SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Desmopressin acetate 100 microgram Tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 100 micrograms of Desmopressin acetate hydrate (equivalent to 89 micrograms desmopressin).

Excipients: lactose monohydrate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Round, white, convex with break marks.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Desmopressin acetate Tablets are indicated for:

• the treatment of vasopressin-sensitive cranial diabetes insipidus.

• the treatment of post-hypophysectomy polyuria/polydipsia.

• the treatment of primary nocturnal enuresis.

4.2 Posology and method of administration

For oral use.

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 200micrograms to 1200micrograms. A suitable starting dose in adults and children is 100micrograms 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 100micrograms to 200micrograms three times daily.

Post-hypophysectomy polyuria/polydipsia:

The dose of Desmopressin acetate Tablets should be controlled by measurement of urine osmolality.

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 200micorgrams at bedtime and only if needed should the dose be increased to 400micrograms.

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

4.3 Contraindications

Hypersensitivity to desmopressin or any of the excipients.

Cardiac insufficiency and other conditions requiring treatment with diuretic agents.

When used to control primary nocturnal enuresis Desmopressin acetate Tablets should only be used in patients with normal blood pressure.

Before prescribing Desmopressin acetate Tablets the diagnoses of psychogenic polydipsia and alcohol abuse should be excluded.

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

Hyponatraemia.

Syndrome of inappropriate secretion of antidiuretic hormone.

4.4 Special warnings and precautions for use

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

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 acetate Tablets would be less than normal.

When Desmopressin acetate Tablets are used for the treatment of enuresis, fluid intake must be limited from 1 hour before until 8 hours after administration.

Patients being treated for primary nocturnal enuresis should be warned to avoid ingesting water while swimming and to discontinue Desmopressin acetate 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

It is important to monitor body weight and blood pressure during treatment with desmopressin.

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.

NSAIDs 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 0.4mg 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/foetal 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 pre-eclampsia.

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

Gastrointestinal tract:

Stomach pain, nausea, abdominal cramps, vomiting

Nervous system disorders:

Headache

Very rare; emotional disturbance in children.

Skin/General:

Allergic skin reactions and more severe general allergic reactions

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 the Yellow Card Scheme (www.mhra.gov.uk/yellowcard).

4.9 Overdose

An overdose of Desmopressin acetate 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. Therefore, symptoms such as an increase in body weight, headache, nausea, abdominal cramps and in severe cases cerebral oedema, convulsions and coma may be expected.

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.

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.

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

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

It is unlikely that desmopressin will interact with drugs affecting hepatic metabolism, since desmopressin has been shown not to undergo significant liver metabolism in in vitro studies with human microsomes. However, formal in vivo interaction studies have not been performed.

5.3 Preclinical safety data

There are no pre-clinical 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

Magnesium stearate

Silica, colloidal anhydrous

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 25°C. Store in the original package. Keep the bottle tightly closed. Keep the bottle in the outer carton.

6.5 Nature and contents of container

30ml High Density Polyethylene (HDPE) bottle with a tamper-proof, twist-off polypropylene (PP) closure with a silica gel desiccant insert. Each bottle contains either 30 or 90 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 35533/0010

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21/01/2022