EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 March 2020
EMA/CHMP/116569/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Pretomanid FGK

pretomanid

On 26 March 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation for the medicinal product Pretomanid FGK[2], intended for the treatment of tuberculosis, in combination with bedaquiline and linezolid. The applicant for this medicinal product is FGK Representative Service GmbH.

Pretomanid FGK will be available as 200-mg tablets. The active substance of Pretomanid FGK is pretomanid, an antimycobacterial (ATC code: not yet assigned). Its activity is thought to involve inhibition of the synthesis of cell wall lipids under aerobic conditions and generation of reactive nitrogen species under anaerobic conditions.

The benefits with Pretomanid FGK, given for 6 months with bedaquiline and linezolid, are its ability to produce favourable outcomes in patients with difficult-to treat-infection. The most common side effects noted are peripheral neuropathy, nausea, anemia, vomiting, headache, dyspepsia, acneiform dermatitis, decreased appetite, increased transaminases and gamma glutamyl transpeptidase, rash, pruritus, abdominal pain, musculoskeletal pain and hyperamylasaemia.

The full indication is:

> Pretomanid FGK is indicated in combination with bedaquiline and linezolid, in adults, for the treatment of pulmonary extensively drug resistant (XDR), or treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB), see sections 4.2, 4.4 and 5.1.
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> Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Pretomanid FGK should be started and monitored by physicians experienced in the treatment of tuberculosis.

Detailed recommendations for the use of this product will be described in the summary of product

[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] This product was designated as orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.