13 December 2024
EMA/586714/2024
EMEA/H/C/004258

Public statement

Alofisel (darvadstrocel)

Withdrawal of the marketing authorisation in the European Union

On 13 December 2024, the European Commission withdrew the marketing authorisation for Alofisel (darvadstrocel) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Takeda Pharma A/S, which notified the European Commission of its decision to permanently stop the marketing of the product in the EU. Further information can be found on the Agency's website.

Alofisel was granted marketing authorisation in the EU on 23 March 2018 for the treatment of complex perianal fistulas.

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European Public Assessment Report (EPAR) for Alofisel will be updated to indicate that the marketing authorisation is no longer valid.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