



MARCH 2023

SUBJECT: Updated information regarding the future supply of DesmoSpray® nasal spray, Octim® nasal spray solution and DDAVP® (Desmopressin) intranasal solution.

To whom it may concern,

As you may know there has been a precautionary Class 2 pharmacy recall on the following products due to out-of-specification results during testing:

- **DesmoSpray nasal spray 0.1 mg/ml (10 micrograms/dose)**
- **Octim nasal spray solution 1.5 mg/ml (15 micrograms/dose)**

Ferring carried out a Health Hazard Evaluation (HHE), which concluded that this out-of-specification treatment could potentially cause adverse health consequences for some patients due to possible increased concentrations of desmopressin. It is important to note that the recall was **not** initiated due to increased adverse event reports related to potential complications from over-exposure to desmopressin.

Following an investigation, the root cause of the out-of-specification results was identified as a tightness issue with the primary packaging materials. To resolve this issue, new machinery is required, and a new assembly process must be designed and validated. Based on the timelines needed to procure, install and qualify a new production line, we anticipate that we will be able to start manufacturing Desmospray, Nasal Spray solution 0.1 mg/ml and Octim, Nasal Spray solution 1.5 mg/ml in **Q2 of 2024**, with first deliveries to the market foreseen around **Q4 2024**, depending on health authority approvals in affected markets.

DDAVP (Desmopressin) Intranasal Solution:

In 2020, Ferring Pharmaceuticals put the production of DDAVP Intranasal solution (Nasal Drops) 0.1 mg/ml on hold due to the detection of a quality issue linked to the primary packaging material. No stock with affected primary packaging material reached the market or patients.

Following a root cause investigation, quality issues were detected with the Sanodropper, a critical packaging component. Developed and supplied by a third-party, the production of the Sanodropper has also been terminated by the supplier.

Due to Ferring's limited level of technical knowledge on the Sanodropper, the observed quality challenges with this component and a lack of IP rights from the historical supplier, Ferring has no immediate or viable alternative to replace this component. Developing a new component to deliver a state-of-the-art product would require extensive development, including clinical trials, leading to long timelines for patient resupply.

During the production hold, Ferring has been working extensively on this case, including engagement with regulatory authorities to explore potential alternative solutions for patients. Ferring continues to manufacture and supply alternative desmopressin formulations which have received approval for the same indications as DDAVP Intranasal solution (Nasal Drops) 0.1 mg/ml. There are currently oral and injective alternatives available as well as the sprays being reintroduced at a later date as mentioned above.

Based on these factors, Ferring has decided to discontinue DDAVP Intranasal solution (Nasal Drops) 0.1 mg/ml. We apologise for any inconveniences but Ferring are committed to ensuring that our medicines adhere to the highest quality standards for our patients.

**Ferring Pharmaceuticals
UK & Ireland**