

MINIRIN(R) NASAL SPRAY

desmopressin acetate

CONSUMER MEDICINE INFORMATION

IMPORTANT

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

Each actuation (press of the nozzle) delivers 10 micrograms of desmopressin acetate (DDAVP). The spray also contains the inactive ingredients benzalkonium chloride as a preservative, sodium chloride, citric acid monohydrate/sodium phosphate (to adjust the acid/alkali balance) and purified water.

WHAT IS MINIRIN SPRAY USED FOR AND HOW DOES IT WORK ?

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

MINIRIN Spray is most commonly used to treat nocturnal enuresis (bedwetting) in patients who have the normal ability to concentrate urine. It is used in patients who have not responded to enuresis alarms (eg. pad and bell) or when such alarms are inappropriate.

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

CHECKLIST BEFORE USING MINIRIN SPRAY

When should MINIRIN Spray not be used?

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

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 Spray can be used by children 6 years of age and older. It is important that their fluid intake is checked carefully while they are using MINIRIN Spray.

It is important, to ensure adult supervision when a child is administering MINIRIN Spray.

If you are pregnant or breastfeeding

MINIRIN Spray 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 Spray.

If you become ill, whilst taking MINIRIN

Tell your doctor, who may wish to monitor your condition.

Can MINIRIN Spray be used with other medications?

MINIRIN Spray may interact with some other medications. Before you start to take MINIRIN Spray, 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 are known to release anti-diuretic hormone eg.

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 medications which may interact with MINIRIN Spray, so you must remember to tell your doctor or pharmacist that you are taking MINIRIN Spray before any new medication is started.

Does MINIRIN Spray interact with alcohol?

No problems have been reported.

Does MINIRIN Spray affect driving or other activities needing alertness?

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

HOW DO I USE MINIRIN SPRAY?

The Instructions for Use are included in the pack.

It is very important that these instructions are followed closely to make sure that you will always receive the correct dose of your medication. MINIRIN Spray is meant to be sprayed into the nostrils.

Before you use MINIRIN Spray for the first time, the pump will need to be primed. This is done by removing the protective cap from the applicator and pressing the white collar of the applicator downwards 4 times, or until an even spray is obtained. Reprime the pump if the bottle is left standing longer than 2 days.

Since the spray cannot deliver doses less than 10 micrograms per actuation, if smaller doses are needed, the MINIRIN Nasal Solution and the rhinyle delivery system will

need to be used.

It is very important when using MINIRIN Spray 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 Spray.

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

If you are using MINIRIN Spray for bedwetting

How much MINIRIN Spray do I need to use?

The starting dose of MINIRIN Spray for both children and adults is usually one actuation 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 Spray?

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 Spray?

MINIRIN Spray 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 Spray?

If you suddenly stop using MINIRIN Spray for bedwetting you may find

that your night-time bedwetting will return.

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

How much MINIRIN Spray 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 Spray 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 Spray?

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

What can I expect after using MINIRIN Spray?

MINIRIN Spray 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 Spray?

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

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

How much MINIRIN Spray 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 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 receive this test under careful supervision in hospital.

How long do I need to use MINIRIN Spray?

Your doctor will explain how the test works.

WHAT ABOUT SIDE EFFECTS?

All medicines can cause unwanted effects and this may occur with the normal use of MINIRIN Spray. Most people using MINIRIN Spray find it causes few problems. Some patients may experience side effects such as headache, dizziness or nausea, flushing, mild stomach cramps, sore eyes or nosebleeds. Some patients develop 'flu' like symptoms including nasal congestion, runny nose, sore throat or cough, chills and weakness. 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 deliver too many actuations of the MINIRIN Spray, 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.

HOW SHOULD I STORE MINIRIN SPRAY?

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

Store MINIRIN Spray below 25 degrees C. Do not freeze. Keep it in its original packaging and protect it from light.

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

The Continence Foundation of Australia in any capital city can provide further information on bladder problems including bedwetting.

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

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

This leaflet does not contain the complete information about MINIRIN Spray. 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 59320

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.**