# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Desmopressin acetate 100 microgram tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 100 micrograms (0.1 mg) of Desmopressin acetate hydrate (equivalent to 0.089 mg desmopressin).

Excipients with known effect:

Each 100 microgram tablet contains 62.90 mg lactose monohydrate.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet

100 micrograms

White to off-white, oval shape, biconvex, uncoated tablets with 'S' debossed on one side and scored on the other side. Diameter approximately 9 mm by 4 mm and thickness 2.5 mm

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

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Desmopressin tablets are indicated for the treatment of primary nocturnal enuresis.

Desmopressin tablets are indicated for the treatment of vasopressin-sensitive cranial diabetes insipidus or in the treatment of post-hypophysectomy polyuria/polydipsia.

## 4.2 Posology and method of administration

Primary nocturnal enuresis:

Children (from 5 years of age) and adults (up to 65 years of age) with normal urine concentrating ability who have primary nocturnal enuresis should take 200 micrograms at bedtime and only if needed should the dose be increased to 400 micrograms.

The need for continued treatment should be reassessed after 3 months by means of a period of at least 1 week without desmopressin tablets.

Treatment of diabetes insipidus:

Dosage is individual in diabetes insipidus but clinical experience has shown that the total daily dose normally lies in the range of 200 micrograms to 1200 micrograms. A suitable starting dose in adults and children is 100 micrograms three times daily. This dosage regimen should then be adjusted in accordance with the patient's response. For the majority of patients, the maintenance dose is 100 micrograms to 200 micrograms three times daily.

Post-hypophysectomy polyuria/polydipsia:

The dose of desmopressin tablets should be controlled by measurement of urine osmolality.

## 4.3 Contraindications

Desmopressin tablets are contraindicated in cases of cardiac insufficiency and other conditions requiring treatment with diuretic agents.

Before prescribing desmopressin tablets the diagnoses of psychogenic polydipsia and alcohol abuse should be excluded.

When used for the treatment of primary nocturnal enuresis, desmopressin tablets should be only be used in patients with normal blood pressure.

Desmopressin should not be prescribed to patients over the age of 65 for the treatment of primary nocturnal enuresis.

## 4.4 Special warnings and precautions for use

Care should be taken with patients who have reduced renal function and/or cardiovascular disease or cystic fibrosis. In chronic renal disease the antidiuretic effect of desmopressin tablets would be less than normal.

When desmopressin tablets are used for the treatment of enuresis, fluid intake must be limited from 1 hour before taking the tablets at bedtime until the next morning and in any case for a minimum of 8 hours after administration.

Patients being treated for primary nocturnal enuresis should be warned to avoid ingesting water while swimming and to discontinue desmopressin tablets during an episode of vomiting and/or diarrhoea until their fluid balance is once again normal.

Precautions to prevent fluid overload must be taken in:

- conditions characterised by fluid and/or electrolyte imbalance

- patients at risk for increased intracranial pressure.

Lactose monohydrate:

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

## 4.5 Interaction with other medicinal products and other forms of interaction

Substances which are known to induce SIADH e.g. tricyclic antidepressants, selective serotonin re-uptake inhibitors, chlorpromazine and carbamazepine, may cause an additive antidiuretic effect leading to an increased risk of water retention and/or hyponatraemia.

NSAID’s may induce water retention and/or hyponatraemia.

Concomitant treatment with loperamide may result in a 3-fold increase of desmopressin plasma concentrations, which may lead to an increased risk of water retention and/or hyponatraemia. Although not investigated, other drugs slowing transport might have the same effect.

A standardised 27% fat meal significantly decreased the absorption (rate and extent) of a 400 micrograms dose of oral desmopressin. Although it did not significantly affect the pharmacodynamic effect (urine production and osmolality), there is the potential for this to occur at lower doses. If a diminution of effect is noted, then the effect of food should be considered before increasing the dose.

## 4.6 Fertility, pregnancy and lactation

*Pregnancy:*

Data on a limited number (n=53) of exposed pregnancies in women with diabetes insipidus indicate rare cases of malformations in children treated during pregnancy. To date, no other relevant epidemiological data are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development.

Caution should be exercised when prescribing to pregnant women. Blood pressure monitoring is recommended due to the increased risk of preeclampsia.

*Lactation:*

Results from analyses of milk from nursing mothers receiving high dose desmopressin (300 micrograms intranasally) indicate that the amounts of desmopressin that may be transferred to the child are considerably less than the amounts required to influence diuresis.

## 4.7 Effects on ability to drive and use machines

None

## 4.8 Undesirable effects

Side effects include headache, stomach pain and nausea. Isolated cases of allergic skin reactions and more severe general allergic reactions have been reported. Very rare cases of emotional disorders including aggression in children have been reported. Treatment with desmopressin without concomitant reduction of fluid intake may lead to water retention/hyponatraemia with accompanying symptoms of headache, nausea, vomiting, weight gain, decreased serum sodium and in serious cases, convulsions.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme: Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

### 4.9 Overdose

An overdose of desmopressin tablets leads to a prolonged duration of action with an increased risk of water retention and/or hyponatraemia.

*Treatment:*

Although the treatment of hyponatraemia should be individualised, the following general recommendations can be given. Hyponatraemia is treated by discontinuing the desmopressin treatment, fluid restriction and symptomatic treatment if needed.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Posterior pituitary lobe hormones.

ATC code: H01BA02

In its main biological effects, Desmopressin does not differ qualitatively from vasopressin. However, Desmopressin is characterised by a high antidiuretic activity whereas the uterotonic and vasopressor actions are extremely low.

In a modelling study in which intravenous desmopressin was infused over two hours in healthy adult male subjects, the $EC_{50}$ value was calculated as 1.7pg/ml based on urinary osmolality and 2.4pg/ml based on urinary volume.

### 5.2 Pharmacokinetic properties

The absolute bioavailability of orally administered desmopressin varies between 0.08% and 0.16%. Mean maximum plasma concentration is reached within 2 hours. The distribution volume is 0.2 – 0.32 l/kg. Desmopressin does not cross the blood-brain barrier. The oral terminal half-life varies between 2.0 and 3.11 hours.

After oral administration of a single dose of 2 x 200 micrograms desmopressin tablets to healthy subjects, 25% of the subjects had plasma concentrations of desmopressin above 1pg/ml up to at least 14 hours post dosing.

In *in vitro* studies in human liver microsome preparations, it has been shown that no significant amount of desmopressin is metabolised, and thus human liver metabolism *in vivo* is not likely to occur. Consequently, it is also unlikely that desmopressin will

interact with drugs affecting hepatic metabolism. However, formal *in vivo* interaction studies have not been performed.

About 65% of the amount of desmopressin absorbed after oral administration could be recovered in the urine within 24 hours.

### 5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Lactose monohydrate

Potato starch

Povidone

Talc

Magnesium stearate

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

36 months

### 6.4 Special precautions for storage

Do not store above 25ºC. Store in the original package in order to protect from light and moisture. Keep the bottle tightly closed.

### 6.5 Nature and contents of container

High density polyethylene (HDPE) bottle with a polypropylene child-resistant closure containing 100 tablets, rayon filler and silica gel desiccant.

### 6.6 Special precautions for disposal

None

## 7 MARKETING AUTHORISATION HOLDER

Glenmark Pharmaceuticals Europe Limited
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## 8 MARKETING AUTHORISATION NUMBER(S)

PLGB 25258/0376

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10/10/2025

## 10 DATE OF REVISION OF THE TEXT

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