NEW ZEALAND DATA SHEET

1. DESMOPRESSIN PH&T NASAL SPRAY SOLUTION

Desmopressin nasal spray solution 0.1mg/ml

2. QUALITITATIVE AND QUANTITATIVE COMPOSITION

1ml nasal spray solution contains 0.1mg desmopressin acetate equivalent to desmopressin 0.089 mg.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Nasal spray solution.

A clear, colourless solution in a glass bottle.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DESMOPRESSIN PH&T nasal spray solution is indicated for the treatment of cranial diabetes insipidus and for establishing renal concentration capacity testing.

DESMOPRESSIN PH&T nasal spray solution is also indicated for the treatment of primary nocturnal enuresis in patients (from 5 years of age) with normal ability to concentrate urine.

4.2 Dose and method of administration

1 dose of the spray provides 0.1ml, which corresponds to 10µg desmopressin acetate.

Cranial diabetes insipidus

Dosage is individual after testing, but normal dosage for adults is 10-20µg 1-2 times daily. For children 5-10µg 1-2 times daily

In the event of signs of water retention/hyponatremia treatment should be interrupted and the dose should be adjusted.

Primary nocturnal enuresis

A clinically effective dose is individual and may vary from 10 to 40µg administered intranasally. A suitable initial dose is 20µg intranasally at bedtime. Fluid restriction should be observed, please see under Warnings and Precautions. In the event of signs of water retention/hyponatremia treatment should be interrupted. Assessment of the necessity of continued treatment should be made after three months during one substance-free week.

Renal function testing

To establish renal concentration capacity, the following single doses are recommended:

The normal dose for adults is 40µg.

For children over 1 year 20µg

For children under 1 year 10μg

After administration of DESMOPRESSIN PH&T nasal spray solution any urine collected within one hour is discarded. During the next 8 hours 2 portions of urine are collected for osmolality testing. Fluid restriction should be observed (see warning and precautions).

4.3 Contraindications

DESMOPRESSIN PH&T nasal spray solution is contraindicated in cases of:

• habitual or psychogenic polydipsia

• cardiac insufficiency and other conditions requiring treatment with diuretics

• hypersensitivity to desmopressin or any of the excipients.

• moderate and severe renal insufficiency (creatinine clearance below 50 mL/min)

4.4 Special warnings and precautions for use

Only use nasal spray in patients where orally administered formulations are not feasible (see Post-Marketing Experience).

DESMOPRESSIN PH&T nasal spray solution should be used with caution in:

• Very young and elderly patients

• Conditions characterised by fluid and/or electrolyte imbalance

• Patients at risk for increased intracranial pressure

Renal concentration capacity testing in children below the age of 1 year should only be performed in hospital and under careful supervision. When used for diagnostic purposes the fluid intake must be limited to a maximum of 0.5 litres to quench thirst from 1 hour before until 8 hours after administration.

When used for enuresis the fluid intake must be limited to a minimum from 1 hour before until 8 hours after administration.

4.5 Interaction with other medicines and other forms of interaction

Substances, which are known to release antidiuretic hormone, e.g. tricyclic antidepressants, chlorpromazine and carbamazepine, may cause an additive antidiuretic effect leading to an increased risk of water retention/hyponatremia.

Indomethacin increases the urine concentrating effect of desmopressin without influencing the duration. The effect is probably without any clinical significance.

4.6 Fertility, pregnancy and lactation

Pregnancy

Reproduction studies performed in rats and rabbits with doses more than 100 times the human dose have revealed no evidence of a harmful action of desmopressin on the foetus. One investigator has reported 3 cases of malformations in children to mothers suffering from diabetes insipidus and receiving desmopressin during pregnancy. However, several other published reports comprising more than 120 cases show that women treated with desmopressin during pregnancy have given birth to normal children. Furthermore a review of a very large data set identifying 29 children who have been exposed to desmopressin during the full pregnancy shows no increase in the malformation rate in the children born.

Lactation

Results from analyses of milk from nursing mothers receiving high dose desmopressin (300µg intranasal), 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

Common (>1/100)

General

Headache

GI

Stomach pain, nausea

Upper respiratory

Nasal congestion/rhinitis, epistaxis.

Treatment without concomitant reduction of fluid intake may lead to water retention/hyponatremia with accompanying signs and symptoms (headache, nausea/vomiting, decreased serum sodium, weight gain, and in serious cases, convulsions).

Post marketing experience:

Very rare cases of emotional disturbances in children have been reported.

Isolated cases of allergic skin reactions and more severe general allergic reactions have been reported.

Hyponatraemia is an infrequent but serious adverse event which has been reported at a rate of approximately 15 cases per 100,000 patient years of exposure for intranasal solutions and 6 cases per 100,000 patient years for oral formulations.

4.9 Overdose

Overdose of desmopressin nasal spray solution can lead to water retention with hyponatremia.

Treatment

Although the treatment of hyponatremia should be individualised, the following general recommendations can be given. Asymptomatic hyponatremia is treated by discontinuing the desmopressin treatment and fluid restriction. Infusion of isotonic or hypertonic sodium chloride may be added in cases with symptoms. When the water retention is severe (convulsions and unconsciousness) treatment with furosemide should be added.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: vasopressin and analogues. ATC code: H01B A02.

DESMOPRESSIN PH&T nasal spray solution contains desmopressin, a structural analogue of the natural pituitary hormone arginine vasopressin. The difference lies in the dissemination of cysteine and substitution of L-arginine by D-arginine. This results in a considerably longer duration of action and a complete lack of pressor effect in the dosages clinically used.

5.2 Pharmacokinetic properties

The bioavailability is about 3-5%. Maximum plasma concentration is reached after approximately one hour. An intranasal dose of 10-20µg provides an antidiuretic effect during 8-12 hours. Desmopressin is excreted mainly in the urine.

5.3 Preclinical safety data

There were no unusual findings during the examination of the safety and safety profile of desmopressin.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorobutanol
hemihydrate
Hydrochloric acid
Nitrogen
Purified water
Sodium chloride

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

DESMOPRESSIN PH&T nasal spray is stable for two years when stored unopened at 2 – 8°C. After opening, discard after 2 months. DESMOPRESSIN PH&T can be stored at 25°C for two months.

6.4 Special precautions for storage

DESMOPRESSIN PH&T nasal spray solution should be stored at in an upright position at 2 – 8°C, in the original package. After opening, discard after 2 months.

DESMOPRESSIN PH&T nasal spray can also be stored at 25°C for two months.

6.5 Nature and contents of container

Amber glass vial (Ph Eur Type 1).

Vial fill-volume: 6ml (60 doses)

DESMOPRESSIN PH&T nasal spray is actuated by a manual dose pump without propellant. The spray pump is designed to deliver 100µl solution (= 10µg desmopressin acetate) per dose.

6.6 Special precautions for disposal

No special requirements.

7. MEDICINE SCHEDULE

Prescription medicine.

8. SPONSOR

AFT Pharmaceuticals Ltd
PO Box 33-203
Takapuna
Auckland 0740
Phone: 0800 423 823
Email: customer.service@aftpharm.com

9. DATE OF FIRST APPROVAL

29 September 2005

10. DATE OF REVISION OF THE TEXT

February 2021

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
4.3	Update in contraindications