25 June 2020
EMA/339403/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Gencebok

caffeine citrate

On 25 June 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 Gencebok, intended for the treatment of primary apnoea of premature newborns. The applicant for this medicinal product is Gennisium Pharma.

Gencebok will be available as 10 mg/ml solution for infusion. The active substance of Gencebok is caffeine citrate, a xanthine derivative (ATC code: N06BC01) which acts through the adenosine receptors as a respiratory stimulant.

The benefits with Gencebok are its ability to decrease the frequency of apnoeic episodes, increase respiratory rate and blood pH, decrease pCO_2, and improve the function of the respiratory muscles in premature infants with recurrent apnoea. The most common side effects are related to central nervous system stimulation and include irritability, tachycardia and hypertension.

Gencebok is a hybrid medicine[2] of Peyona which has been authorised in the EU since 2 July 2009. Gencebok contains the same active substance as Peyona, but it is available in a different strength.

Studies have demonstrated the satisfactory quality of Gencebok. Since Gencebok is administered intravenously and is 100% bioavailable, a bioequivalence (BE) study versus the reference product Peyona was not required. As the maintenance dose can be given by mouth and the strength of Gencebok is different from that of Peyona, the company also provided justification for not performing a BE study in this context, which was considered acceptable.

The full indication is:

> Treatment of primary apnoea of premature newborns.

Gencebok should be prescribed by physicians experienced in neonatal intensive care.

[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] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

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

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.