

# MINIRIN(R) INTRANASAL SOLUTION

*desmopressin acetate*

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## CONSUMER MEDICINE INFORMATION

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### IMPORTANT

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Please read this leaflet carefully before using MINIRIN Intranasal Solution. This leaflet is intended to answer questions you may have about MINIRIN Intranasal Solution. 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.

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### WHAT IS MINIRIN INTRANASAL SOLUTION ?

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MINIRIN Intranasal Solution 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.

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### WHAT IS MINIRIN INTRANASAL SOLUTION USED FOR AND HOW DOES IT WORK ?

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The active ingredient of MINIRIN Intranasal Solution (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 MINIRIN Intranasal Solution can be used for several different conditions.

MINIRIN Intranasal Solution is most commonly used for treatment of antidiuretic hormone (ADH)-sensitive Cranial Diabetes Insipidus (CDI) or testing if the kidneys have the ability to concentrate urine.

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### CHECKLIST BEFORE USING MINIRIN INTRANASAL SOLUTION

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#### ***When should MINIRIN Intranasal Solution not be used?***

MINIRIN Intranasal Solution is not suitable for some patients. You should not use MINIRIN Intranasal Solution 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.

#### ***What precautions should be taken?***

The presence of other medical problems may affect the use of MINIRIN Intranasal Solution. Please tell your doctor before you are started on MINIRIN Intranasal Solution if you:

- \* have a known allergy to antidiuretic 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).

MINIRIN Intranasal Solution 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 Intranasal Solution 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 Intranasal Solution.

### ***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***

It is very important that the child's fluid intake is checked carefully while they are using MINIRIN Intranasal Solution. 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.

### ***If you are pregnant or breastfeeding***

MINIRIN Intranasal Solution 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 Intranasal Solution.

### ***Can MINIRIN Intranasal Solution be used with other medications?***

MINIRIN Intranasal Solution may interact with some other medications. Before you start to take MINIRIN Intranasal Solution, 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 Intranasal Solution e.g. indomethacin, glibenclamide, clofibrate or chlorpromamide.
- \* medications which are known to release anti-diuretic hormone e.g. tricyclic antidepressants, chlorpromazine or carbamazepine, as they can increase the risk of fluid build up in the body.
- \* medications which may induce water retention/hyponatraemia (eg NSAIDs).

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

### ***Does MINIRIN Intranasal Solution interact with alcohol?***

No problems have been reported.

### ***Does MINIRIN Intranasal Solution affect driving or other activities needing alertness?***

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

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## **HOW DO I USE MINIRIN INTRANASAL SOLUTION?**

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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 a 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 Intranasal Solution 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 Intranasal Solution.**

**Some of the details for MINIRIN Intranasal Solution will vary depending on the purpose for which it is being used:**

***If you are using MINIRIN Intranasal Solution for ADH sensitive cranial diabetes insipidus***

**How much MINIRIN Intranasal Solution do I need to use?**

The average daily dose for adults is 10-40 micrograms. The dose for children will vary between 2.5-20 micrograms. The dose you receive will be adjusted to suit your personal requirement. MINIRIN Intranasal Solution 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 Intranasal Solution?**

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

### **What can I expect after using MINIRIN Intranasal Solution?**

MINIRIN Intranasal Solution 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 Intranasal Solution?**

If you suddenly stop using MINIRIN Intranasal Solution you may find that the thirst and frequent urination will return.

### ***If you are using MINIRIN Intranasal Solution to test the ability of the kidneys to concentrate urine***

### **How much MINIRIN Intranasal Solution do I need to use?**

Adults will receive a single dose of up to 40 micrograms at any one time. Children will receive a single dose of 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 Intranasal Solution?**

Your doctor will explain the details of the test.

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## **WHAT ABOUT SIDE-EFFECTS?**

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All medicines can cause unwanted effects and this may occur with the normal use of MINIRIN Intranasal Solution. Most people using MINIRIN Intranasal Solution 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.

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## **WHAT ABOUT OVERDOSAGE?**

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If you accidentally take too much of the MINIRIN Intranasal Solution, immediately telephone your doctor or Poisons Information Centre for advice, or go to the nearest hospital casualty 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.

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## **HOW SHOULD I STORE MINIRIN INTRANASAL SOLUTION?**

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Keep MINIRIN Intranasal Solution in a safe place where children cannot reach it.

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

MINIRIN Intranasal Solution 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.

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## **IS THERE ANY OTHER INFORMATION I SHOULD KNOW ?**

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MINIRIN Intranasal Solution is only available with a doctor's prescription.

The Australian Pituitary Foundation can provide further information on cranial diabetes insipidus.

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## **WHERE DO I GO TO FIND MORE INFORMATION ON MINIRIN INTRANASAL SOLUTION?**

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This leaflet does not contain the complete information about MINIRIN Intranasal Solution. 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:***

Ferring Pharmaceuticals Pty Ltd  
Suite 2B, Level 2, 802 Pacific  
Highway,  
Gordon, NSW, 2072

### ***AUSTRALIAN REGISTER NUMBER:***

AUST R 16828

MINIRIN(R) is a registered  
trademark of Ferring A/B.

### ***DATE OF INFORMATION:***

October 2007

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