

MINIRIN[®] INJECTION

DESMOPRESSIN ACETATE

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 on 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 Central 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 and for control of prolonged bleeding or von Willebrand's/haemophilia during surgery.

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).
- have chest pain or Willebrand's type IIB

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 Injection. Please tell your doctor before you are started on MINIRIN Injection if you:

- have a known allergy to anti-diuretic 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 important that the child's fluid intake is checked carefully while they are using MINIRIN Injection. It is not recommended to use the injection in children to test if the kidneys have the ability to concentrate urine, unless the intranasal form can't be used.

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.
- 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 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.

How to 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:

If you are using MINIRIN Injection for ADH sensitive cranial diabetes insipidus

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 2 micrograms 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.

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

How much MINIRIN Injection will be used?

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

Children above 1 year will receive up to 2 micrograms as a single dose and under 1 year olds up to 0.4 micrograms as a single dose.

How long do I need to use MINIRIN Injection?

Your doctor will explain the details of the test.

Side effects

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, allergic skin reactions, fatigue, 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 are accidentally given too much of the MINIRIN Injection, 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[®] Injection

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°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.

IS THERE ANY OTHER INFORMATION I SHOULD KNOW?

MINIRIN Injection is only available with a doctor's prescription.

WHERE DO I GO TO FIND MORE INFORMATION ON MINIRIN INJECTION?

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.

Distributor

MINIRIN Injection is distributed in NZ by:

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

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This leaflet was prepared in February 2009.

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