

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Nordurine 0.2 mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains desmopressin acetate 0.2 mg equivalent to desmopressin (free base) 0.178 mg.

Excipient(s) with known effect: lactose monohydrate

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Tablet

*Product imported from Bulgaria:*

White, round, convex tablet with '0.2' engraved on one side and a score line on the other.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal halves.

## 4 CLINICAL PARTICULARS

As per PA1009/017/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1009/017/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Lactose monohydrate

Potato starch

Povidone

Magnesium stearate

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the bottle and outer package of the product on the market in the country of origin.

### 6.4 Special precautions for storage

Do not store above 25°C

Store in the original package and keep the bottle tightly closed in order to protect from light and moisture.

### 6.5 Nature and contents of container

HDPE bottle with a child resistant PP cap and a desiccant capsule.

Pack sizes of 30 tablets.

**6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

IMED Healthcare Ltd.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/236/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 14<sup>th</sup> March 2025

**10 DATE OF REVISION OF THE TEXT**