicin and a fluoroquinolone, with or without resistance to isoniazid (see sections 4.2, 4.4 and 5.1).

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.