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### Package Leaflet: Information for the User

## Desmospray<sup>®</sup>, Desmopressin Nasal Spray

Desmopressin acetate

#### Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. **See section 4.**

- if you have difficulty or problems passing urine
- if you suffer from bladder problems e.g. incontinence (inability to hold in urine), hesitance in starting urination, frequent urination and/or urgent urination
- if you have been warned that you are at risk of increased intracranial pressure
- For nocturia associated with multiple sclerosis: STOP using Desmospray when suffering from vomiting and diarrhoea until you are better

Desmospray should be used with caution in very young and older patients.

If any of these apply to you, or if you are not sure, contact your doctor or pharmacist before taking Desmospray.

#### What is in this leaflet:

1. What Desmospray is and what it is used for
2. What you need to know before you use Desmospray
3. How to use Desmospray
4. Possible side effects
5. How to store Desmospray
6. Contents of the pack and other information

#### 1. What Desmospray is and what it is used for

Desmospray is a solution for nasal use only. It contains desmopressin acetate, an antidiuretic (reduces urine production).

It is used:

- to treat patients with multiple sclerosis suffering from nocturia (the need to get up at night to pass urine)
- to diagnose and treat cranial diabetes insipidus (a condition which causes extreme thirst and the continuous production of large volumes of dilute urine). **IMPORTANT: This should not be confused with diabetes mellitus (sugar diabetes)**
- as a test to check if the kidneys are functioning properly (renal function test).

#### 2. What you need to know before you use Desmospray

##### Do not use Desmospray:

- if you are allergic to desmopressin or any of the other ingredients of this medicine (listed in section 6)
- if you have a serious heart or kidney disease
- if you are taking diuretics (water tablets)
- if you drink unusually large quantities of fluids, including alcohol
- if you have known hyponatraemia (serum sodium levels below normal range)
- if you have syndrome of inappropriate secretion of anti-diuretic hormone, a hormone regulating urine production (SIADH)

##### When used for nocturia associated with multiple sclerosis, do not use Desmospray:

- if you are over 65 years old
- if you are taking medication for high blood pressure or have been told that your blood pressure is abnormal

#### Warnings and Precautions

Talk to your doctor or pharmacist before using Desmospray.

Take special care with Desmospray:

- if you have an illness causing fluid and/or electrolyte imbalance e.g. vomiting, diarrhoea, infections or fever
- if you have a medical condition that could be made worse by fluid and/or electrolyte disturbance (conditions where your blood sodium levels are too low or you are likely to build up too much water in your body, e.g. hyponatraemia)
- if you have cystic fibrosis

#### Other medicines and Desmospray

Tell your doctor or pharmacist if you are using, have recently taken or might use any other medicines.

Please inform your doctor or pharmacist:

- if you are on medication for depression, epilepsy or type II diabetes
- if you are taking a medicine for pain and/or inflammation containing non-steroidal anti-inflammatory drugs (also known as NSAIDs) e.g. indomethacin

#### Desmospray with food and drink

- For nocturia associated with multiple sclerosis: fluid intake must be limited to a minimum from 1 hour before taking the dose at bedtime until the following morning (and, in any case, for at least 8 hours).
- For the diagnosis of diabetes insipidus or for the renal function test: limit fluid intake to no more than 500ml, from 1 hour before until 8 hours after the dose.
- You should avoid drinking large amounts of fluid while you are being treated with Desmospray, as this could lead to a build-up of water which dilutes the salt in the body. This is a serious problem and may lead to convulsions.
- Avoid swallowing water while swimming to prevent a build-up of water in the body.

#### Pregnancy and breast feeding

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are breast-feeding ask your doctor or pharmacist for advice before using Desmospray.

#### Desmospray contains benzalkonium chloride

Desmospray contains benzalkonium chloride which may cause bronchospasm (when your breathing airway suddenly narrows, causing coughing and difficulty in breathing).

#### 3. How to use Desmospray

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

#### The recommended doses are:

##### Nocturia (the need to get up at night to pass urine) caused by multiple sclerosis:

Your doctor will prescribe a dose of one or two sprays at bedtime. If your dose is two sprays, use one spray in each nostril. The prescribed dose should NOT be used more than once in any 24 hour period. Your doctor will check your blood pressure and weight at regular intervals.

##### Diagnosis of diabetes insipidus (adults and children):

Your doctor will prescribe a dose of two sprays. Use one spray in each nostril.

##### Treatment of diabetes insipidus:

Your doctor will prescribe the dose most suitable for you. The most common dosing in adults and children is one or two sprays into the nostril, once or twice daily. If your dose is two sprays, use one spray in each nostril.

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**Renal function test:**

To check if the kidneys are functioning properly, your doctor will prescribe the following single dose:

*Adults:* Two sprays into each nostril

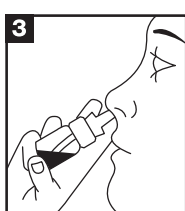
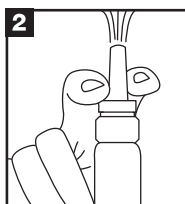
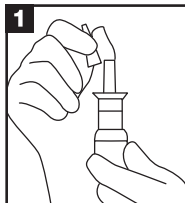
*Children (1-15 years):* One spray into each nostril

*Infants (to 1 year):* One spray into one nostril

**PATIENT INSTRUCTIONS****How to use Desmospray**

You should blow your nose before using the spray.

1. Remove the protective cap.
2. When first used, prime the spray by pressing several times until a consistent, fine spray is seen.
3. Ensure that the dip-tube is in the liquid when using Desmospray. With your head tilted slightly back, place the nozzle just inside the nostril.
4. Hold your breath (DO NOT SNIFF) and press the spray once.
5. Repeat this procedure using alternate nostrils until the prescribed dose is reached.
6. Replace the protective cap after use.
7. Do not store above 25°C. Keep container in the outer carton. Always store the bottle in an upright position.
8. If the spray is not used within 7 days of the previous dose, re-prime by pressing the spray at least once before using.
9. If this product is for a child, the dose should be given or supervised by an adult.



Do NOT use more than the prescribed dose in any 24 hour period.

If you have the impression that the effect of Desmospray is too strong or too weak, talk to your doctor or pharmacist.

**If you use more Desmospray than you should**

If you use more Desmospray than you should, talk to your doctor or pharmacist immediately.

**If you forget to use Desmospray**

Do not take a double dose to make up for a forgotten dose.

If you are a patient with nocturia caused by multiple sclerosis, do not use Desmospray until the usual time for your next dose.

If you are a patient with diabetes insipidus, please consult your doctor or pharmacist for advice.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible Side Effects**

Like all medicines, Desmospray can cause side effects, although not everybody gets them.

**STOP USING DESMOSPRAY if you experience:**

- allergic reactions including itching, skin rashes, swelling of the face, lips or throat, difficulty in breathing, wheeziness, chest tightness or coughing
- unusually bad or prolonged headache, confusion, unexplained weight gain, ankle swelling, nausea or vomiting (signs and symptoms of water retention which can occur if too much fluid is consumed)

Low levels of sodium in your blood can lead to fits. This is more likely to happen if you drink large amounts of fluid while receiving this medication.

If you experience any of the above side effects you should contact your doctor or go to the nearest casualty department immediately.

**Other side effects associated with Desmospray are listed below, starting with the most common.**

**Very common:** may affect more than 1 in 10 people

- blocked or runny nose

- *reported primarily in children and adolescents:* body temperature increased

**Common:** may affect up to 1 in 10 people

- trouble sleeping (insomnia)
- nose bleeds
- gastroenteritis
- abdominal pain (primarily in connection with hyponatraemia)
- *reported primarily in children and adolescents:* emotional instability, nightmare, nervousness, aggression, upper respiratory tract infection

**Not known:** frequency cannot be estimated from the available data

- dehydration
- convulsions, coma
- dizziness
- sleepiness
- high blood pressure
- shortness of breath (dyspnoea)
- diarrhoea
- hives
- muscle spasms
- fatigue
- swelling due to a build-up of fluid
- chest pain
- chills

If you experience any of the above side effects, you should contact your doctor or go to the nearest casualty department immediately.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Desmospray**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep container in the outer carton. Store in an upright position.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information****What Desmospray contains**

The active substance is desmopressin acetate. Each spray contains 10 micrograms of desmopressin acetate. Each vial contains a volume of 6 ml to allow the delivery of 60 sprays.

The other ingredients are citric acid monohydrate, disodium phosphate dihydrate, sodium chloride, benzalkonium chloride solution 50% and purified water.

**What Desmospray looks like and contents of the pack**

Desmospray is a solution for nasal use only. It is presented in a glass vial with a pump spray device.

**Marketing Authorisation Holder**

Ferring Ireland Ltd., United Drug House, Magna Drive, Magna Business Park, Citywest Road, Dublin 24

PA 1009/5/1


**Manufacturer**


Ferring GmbH, Wittland 11, D-24109 Kiel, Germany

**This leaflet was last revised in 02/2015.**

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