19 September 2024
EMA/418293/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Imvanex

smallpox and monkeypox vaccine (live modified vaccinia Ankara virus)

On 19 September 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 Imvanex. The marketing authorisation holder for this medicinal product is Bavarian Nordic A/S.

The CHMP adopted an extension to an existing indication to include use in adolescents 12 to 17 years of age.

For information, the full indications for Imvanex will be as follows:[2]

> Active immunisation against smallpox, monkeypox and disease caused by vaccinia virus in ~~adults~~ **individuals 12 years of age and older**.

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