25 April 2024
EMA/160345/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Sirturo

bedaquiline

On 25 April 2024, 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 Sirturo. The marketing authorisation holder for this medicinal product is Janssen-Cilag International NV.

The CHMP adopted a change to the existing indication as follows:[2]

> SIRTURO is indicated for use as part of an appropriate combination regimen **in adult and paediatric patients (5 years to less than 18 years of age and weighing at least 15 kg)** ~~for~~ **with** pulmonary ~~multidrug-resistant~~ tuberculosis ~~MDR-TB)~~ **(TB) due to *Mycobacterium tuberculosis* resistant to at least rifampicin and isoniazid.**~~in adult and paediatric patients (5 years to less than 18 years of age and weighing at least 15 kg) when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability (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 indication is as follows:

> SIRTURO is indicated for use as part of an appropriate combination regimen in adults and paediatric patients (5 years to less than 18 years of age and weighing at least 15 kg) with pulmonary tuberculosis (TB) due to *Mycobacterium tuberculosis* resistant to at least rifampicin and isoniazid.
>
> 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 in the revised European public assessment report (EPAR) and made available in all official European Union languages after a decision on this change to 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
[2] New text in bold, removed text as strikethrough

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union