

Desmopressin PH&T, Nasal Sapray

IMPORTANT: Please read this leaflet carefully before using Desmopressin PH&T nasal spray.

What is in this leaflet

This leaflet is intended to answer questions you may have about Desmopressin PH&T nasal spray. It does not replace the advice from your doctor or pharmacist. If you have any questions before, during or after using this medication be sure to ask your doctor or pharmacist.

What is DESMOPRESSIN PH&T Nasal Spray

Each actuation (press of the nozzle) delivers 10 micrograms of desmopressin acetate. The spray also contains the inactive ingredients sodium chloride, hydrochloric acid (for pH adjustment), chlorobutanol hemihydrate (preservative) and purified water.

What is DESMOPRESSIN PH&T Nasal Spray used for and how does it work

The active ingredient of DESMOPRESSIN PH&T Nasal Spray (desmopressin acetate) is a synthetic version of a natural hormone in the body called antidiuretic hormone (ADH). It has a number of different actions in the body, including an action on the kidneys to reduce the amount of urine produced. This means that DESMOPRESSIN PH&T nasal spray can be used for several different conditions. DESMOPRESSIN PH&T nasal spray is most commonly used to treat nocturnal enuresis (bedwetting) in patients who have the normal ability to concentrate urine. DESMOPRESSIN PH&T nasal spray may also be used for treatment of antidiuretic hormone (ADH)-sensitive Cranial Diabetes Insipidus (CDI) or testing if the kidneys have the ability to concentrate urine.

Checklist before using DESMOPRESSIN PH&T nasal spray

When should Desmopressin PH&T nasal spray not be used

Desmopressin PH&T nasal spray is not suitable for some patients. You should not use Desmopressin PH&T nasal spray if you:

- have a known allergy to any of the ingredients in this medication.
- are in the habit of drinking large amounts of fluid.
- have heart disease or any other disease for which you take diuretics (fluid tablets).

What precautions should be taken

The presence of other medical problems may affect the use of Desmopressin PH&T nasal spray. Please tell your doctor before you are started on Desmopressin PH&T nasal spray if you:

- have a known allergy to anti-diuretic hormone (ADH).
- have too little or too much fluid in the body.
- currently have a nasal infection or blocked up or runny nose.
- have heart or blood vessel disease.
- have low blood pressure.
- have cystic fibrosis or any other disease which causes fluid or salt imbalance.
- have any disease of the blood clotting cells (platelets).

It is very important when using Desmopressin PH&T nasal spray to keep your body water at a constant level and that you do not let yourself get too thirsty or drink too much fluid. You should only drink a few sips of water or other fluids for one hour before and 8 hours after you take your dose of Desmopressin PH&T nasal spray.

If you are elderly

You may be more sensitive to the effects and side-effects of this medication. You should be careful how much fluid you drink.

Use in children

Desmopressin PH&T nasal spray can be used by children 5 years of age and older. It is important that their fluid intake is checked carefully while they are using Desmopressin PH&T nasal spray.

If you are pregnant or breastfeeding

Desmopressin PH&T nasal spray should only be given to a pregnant woman if it is needed. You should discuss this with your doctor. It is recommended that you do not breastfeed whilst using Desmopressin PH&T nasal spray.

Can Desmopressin PH&T nasal spray be used with other medications

Desmopressin PH&T nasal spray may interact with some other medications. Before you start to take Desmopressin PH&T nasal spray, you must tell your doctor or pharmacist if you are taking any other medications, including any that you have bought at a pharmacy or supermarket. It is especially important if you are taking:

indomethacin (can increase the effects of Desmopressin PH&T)

medications which are known to release anti-diuretic hormone eg. tricyclic antidepressants, chlorpromazine or carbamazepine as they can increase the risk of fluid build up in the body.

This is not a complete list of all medications which may interact with Desmopressin PH&T nasal spray, so you must remember to tell your doctor or pharmacist that you are taking Desmopressin PH&T nasal spray before any new medication is started.

Does Desmopressin PH&T nasal spray interact with alcohol

No problems have been reported.

Does Desmopressin PH&T nasal spray affect driving or other activities needing alertness

Desmopressin PH&T nasal spray does not cause drowsiness and has no effect on the ability to drive or operate machinery.

How do I use DESMOPRESSIN PH&T nasal spray

Desmopressin PH&T nasal spray is meant to be sprayed into the nostrils.

Before you use Desmopressin PH&T nasal spray for the first time, the pump will need to be primed. This is done by removing the protective cap from the applicator and pressing the collar of the applicator downwards 5 times, or until an even spray is obtained. . If you have not used DESMOPRESSIN PH&T Nasal Spray for more than one week, it is necessary to prime it again by pressing it downwards once, or until an even spray appears. Your doctor will tell you how many sprays to use and how often.

The Instructions for Use:

Gently blow your nose to clear it.

1. Remove the protective cap from the applicator.
2. Hold the bottle in one hand with second and third fingers on collar of spray.
3. Tilt your head backwards slightly. Insert the nasal applicator into one nostril. Hold your breath as you administer the dose (press down with fingers on collar of spray to release one dose).
4. If more than 1 dose is prescribed by your doctor, repeat the administration in the other nostril. Use alternate nostrils for each additional dose.
5. Replace the protective cap. Always store the bottle upright.

It is very important that these instructions are followed closely to make sure that you will always receive the correct dose of your medication.

It is very important when using Desmopressin PH&T nasal spray to keep your body water at a constant level and that you do not let yourself get too thirsty or drink too much fluid.

You should only drink a few sips of water or other fluids for one hour before and 8 hours after you take your dose of Desmopressin PH&T nasal spray.

Some of the details for Desmopressin PH&T nasal spray will vary depending on the purpose for which it is being used. For example, how much Desmopressin PH&T nasal spray you need to use, how long you need to use it, what you can expect after using it and what happens if you stop using it. You should discuss these details with your doctor.

What do I do if I miss a dose

Take the next dose at the usual time. Do not take a double dose.

What about side effects

All medicines can cause unwanted effects and this may occur with the normal use of Desmopressin PH&T nasal spray. Some patients may experience side effects such as headache, dizziness or nausea, flushing, mild stomach cramps, sore eyes or nosebleeds. Some patients develop 'flu' like symptoms including nasal congestion, runny nose, sore throat or

cough, chills and weakness. Your doctor will be monitoring for the more severe side-effect of loss of fluid and salt balance.

When you are taking Desmopressin PH&T nasal spray you must not drink too much fluid or your body will retain too much water which could cause unwanted side effects including low salt levels, weight gain, lethargy, confusion and, in severe cases blackouts, convulsions or fitting.

If you experience these or other side effects you should tell your doctor or pharmacist.

You should remember that all medications carry some risks. It is possible that all risks might not yet have been detected despite many years of experience with the medication.

What about overdose

You should only use the number of sprays you have been told. If you accidentally deliver too many actuations of the Desmopressin PH&T nasal spray, immediately telephone your doctor or Poisons Information Centre (03 474-7000) for advice, or go to the nearest hospital emergency department even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Possible signs of overdose may include confusion, drowsiness, continuing headache, fitting, problems with passing urine and rapid weight gain due to a build-up of water in the body.

How should I store DESMOPRESSIN PH&T nasal spray

Keep Desmopressin PH&T nasal spray in a safe place where children cannot reach it.

Desmopressin PH&T nasal spray should be stored in upright position at 2 – 8°C (in the refrigerator), in the original package. Desmopressin PH&T can also be stored at 25°C after opening. Discard contents after 2 months.

Discard contents 2 months after opening.

Desmopressin PH&T nasal spray should not be used after the expiry date (month/year) which is printed on the bottle. Unused or expired medication should be disposed of properly. Ask your pharmacist if you are unsure of how to dispose of your old medication.

Is there any other information I should know

Desmopressin PH&T nasal spray is only available with a doctor's prescription.

Where do I go to find more information on DESMOPRESSIN PH&T nasal spray?

This leaflet does not contain the complete information about Desmopressin PH&T nasal spray. It is only a summary. If you have any questions about the information or about your medication please speak to your doctor or pharmacist who have more detailed information and can advise you.

Name and Address of Sponsor:

Desmopressin PH&T Nasal Spray is distributed in New Zealand by:

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YOU MAY WISH TO READ THIS LEAFLET AGAIN. DO NOT THROW IT AWAY UNTIL YOU
HAVE FINISHED USING THIS MEDICATION.