15 July 2022
EMA/366849/2022
EMEA/H/C/003938

Public statement

Episalvan

Withdrawal of the marketing authorisation in the European Union

On 7 June 2022, the European Commission withdrew the marketing authorisation for Episalvan (birch bark extract) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Amryt GmbH, which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Episalvan was granted marketing authorisation in the EU on 14 January 2016 for the treatment of partial thickness wounds in adults.

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European Public Assessment Report (EPAR) for Episalvan will be updated to indicate that the marketing authorisation is no longer valid.

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