

# MINIRIN(R) INJECTION

## CONSUMER MEDICINE INFORMATION

### IMPORTANT:

Please read this leaflet carefully before using MINIRIN Injection. This leaflet is intended to answer questions you may have about MINIRIN Injection. 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 INJECTION ?

MINIRIN Injection contains 4 micrograms of the active ingredient, desmopressin acetate, in 1mL solution. It is a clear colourless solution for injection packed in 1mL ampoules. The ampoules are available in boxes of 10. MINIRIN Injection also contains the inactive ingredients, sodium chloride, hydrochloric acid to adjust the acid/alkali balance and Water for Injections.

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

The active ingredient of MINIRIN Injection (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 Injection can be used for

several different conditions.

MINIRIN Injection may be used for treatment of antidiuretic hormone (ADH)-sensitive Cranial Diabetes Insipidus (CDI) where intranasal administration is inconvenient.

It may also be used in adults by intramuscular administration for testing if the kidneys have the ability to concentrate urine.

### CHECKLIST BEFORE USING MINIRIN INJECTION

#### ***When should MINIRIN Injection NOT be used?***

MINIRIN Injection is not suitable for some patients. You should not use MINIRIN Injection 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 MINIRIN Injection. Please tell your doctor before you are started on MINIRIN Injection if you:

- \* have a known allergy to antidiuretic hormone (ADH).
- \* have too little or too much fluid

in the body.

- \* 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 MINIRIN Injection 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 Injection.

#### ***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 Injection. It is not recommended for use in children to test if the kidneys have the ability to concentrate urine.

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

MINIRIN Injection 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 Injection.

## **Can MINIRIN Injection be used with other medications?**

MINIRIN Injection may interact with some other medications. Before you start to take MINIRIN Injection, 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 Injection e.g. indomethacin, glibenclamide, clofibrate or chlorpromamide.
- \* medications which are known to release antidiuretic hormone e.g. 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 the medications which may interact with MINIRIN Injection, so you must remember to tell your doctor or pharmacist that you are taking MINIRIN Injection before any new medication is started.

## **Does MINIRIN Injection interact with alcohol?**

No problems have been reported.

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

MINIRIN Injection 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 INJECTION?**

MINIRIN Injection is not intended for self administration. MINIRIN may be given by injection into a muscle or into a vein, depending on its use.

It is very important when using MINIRIN Injection 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 Injection.**

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

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## **If MINIRIN Injection is being used for ADH sensitive cranial diabetes insipidus**

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### **How much MINIRIN Injection will be used?**

The average daily dose for adults is 1 - 4 micrograms by injection. The dose for children will be up to 400 nanograms daily. The dose you receive will be adjusted to suit your personal requirement. MINIRIN Injection 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 Injection?**

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

### **What can I expect after using MINIRIN Injection?**

MINIRIN Injection 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 Injection?**

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

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## **If MINIRIN Injection is being used to test the ability of the kidneys to concentrate urine**

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### **How much MINIRIN Injection will be used?**

Adults will receive a single dose of up to 4 micrograms at any one time.

### **How long do I need to use MINIRIN Injection?**

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 Injection. Most people using MINIRIN Injection 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 are accidentally given too much of the MINIRIN Injection, 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 INJECTION?**

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

Store MINIRIN Injection 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 Injection should not be used after the expiry date (month/year) which is printed on the pack. 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 Injection 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 INJECTION?**

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This leaflet does not contain the complete information about MINIRIN Injection. 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 40689

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

### **DATE OF INFORMATION:**

November 2001

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