

July 20<sup>th</sup> 2020

# Statement on Desmopressin Nasal Sprays availability

The European Haemophilia Consortium (EHC) has become aware of an international recall of all *Ferring Parmaceuticals Limited* nasal sprays containing **desmopressin**, including Octim<sup>®</sup>, Octostim<sup>®</sup>, Desmospray<sup>®</sup>, DDAVP Spray<sup>®</sup>. This may lead to shortages over the course of 2020.

# About Desmopressin nasal sprays

Desmopressin acetate is the active ingredient in the nasal sprays manufactured by *Ferring Pharmaceuticals Limited*. This spray is typically used in people with Von Willebrand Disease types 1 and 2 (except 2B) and mild haemophilia. It is also used for women with heavy menstrual bleeding.

# About the recall of Desmopressin nasal sprays

On 15<sup>th</sup> July 2020, Ferring Pharmaceuticals Limited recalled all unexpired stock of all strengths of desmopressin nasal spray from pharmacies and wholesalers worldwide. The decision was made as a precautionary measure due to efficacy issues. The vials of these nasal sprays were found to contain a lower volume of solution and hence out of specification for the content of the desmopressin acetate (active substance) and benzalkonium chloride (excipient). The precise cause of this defect remains to be determined.

Ferring Pharmaceuticals Limited has announced that the product will remain unavailable until 2021.

# Advice to patients

It is advised to patients who use this product to seek advice from your haematologist, gynaecologist or other healthcare professional with regard to suitable alternatives to desmopressin nasal spray such as intravenous or subcutaneous formulations of desmopressin.

The EHC will continue to monitor the situation and provide further information as the situation evolves.

# Further information from governmental sources

- <u>https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-ferring-pharmaceuticals-limited-desmopressin-nasal-spray-all-strengths-pl-03194-0024-pl-03194-0090-pl-03194-0056-el-20-a-29</u>
- https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/73567a-eng.php
- <u>https://www.basg.gv.at/en/market-surveillance/official-announcements/detail/octostim-15-mg-ml-nasalspray</u>

