

MINIRIN[®]

Nasal Spray

desmopressin acetate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MINIRIN Nasal Spray.

It does not contain all the available information. It does not replace of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking MINIRIN Nasal Spray against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What MINIRIN Nasal Spray is used for

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

It has a number of different actions on the body including an action on the kidney to reduce the amount of urine produced. This means that MINIRIN Nasal Spray can be 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

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

Before you use MINIRIN Nasal Spray

When you must not use it

Do not use MINIRIN Nasal Spray if you have an allergy to:

- any medicine containing desmopressin or any of the ingredients listed at the end of this leaflet.

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 use MINIRIN Nasal Spray if 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
- have cardiac insufficiency (heart failure in which the heart is not able to pump enough blood throughout the body resulting in shortness of breath, swelling of the feet or legs due to fluid build-up)
- you are taking diuretics (water or fluid tablets)
- have moderately or severely reduced kidney function where you pass little or no urine
- have low levels of sodium in your blood have SIADH (hormone secretion disorder where there is an overproduction of a hormone causing fluid retention, resulting in weakness, tiredness or confusion).

Do not breast-feed if you are using this medicine.

MINIRIN Nasal Spray is not recommended while you are breast-feeding.

Do not give this medicine to a child under the age of 6 years.

Safety and effectiveness in children younger than 6 years have not been established.

Do not use 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.

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.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, food, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- a known allergy to anti-diuretic hormone (ADH)
- too little or too much fluid in the body
- currently have a nasal infection or blocked up or runny nose
- heart or blood vessel disease or any other disease for which you take diuretics
- low blood pressure
- cystic fibrosis 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.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

MINIRIN Nasal Spray should only be used in a pregnant woman if necessary. Your doctor can discuss

with you the risks and benefits involved.

Do not breast-feed if you are using this medicine.

The active ingredient in MINIRIN Nasal Spray passes into breast milk. Therefore this medicine is not recommended while you are breast-feeding.

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

Taking other medicines

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

Some medicines and MINIRIN Nasal Spray may interfere with each other. These include:

- tricyclic antidepressants, which are medicines used to treat e.g. depression (such as clomipramine, imipramine, desipramine)
- selective serotonin reuptake inhibitors (SSRIs), which are medicines used to treat e.g. depression or anxiety (such as citalopram, paroxetine, sertraline)
- chlorpromazine, which is an anti-psychotic medicinal product used to treat e.g. schizophrenia
- carbamazepine, which is used to treat e.g. bipolar disorder and epilepsy
- antidiabetic medicinal products used for type II diabetes (medicines in the sulfonylurea group), particularly chlorpropamide
- 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), which are

medicinal products used for the treatment of pain and inflammation (e.g. aspirin and ibuprofen).

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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to 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.

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.

When to use it

Bedwetting (nocturnal enuresis)

- use MINIRIN Nasal Spray at bedtime.

Cranial diabetes insipidus

- use MINIRIN Nasal Spray at times specified by your doctor.

How long to use it

Continue taking 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 taking 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 a dose is missed

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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much MINIRIN Nasal Spray. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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.

While you are using MINIRIN Nasal Spray

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using MINIRIN Nasal Spray.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

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 of 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.

Things you must 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).

Side effects

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

This medicine helps most people but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 60 years of age you may have an increased chance of getting side effects.

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

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nasal congestion
- runny or blocked nose, sneezing, facial pressure or pain
- increased body temperature (fever)
- trouble sleeping
- nightmare
- nervousness
- headache
- nose bleed
- upper respiratory tract infection
- inflammation of the stomach and intestines
- stomach pain or nausea.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- emotional, behavioural or visual disturbances
- allergic reactions including skin rash or more general reactions.

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

If you notice any of the following, tell your doctor immediately or go

to Accident and Emergency at your nearest hospital:

- confusion or drowsiness
- continuing headache
- nausea or vomiting
- rapid weight gain, which may be due to a build-up of water in the body
- convulsions, fitting and blackouts.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using MINIRIN Nasal Spray

Storage

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

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

Keep MINIRIN Nasal Spray in a cool dry place where the temperature stays below 25°C.

Do not store MINIRIN Nasal Spray, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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Product description

What it looks like

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

Ingredients

MINIRIN Nasal Spray contains 10 micrograms of desmopressin acetate, as the active ingredient per one actuation/spray.

It also contains:

- sodium chloride
- citric acid monohydrate
- dibasic sodium phosphate dihydrate
- benzalkonium chloride
- purified water.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

MINIRIN Nasal Spray is supplied in Australia by:

Ferring Pharmaceuticals Pty Ltd

Suite 2, Level 1, Building 1

20 Bridge Street

Pymble, NSW 2073

Australia.

AUST R 59320 - MINIRIN
desmopressin acetate 10 microgram/
actuation nasal spray

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