19 June 2019
EMA/324558/2019
EMEA/H/C/000354

Public statement

Ketek

Withdrawal of the marketing authorisation in the European Union

On 7 June 2019, the European Commission withdrew the marketing authorisation for Ketek (telithromycin) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Aventis Pharma S.A., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Ketek was granted marketing authorisation in the EU on 9 July 2001 for the treatment of community-acquired pneumonia, acute exacerbation of chronic bronchitis, acute sinusitis, and tonsillitis/pharyngitis caused by *Streptococcus pyogenes*.

The marketing authorisation was initially valid for a 5-year period. It was subsequently renewed for an additional 5-year period and then granted unlimited validity in 2011. The product had not been marketed in the EU since 1 July 2018.

The European Public Assessment Report (EPAR) for Ketek will be updated to indicate that the marketing authorisation is no longer valid.

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