

# MINIRIN® NASAL SPRAY

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using MINIRIN Nasal Spray?

MINIRIN Nasal Spray contains the active ingredient desmopressin acetate, which is a synthetic version of a naturally occurring

substance produced in the brain called vasopressin. It is used for several different conditions including **primary nocturnal enuresis (bedwetting)**, **cranial diabetes insipidus** and as a **diagnostic test to establish the kidneys ability to concentrate urine in adults**.

For more information, see Section [1. Why am I using MINIRIN Nasal Spray?](#) in the full CMI.

### 2. What should I know before I use MINIRIN Nasal Spray?

Do not use if you have ever had an allergic reaction to desmopressin acetate or any of the ingredients listed at the end of the CMI. (see Section [7. Product details](#) in the full CMI.) **Talk to your doctor if you have any**

**other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use MINIRIN Nasal Spray?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with MINIRIN Nasal Spray and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use MINIRIN Nasal Spray?**

MINIRIN Nasal Spray is meant to be sprayed into the nostrils. Do not inhale (sniff the spray).

- **Bedwetting (nocturnal enuresis)** - The usual starting dose is one spray (10 micrograms) into each nostril at bedtime. The dose will then be adjusted by your doctor according to your response. The maximum dose is two sprays in each nostril (40 micrograms).
- **Cranial diabetes insipidus** - For children the daily doses vary up to two sprays (20 micrograms). For adults the daily doses vary up to four sprays (40 micrograms). The daily dose is usually given as two divided doses. Sometimes a single daily dose is sufficient to control your condition.
- **Test the ability of the kidneys to concentrate urine**
  - If you are an adult, you will require a single dose of up to 40 micrograms at any one time. If you are

a child, you will require a single dose of up to 10 micrograms at any one time.

More instructions can be found in Section [4. How do I use MINIRIN Nasal Spray?](#) in the full CMI.

## 5. What should I know while using MINIRIN Nasal Spray?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using MINIRIN Nasal Spray.</li><li>• If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use MINIRIN Nasal Spray to treat any other complaints unless your doctor tells you to do so.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep MINIRIN Nasal Spray in the original container in upright position to protect from moisture and light until it is time to use it.</li><li>• Store it in a cool dry place, where the</li></ul>

	temperature stays below 25°C, away from moisture, heat or sunlight.
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For more information, see Section [5. What should I know while using MINIRIN Nasal Spray?](#) in the full CMI.

## **6. Are there any side effects?**

All medicines can have side effects. Most of them are minor and temporary but some may need medical attention.

Tell your doctor if you experience any side effects, including headache, stomach pain, nausea or vomiting, rapid weight gain, confusion or drowsiness. These are signs and symptoms of hyponatraemia (low sodium levels in the blood), an uncommon, but serious possible side effect of MINIRIN Nasal Spray. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# MINIRIN® NASAL SPRAY

**Active ingredient(s):** *desmopressin acetate*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using MINIRIN Nasal Spray. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MINIRIN Nasal Spray.**

**Where to find information in this leaflet:**

- [1. Why am I using MINIRIN Nasal Spray?](#)
- [2. What should I know before I use MINIRIN Nasal Spray?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MINIRIN Nasal Spray?](#)
- [5. What should I know while using MINIRIN Nasal Spray?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using MINIRIN Nasal Spray?

MINIRIN Nasal Spray contains the active ingredient desmopressin acetate. MINIRIN Nasal Spray is a synthetic version of the naturally occurring substance produced in the brain called vasopressin.

MINIRIN Nasal Spray has several different actions on the body including an action on the kidney to reduce the amount of urine produced. It is used for several different conditions including:

- primary nocturnal enuresis (bedwetting) in patients over 6 years of age, who have a normal ability to concentrate urine and who have not responded to treatment with an enuresis alarm or in patients in whom an enuresis alarm is contraindicated or inappropriate and where the oral administration of desmopressin is not feasible
- cranial diabetes insipidus (large amounts of urine being produced day and night and constant thirst)
- as a diagnostic test to establish if the kidneys have the ability to concentrate urine.

## **2. What should I know before I use MINIRIN Nasal Spray?**

### **Warnings**

#### **Do not use MINIRIN Nasal Spray if:**

- you are allergic to desmopressin, or any of the ingredients listed at the end of this leaflet
- you suffer from polydipsia (excessive thirst and increased fluid intake) or psychogenic polydipsia (psychologically caused increased thirst and increased fluid intake) or where you are in the habit of drinking large amounts of fluid

- you have cardiac insufficiency (shortness of breath, swelling of the feet or legs due to fluid build-up)
- you are taking diuretics (water or fluid tablets)
- you have moderately or severely reduced kidney function where you pass little or no urine
- you have low levels of sodium in your blood (hyponatraemia)
- you have a disorder which causes excessive release of anti-diuretic hormone (SIADH), resulting in weakness, tiredness or confusion
- you are breast-feeding
- for a child under the age of 6 years. Safety and effectiveness in children younger than 6 years have not been established
- the expiry date printed on the pack has passed
- the package is torn or shows signs of tampering.

Always check the ingredients to make sure you can use this medicine.

**MINIRIN Nasal Spray should only be used when oral forms of MINIRIN are inappropriate.**

This is because a side-effect that can change the fluid and salt balance in your body is less common with oral forms. For further information, please discuss this with your doctor.

### **Check with your doctor if you:**

- have any other medical conditions especially the following:
  - a known allergy to anti-diuretic hormone

- too little or too much fluid in the body
- a nasal infection, blocked or runny nose
- heart or blood vessel disease or any other disease for which you take diuretics
- low blood pressure
- cystic fibrosis or any medical condition causing fluid and/or electrolyte imbalance
- any medical condition that could be made worse by fluid and/or electrolyte disturbance
- any disease of the blood clotting cells (platelets)
- serious problems with bladder function or with passing urine.
- raised pressure within your head (increased intracranial pressure)
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

MINIRIN Nasal Spray should only be used in a pregnant woman if necessary. Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.



The active ingredient in MINIRIN Nasal Spray passes into breast milk.

**Do not breastfeed if you are using this medicine.**

If you have not told your doctor about any of the above, tell him/her before you start using MINIRIN Nasal Spray.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with MINIRIN Nasal Spray and affect how it works.**

**Medicines that may increase the effect of MINIRIN Nasal Spray include:**

- medications which are known to release antidiuretic hormone (e.g. tricyclic antidepressants, selective serotonin reuptake inhibitors (SSRIs) chlorpromazine, carbamazepine) or some medications (such as chlorpropamide) which are known to treat high blood sugar (diabetes), as they can increase the risk of fluid buildup in the body
- medicines used to treat high blood pressure and some other conditions (ACE inhibitors or angiotensin receptor blockers e.g. enalapril, perindopril, irbesartan etc.)
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain and inflammation.

NSAIDs may induce water retention/low sodium levels in the blood (hyponatraemia).

These medicines may be affected by MINIRIN Nasal Spray or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MINIRIN Nasal Spray.**

#### **4. How do I use MINIRIN Nasal Spray?**

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

The instructions on how to use MINIRIN Nasal Spray are included in the carton.

Prime the spray before using it for the first time by pressing it at least four times, or until an even spray is obtained. If the spray has not been used during the last 7 days, it is necessary to prime it again by pressing it a couple of times until an even spray is obtained before placing the nozzle in the nostril.

It is very important for you to follow these instructions closely to make sure that you will always receive the correct dose of your medication. MINIRIN Nasal Spray

is meant to be sprayed into the nostrils. **Do not inhale (sniff the spray).**

If you do not understand the instructions in the leaflet, ask your doctor or pharmacist for help.

## **How much to use**

Some of the details for MINIRIN Nasal Spray will vary depending on the purpose for which it is used.

### **Bedwetting (nocturnal enuresis)**

- The usual starting dose is one spray (10 micrograms) into each nostril at bedtime. The dose will then be adjusted by your doctor according to your response. The maximum dose is two sprays in each nostril (40 micrograms).
- Fluid intake should be limited in preparation for your dose of MINIRIN Nasal Spray (see '**Things to be careful of**').

### **Cranial diabetes insipidus**

- The dose you need will be adjusted to suit your personal requirements. The daily dose is usually given as two divided doses. Sometimes a single daily dose is sufficient to control your condition.
- For children the daily doses vary up to two sprays (20 micrograms). For adults the daily doses vary up to four sprays (40 micrograms).
- Since MINIRIN Nasal Spray cannot deliver doses less than 10 micrograms per spray, the MINIRIN Intranasal

Solution and the rhinyle delivery system will need to be used, if lower doses are needed.

Follow the instructions provided and use MINIRIN Nasal Spray until your doctor tells you to stop.

## **When to use MINIRIN Nasal Spray**

### **Bedwetting (nocturnal enuresis)**

- MINIRIN Nasal Spray should be used at bedtime.

### **Cranial diabetes insipidus**

- MINIRIN Nasal Spray should be used at times specified by your doctor.

## **How long to use MINIRIN Nasal Spray**

**Continue using your medicine for as long as your doctor tells you.**

This medicine helps to control your condition but does not cure it. It is important to keep using your medicine even if you feel well.

### **Bedwetting (nocturnal enuresis)**

- MINIRIN Nasal Spray for bedwetting is usually taken for periods up to three months.
- After this period, you should have at least one week without MINIRIN Nasal Spray to check if your bedwetting has stopped. If not, continue for another three months.

### **Cranial diabetes insipidus**

- Your doctor will advise you.

### **Test the ability of the kidneys to concentrate urine**

- Your doctor will advise you.

## **If you forget to use MINIRIN Nasal Spray**

### **Bedwetting (nocturnal enuresis)**

- Skip the missed dose and take the next dose when you are meant to.

### **Cranial diabetes insipidus**

- Take the next dose as soon as you remember. You will then have to adjust the time of the following dose. When this is done, go back to taking your medicine as you would normally. You should talk to your doctor about this situation. Do not take a double dose.
- If you are not sure what to do, ask your doctor or pharmacist.
- If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

### **Test the ability of the kidneys to concentrate urine**

- If you are an adult, you will require a single dose of up to 40 micrograms at any one time.
- If you are a child, you will require a single dose of up to 10 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 require this test under careful supervision in hospital.

## **If you use too much MINIRIN Nasal Spray**

If you think that you have used too much MINIRIN Nasal Spray, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

Symptoms of an overdose may include confusion, drowsiness, continuing headache, nausea or vomiting, rapid weight gain due to a build-up of water in the body, or, in severe cases, convulsions.

## **5. What should I know while using MINIRIN Nasal Spray?**

### **Things you should do**

- If you are about to start any new medicine, remind your doctor and pharmacist that you are using MINIRIN Nasal Spray.
- **If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.**

- It may affect other medicines used during surgery.
- **If you become pregnant while using this medicine, tell your doctor immediately.**
- **If you are about to have any blood tests, tell your doctor that you are using this medicine.**
- It may interfere with the results of some tests.
- **Keep all your doctor's appointments so that your progress can be checked.**
- Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.
- Remind any doctor, dentist or pharmacist you visit that you are using MINIRIN Nasal Spray.

## **Things you should not do**

- **Do not use MINIRIN Nasal Spray to treat any other complaints unless your doctor tells you to do so.**
- Do not give your medicine to anyone else, even if they have the same condition as you.
- **Do not stop using your medicine or change the dosage without checking with your doctor.**
- If you stop taking it suddenly, your condition may worsen.

## **Things to be careful of**

**All patients on treatment with this medicine should avoid excessive fluid intake as this may lead to a build-up of water in the body.**

### **Bedwetting (nocturnal enuresis)**

- **You must avoid drinking fluids from one hour before using MINIRIN Nasal Spray until at least eight hours after administration of the nasal spray.**
- Over this period, drink no more than a few sips of water or other fluids. This is because a high fluid intake during this period can increase the chance that you will feel unwell (e.g. headache, nausea, dizziness).
- **Remember to drink normally throughout the day.**
- This is very important to prevent dehydration.

### **Cranial diabetes insipidus**

- **Carefully follow your doctor's instruction about fluid intake.**
- It is very important to keep your body water in balance, so that you do not let yourself get too thirsty or drink too much fluid.

### **Test the ability of the kidneys to concentrate urine**

- **You must avoid drinking fluids from one hour before using MINIRIN Nasal Spray until at least eight hours after administration of the nasal spray.**
- Over this period, drink no more than a few sips of water or other fluids. This is because a high fluid intake during this period can increase the chance that you will feel unwell (e.g. headache, nausea, dizziness).



## **Driving or using machines**

This medicine is not expected to affect your ability to drive a car or operate machinery.

## **Looking after your medicine**

**Keep MINIRIN Nasal Spray in the original container in upright position to protect from moisture and light until it is time to use it.**

If you store the medicine out of its original packaging it may not keep well.

Store it in a cool dry place, where the temperature stays below 25°C, away from moisture, heat or sunlight.

For example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Follow the instructions in the carton on how to take care of your medicine properly.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date. The expiry date refers to the last day of that month.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

If you are an elderly patient, you may have an increased chance of getting side effects.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

### Side effects

Side effects	What to do
<b>Very common side effects (affects 1 or more in 10 users):</b> <ul style="list-style-type: none"><li>• nasal congestion</li></ul>	<b>These side effects are not usually serious but can become serious.</b>

Side effects	What to do
<ul style="list-style-type: none"> <li>• runny or blocked nose, sneezing, facial pressure or pain</li> <li>• increased body temperature (fever).</li> </ul> <p><b>Common side effects (affect less than 1 in 10 users):</b></p> <ul style="list-style-type: none"> <li>• trouble sleeping</li> <li>• nightmare</li> <li>• nervousness</li> <li>• nosebleed</li> <li>• upper respiratory tract infection</li> <li>• inflammation of stomach and intestines</li> </ul> <p><b>Hyponatraemia or low sodium levels in the blood may have the following signs or symptoms (uncommon side effects - affect less than 1 in 100 users):</b></p> <ul style="list-style-type: none"> <li>• headache</li> <li>• stomach pain</li> <li>• nausea or vomiting.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

Side effects	What to do
Hyponatraemia can potentially become a serious side effect, see below.	

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• emotional, behavioural or visual disturbances</li> </ul> <p><b>Hypersensitivity or allergic reactions (unknown frequency):</b></p> <ul style="list-style-type: none"> <li>• shortness of breath, wheezing or</li> <li>• difficulty breathing</li> <li>• swelling of the face, lips, tongue</li> <li>• or other parts of the body</li> <li>• rash, itching or hives on the skin.</li> <li>•</li> </ul> <p><b>*Hyponatraemia or low sodium levels in the blood may have the</b></p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

Serious side effects	What to do
<p><b>following serious signs or symptoms:</b></p> <ul style="list-style-type: none"> <li>• confusion or drowsiness</li> <li>• continuing headache</li> <li>• nausea or vomiting</li> <li>• rapid weight gain or swelling of hands, ankles or feet, which may be due to a buildup of water in your body</li> <li>• convulsions, fitting and blackouts (including coma)</li> </ul> <p><b>*These side effects are rare.</b></p>	

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using MINIRIN Nasal Spray.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side

effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What MINIRIN Nasal Spray contains

<b>Active ingredient (main ingredient)</b>	desmopressin acetate
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• sodium chloride</li><li>• citric acid monohydrate</li><li>• dibasic sodium phosphate dihydrate</li><li>• benzalkonium chloride</li><li>• purified water</li></ul>

**MINIRIN Nasal Spray:** Contains 10 micrograms desmopressin acetate per one actuation/spray.

**Do not use this medicine if you are allergic to any of these ingredients.**

## **What MINIRIN Nasal Spray looks like**

MINIRIN Nasal Spray 6 mL is supplied in a brown, glass bottle equipped with a pre-compression spray pump delivering 60 doses of 10 micrograms desmopressin acetate. (AUST R 59320)

## **Who distributes MINIRIN Nasal Spray**

Ferring Pharmaceuticals Pty Ltd

Suite 2, Level 1, Building 1

20 Bridge Street

Pymble NSW 2073

Toll free: 1800 337 746

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