

Desmopressin Spray 10 micrograms/dose Nasal Spray solution

Desmopressin

Read all of this leaflet carefully before you start taking 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 your 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.

What is in this leaflet:

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

The name of your medicine is “Desmopressin Spray, 10 micrograms/dose, nasal spray, solution” (referred to as Desmopressin Spray throughout this leaflet).

① What Desmopressin Spray is and what it is used for

Desmopressin Spray contains the active ingredient desmopressin which belongs to a group of medicines called “posterior pituitary lobe hormones, vasopressin and analogues”. Desmopressin is very similar to a natural hormone in the body which can reduce the amount of urine that the body produces.

Desmopressin Spray is used to treat diabetes insipidus; this is a condition which causes extreme thirst and the production of large volumes of dilute urine.

Desmopressin Spray can also be used to test how well your kidneys are working.

② What you need to know before you take Desmopressin Spray

Do not take Desmopressin Spray:

- If you are allergic to desmopressin or any of the other ingredients of this medicine (listed in Section 6).
- If you have primary polydipsia (compulsive water drinking) or excessive thirst due to alcohol abuse.
- If you have or have had hyponatremia (low levels of sodium in your blood).
- If you have heart failure or any other condition requiring treatment with a diuretic medicine (“water tablets”).
- If you have a condition known as “syndrome of inappropriate secretion of diuretic hormone” (your doctor will have told you if you have this condition).
- If you have polyuria (producing too much urine) which has not been diagnosed as diabetes insipidus.
- If you have Type IIb von Willebrand’s disease (your doctor will have told you if you have this disease).
- If you have thrombotic thrombocytopenic purpura (TTP), a blood disorder causing small blood clots to form in blood vessels around the body (your doctor will have told you if you have this disorder).

Warnings and precautions:

Talk to your doctor or pharmacist before taking Desmopressin Spray. If any of the following apply to you, tell your doctor or pharmacist so that they can closely monitor your treatment and any worsening of these conditions:

- If you have heart disease
- If you have problems with your kidneys
- If you have cystic fibrosis
- If you are pregnant or trying to become pregnant
- If you have swelling or scarring on the lining inside your nose.

It will be normal for your doctor to monitor your bodyweight and blood pressure during treatment with Desmopressin Spray.

If you suffer from vomiting and/or diarrhoea, stop taking Desmopressin Spray until you feel better.

Other medicines and Desmopressin Spray

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The following medicines may increase the effect of Desmopressin Spray and lead to side effects:

- Clofibrate (for treatment of high cholesterol)
- Chlorpromazine (for schizophrenia)
- Carbamazepine (for epilepsy)
- Tricyclic antidepressants (for depression)
- Serotonin reuptake inhibitors (for depression)
- Non steroidal anti-inflammatory medicinal products (for pains and inflammatory conditions).

The following medicines may reduce the effect of Desmopressin Spray:

- Glibenclamide (for diabetes)
- Lithium (for depression).

Desmopressin may increase the effects of some medicines used to treat low blood pressure.

Desmopressin may reduce the effects of some medicines used to treat high blood pressure.

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Desmopressin Spray with food and drink

Your doctor will tell you to reduce your fluid intake while taking Desmopressin Spray to avoid your body retaining too much fluid. Otherwise this can lead to headache, nausea (feeling sick), tummy cramps, and in severe cases it can cause fits.

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.

Driving and using machines

Desmopressin Spray has no known effect on the ability to drive and use machines.

③ How to take Desmopressin Spray

Desmopressin Spray should only be used by the nasal route. Always take Desmopressin Spray exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The recommended doses are given below.

Treatment of diabetes insipidus

Adults: 1 or 2 sprays each day (2 sprays should be given as one spray into each nostril).

Children and Adolescents below 18 years: 1 spray each day.

Your doctor may increase the dose to 4 sprays each day (taken as one spray into each nostril, in the morning and at bedtime).

To test how well your kidneys are working:

The dosage will depend on your weight and will vary from 1 to 4 sprays.

Before using the spray, you will be asked to empty your bladder. Samples of your urine will then be taken at regular intervals after you have used the spray. Your fluid intake will also be restricted during the first 12 hours after using the spray.

Instructions for use:

Before using Desmopressin Spray for the first time, you must prime the nozzle (i.e. fill it with the medicine). To do this remove the protective cap. Then hold the bottle upright (Figure 1) and pump the nozzle up and down 3 times, spraying into the air until an even mist is seen. Desmopressin Spray is now ready to use.

1. **Blow your nose.** Remove the protective cap.
2. Hold the bottle as shown in Figure 2.
3. Tilt your head back and insert the tip of the nozzle into your nostril, as shown. Spray into the nostril while breathing in slightly. When pressing the pump down, ensure that you apply even pressure and press down quickly to produce a consistent spray.
4. If necessary, spray into the other nostril in the same way.
5. Wipe the nozzle with a clean tissue and replace the protective cap. Store the bottle in an upright position.

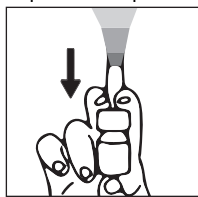


Figure 1

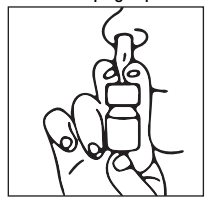


Figure 2

If the spray is not used within 7 days of the previous dose, re-prime by pressing the nozzle at least once before using.

Ensure that the dip-tube is in the liquid when using Desmopressin Spray. Hold the bottle as upright as possible when using (see figure 2).

Make sure you do not run out of Desmopressin Spray

The nasal spray has been designed to deliver 60 sprays of your medicine. However, it has **also been designed to contain a ‘fill overage’** so there will always be a small amount of fluid left over in the bottle which it is not possible to use. Please make sure that your nasal spray **is replaced in advance of you taking 60 sprays and within 4 weeks of first opening/using the product** so that you can be certain that you will not run out of the medicine, especially if you have to re-prime the spray between uses.

If you take more Desmopressin Spray than you should

Talk to your doctor or pharmacist straight away and also reduce your fluid intake. An overdose of this medicine can lead to headache, nausea (feeling sick), tummy cramps, and in severe cases it can cause fits.

If you forget to take Desmopressin Spray

Do not worry. Simply leave out that dose completely and then take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Desmopressin Spray

The symptoms may return that you had before starting treatment.

④ Possible side effects

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

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

If you suffer from a headache with nausea (feeling sick) and/or vomiting, or you have a “fit” (convulsion), contact your doctor straight away.

The following side effects have also been reported:

Common side effects

(may affect up to 1 in 10 people)

- Conjunctivitis (red eyes caused by an infection)
- asthenia (weakness).

Uncommon side effects

(may affect up to 1 in 100 people)

- Nasal congestion
- epistaxis (nose bleeds)
- rhinitis (runny nose)
- nausea (feeling sick)
- abdominal cramps
- vomiting
- headache.

Rare side effects

(may affect up to 1 in 1,000 people)

- Cerebral oedema (water on the brain)
- hyponatremia (low levels of sodium in the blood).

Very rare

(may affect up to 1 in 10,000 people)

- Emotional disturbance (in cases of bedwetting)
- allergic reactions, e.g. pruritus (itching), exanthema (rash)
- fever
- bronchospasms (difficulty in breathing or wheezing)
- anaphylaxis (serious allergic reaction which causes difficulty in breathing or dizziness).

Due to increased water reabsorption, blood pressure may rise and in some cases hypertension (high blood pressure) may develop. If you suffer from coronary heart disease, chest pain (angina) may occur.

These side effects, except for allergic reactions, may be prevented or disappear if the Desmopressin dose is reduced. Tell your doctor straight away if you get any of these side effects.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (website: www.mhra.gov.uk/yellowcard). By reporting side effects, you can help provide more information on the safety of this medicine.

⑤ How to store Desmopressin Spray

Keep Desmopressin Spray out of the sight and reach of children.

Store in the original package.

Do not store above 25°C.

Store in an upright position.

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

Discard 4 weeks after first opening. 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 Desmopressin Spray contains:**

- The active substance is desmopressin (as acetate trihydrate) 100 micrograms/ml.
- The other ingredients are citric acid monohydrate, disodium phosphate dihydrate, sodium chloride and water for injections.

What Desmopressin Spray looks like and the contents of the pack:

Your medicine is a nasal spray solution containing 100 micrograms desmopressin acetate trihydrate per ml of solution.

Each spray delivers 10 micrograms of desmopressin acetate trihydrate. The 6ml bottle contains 60 doses (sprays). There will always be a small amount of fluid left over in the bottle which it is not possible to use.

The spray is contained in a brown glass bottle fitted with a metering pump.

Marketing Authorisation Holder:

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