22 February 2024
EMA/CHMP/50/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Cibinqo

abrocitinib

On 22 February 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 Cibinqo. The marketing authorisation holder for this medicinal product is Pfizer Europe MA EEIG.

The CHMP adopted an extension to the existing indication to include treatment of adolescents aged 12 years and older. For information, the full indication will therefore be as follows:[2]

> Cibinqo is indicated for the treatment of moderate-to-severe atopic dermatitis in adults **and adolescents 12 years and older** who are candidates for systemic therapy.

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 will be 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

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