28 May 2020
EMA/CHMP/265461/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Xenleta

lefamulin

On 28 May 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Xenleta, intended for the treatment of community-acquired pneumonia (CAP) in adults. The applicant for this medicinal product is Nabriva Therapeutics Ireland DAC.

Xenleta will be available as a 150 mg concentrate and solvent for solution for infusion and 600 mg film-coated tablets. The active substance of Xenleta is lefamulin, a pleuromutilin antibacterial for systemic use (ATC code: J01XX12) which inhibits bacterial protein synthesis.

The benefit with Xenleta is its ability to treat community-acquired pneumonia, as shown in two large clinical trials. The most common side effects are diarrhoea, nausea, vomiting, hepatic enzyme elevation and QT prolongation.

The full indication is:

> Xenleta is indicated for the treatment of community-acquired pneumonia (CAP) in adults when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of CAP or when these have failed.

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

[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

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