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Public statement

Helixate NexGen (SRD)

Withdrawal of the marketing authorisation in the European Union

On 16 December 2019, the European Commission withdrew the marketing authorisation for Helixate NexGen (SRD) (octocog alfa) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Bayer AG, which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Helixate NexGen (SRD) was granted marketing authorisation in the EU on 4 August 2000 for treatment of haemophilia A. The marketing authorisation was initially valid for a 5-year period. It was subsequently renewed for an additional 5-year period in 2010. It was then granted unlimited validity in 2010. The product had not been marketed in the EU since 2019.

Helixate NexGen (SRD) is an identical product to Kogenate Bayer. The marketing authorisation holder will maintain the marketing authorisation for Kogenate Bayer.

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Assessment Report (EPAR) for Helixate NexGen (SRD) will be updated to indicate that the marketing authorisation is no longer valid.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