

MINIRIN[®] NASAL DROPS

DESMOPRESSIN ACETATE

Consumer Medicine Information

IMPORTANT: Please read this leaflet carefully before using MINIRIN[®] Nasal Drops. This leaflet is intended to answer questions you may have about MINIRIN[®] Nasal Drops. 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 Minirin[®] Nasal Drops?

MINIRIN Nasal Drops contains 2.5mL solution. Each mL contains 100 micrograms of the active ingredient, desmopressin acetate (DDAVP). It also contains the inactive ingredients chlorbutanol as a preservative, sodium chloride, hydrochloric acid to adjust the acid/alkali balance and purified water.

What is MINIRIN[®] Nasal Drops used for and how does it work?

The active ingredient in MINIRIN[®] Nasal Drops (desmopressin acetate) is a synthetic version of a natural hormone in the body, called antidiuretic hormone (ADH). It has a number of different actions on the body including an action on the kidneys to reduce the amount of urine produced. This means that MINIRIN[®] Nasal Drops can be used for several different conditions.

MINIRIN[®] Nasal Drops is most commonly used to treat nocturnal enuresis (bedwetting) in patients over 5 years who have the normal ability to concentrate urine.

It may also be used for treatment of antidiuretic hormone (ADH)-sensitive Central Diabetes Insipidus (CDI) or testing if the kidneys have the ability to concentrate urine.

Before using Minirin[®] Nasal Drops

When should Minirin[®] Nasal Drops not be used?

MINIRIN[®] Nasal Drops is not suitable for some patients. You should not use MINIRIN[®] Nasal Drops 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).
- have a disease (SIADH) which causes excessive release of antidiuretic hormone (ADH).
- have moderate or severe renal insufficiency.
- have low levels of sodium in your bloodstream.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

The presence of other medical problems may affect the use of MINIRIN Nasal Drops. Please tell your doctor before you are started on MINIRIN Nasal Drops 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).
- have serious problems with bladder function or with passing urine.

MINIRIN Nasal Drops should only be used when MINIRIN Tablets are inappropriate. This is because a side-effect that can change the fluid and salt balance in your body is less common with tablets. For further information, please discuss this with your doctor.

It is very important when using MINIRIN Nasal Drops 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 MINIRIN Nasal Drops.

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

MINIRIN Nasal Drops can be used by children from 5 years of age and older. It is very important that the child's fluid intake is checked carefully while they are using MINIRIN Nasal Drops. Children who are less than one year of age and need to be tested for the ability of the kidney to concentrate

urine should receive this test under careful supervision in hospital.

It is important to ensure adult supervision when a child is administering MINIRIN Nasal Drops.

If you are pregnant or breastfeeding

MINIRIN Nasal Drops 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 MINIRIN Nasal Drops.

Can MINIRIN Nasal Drops be used with other medications?

MINIRIN Nasal Drops may interact with some other medications. Before you start to take MINIRIN Nasal Drops, 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:

- medications which may increase or decrease the effects of MINIRIN Nasal Drops e.g. indomethacin.
- medications which are known to release antidiuretic hormone e.g. tricyclic antidepressants, SSRIs, chlorpromazine or carbamazepine, as they can increase the risk of fluid build up in the body.
- medications which may induce water retention/hyponatraemia (e.g. NSAIDs).

This is not a complete list of all medications which may interact with MINIRIN Nasal Drops, so you must remember to tell your doctor or pharmacist that you are taking MINIRIN Nasal Drops before any new medication is started.

Does MINIRIN Nasal Drops interact with alcohol?

No problems have been reported.

Does MINIRIN Nasal Drops affect driving or other activities needing alertness?

MINIRIN Nasal Drops does not cause drowsiness and has no effect on the ability to drive or operate machinery.

How to use MINIRIN[®] Nasal Drops

The required dose should be loaded from the dropper bottle into the plastic catheter according to the detailed Instructions for Use in the pack.

One end of the catheter is placed into the mouth and the other end into the nostril and the contents of the catheter are blown into the nasal cavity.

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

It is very important when using MINIRIN Nasal Drops 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 MINIRIN Nasal Drops.

Some of the details for MINIRIN Nasal Drops will vary depending on the purpose for which it is being used:

If you are using MINIRIN Nasal Drops for bedwetting

How much MINIRIN Nasal Drops do I need to use?

The starting dose of MINIRIN Nasal Drops for both children and adults is 10 micrograms into each nostril at bedtime. The dose will

then be adjusted by your doctor according to your response.

How long do I need to use MINIRIN Nasal Drops?

Most patients will need an initial treatment period of one to three months. The treatment is then stopped for one week to assess the cure rate. If your pre-treatment urination pattern returns then a further one to three month treatment period may be necessary.

What can I expect after using MINIRIN Nasal Drops?

MINIRIN Nasal Drops can provide an increase in the number of “dry nights” per week and in some patients is able to completely prevent night-time bedwetting.

What do I do if I miss a dose?

If you miss your bedtime dose, do not take another dose until the next night. You can then return to your regular bedtime dosing schedule. **Do not take a double dose.**

What happens if I stop using MINIRIN Nasal Drops?

If you suddenly stop using MINIRIN Nasal Drops for bedwetting you may find that your night-time bedwetting will return.

If you are using MINIRIN Nasal Drops for ADH sensitive cranial diabetes insipidus

How much MINIRIN Nasal Drops do I need to use?

The average daily dose for adults is 10-40 micrograms. The dose for children will vary between 5-20 micrograms. The dose you receive will be adjusted to suit your personal requirement. MINIRIN Nasal Drops is usually given in two doses each day. Sometimes a single daily dose is sufficient to control your condition.

How long do I need to use MINIRIN Nasal Drops?

It is likely that you will need to use MINIRIN Nasal Drops or other forms of MINIRIN for the rest of your life.

What can I expect after using MINIRIN Nasal Drops?

MINIRIN Nasal Drops can prevent or control the thirst and frequent urination associated with CDI. You will be less thirsty and urinate a smaller volume less often.

What do I do if I miss a dose?

If you miss a dose, take your missed dose as soon as you remember. You will then have to adjust the time of your next dose. When this is done, go back to your regular dosing schedule. You should speak to your doctor about this situation.

Do not take a double dose.

What happens if I stop using MINIRIN Nasal Drops?

If you suddenly stop using MINIRIN Nasal Drops you may find that your thirst and frequent urination will return.

If you are using MINIRIN Nasal Drops to test the ability of the kidneys to concentrate urine

How much MINIRIN Nasal Drops do I need to use?

Adults will receive a single dose of up to 40 micrograms at any one time. Children under 1 year of age will receive a single dose of up to 10 micrograms at any one time and over 1 year of age up to 20 micrograms at any one time.

Children who are less than one year of age and need to be tested for the ability of the kidney to concentrate urine should receive this test under careful supervision in hospital.

How long do I need to use MINIRIN Nasal Drops?

Your doctor will explain how the test works.

Side effects

All medicines can cause unwanted effects and this may occur with the normal use of MINIRIN Nasal Drops. Most people using MINIRIN Nasal Drops find it causes few problems. Some patients may experience side effects such as rapid heartbeat, a drop in blood pressure, headache, nausea, mild abdominal cramp, vomiting, nasal congestion, facial flushing, vulval pain. Your doctor will be monitoring for the more severe side-effect of loss of fluid and salt balance.

When you are taking MINIRIN 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 OVERDOSAGE?

If you accidentally take too much of the MINIRIN Nasal Drops, immediately telephone your doctor or Poisons Information Centre, telephone 0800 POISON or 0800 764766 for advice, or go to the nearest hospital Accident and Emergency department. 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 to store MINIRIN[®] Nasal Drops

Keep MINIRIN Nasal Drops in a safe place where children cannot reach it.

Store MINIRIN Nasal Drops in a refrigerator at a temperature between 2 and 8°C. Do not freeze. Keep it in its original packaging and protect it from light.

MINIRIN Nasal Drops 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?

MINIRIN Nasal Drops is only available with a doctor's prescription.

WHERE DO I GO TO FIND MORE INFORMATION ON MINIRIN NASAL DROPS?

This leaflet does not contain the complete information about MINIRIN Nasal Drops. 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.

Distributor

MINIRIN Nasal Drops is distributed in NZ by:

Pharmaco (NZ) Ltd, PO Box 4079, Auckland 1140.

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This leaflet was prepared in June 2017.

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