

MINIRIN(R) TABLETS

DESMOPRESSIN ACETATE

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MINIRIN(R) Tablets.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking MINIRIN(R) 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(R) is used for

The active ingredient in MINIRIN(R) Tablets 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 kidney to reduce the amount of urine produced. This means that MINIRIN(R) Tablets can be used for several different conditions including:

- * nocturnal enuresis (bedwetting) in patients over 6 years who have a normal ability to concentrate urine.
- * cranial diabetes insipidus.

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 take Minirin(R)

When you must not take it

Do not take MINIRIN(R) if you

- * have an allergy to any medicine containing desmopressin or any of the ingredients listed at the end of this leaflet.
- * are in the habit of drinking large amounts of fluid
- * have cardiac insufficiency
- * have moderate or severe renal insufficiency
- * have low levels of sodium in your bloodstream
- * have a disease (SIADH) which causes excessive release of antidiuretic hormone (ADH).

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

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

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

- * 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 or any other disease for which you take diuretics
- * 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.

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

MINIRIN(R) Tablets should only be given to a pregnant woman if they are needed. Your doctor can discuss with you the risks and benefits involved. It is recommended that you do not breastfeed while using MINIRIN(R) Tablets.

If you have not told your doctor about any of the above, tell him/her before you start taking MINIRIN(R) Tablets.

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(R) Tablets may interfere with each other. These include:

- * loperamide
- * medications which are known to release antidiuretic 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)

These medicines may be affected by MINIRIN(R) 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 take MINIRIN(R)

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

Some of the details for MINIRIN(R) Tablets will vary depending on the purpose for which it is used.

How much to take

If MINIRIN(R) Tablets are being taken for bedwetting, the starting dose is 200 micrograms at bedtime. If this dose is inadequate, your doctor may recommend to increase the dose to 400 micrograms at bedtime. Fluid intake should be limited. (see Things to be careful of).

If you are taking MINIRIN(R) Tablets for cranial diabetes insipidus, the dose you receive will be adjusted to suit your personal requirement. A suitable starting dose in adults and children is 100 micrograms three times daily. For the majority of patients the maintenance dose is 100 micrograms to 200 micrograms three times daily.

When to take it

Food has not been shown to have a significant effect on the actions of MINIRIN(R) Tablets.

How long to take 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.

If a dose is missed

If MINIRIN(R) Tablets are being taken for bedwetting, skip the missed dose and take the next dose when you are meant to.

If you are taking MINIRIN(R) Tablets for cranial diabetes insipidus, take it as soon as you remember. You will then have to adjust the time of your next 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.

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(R) Tablets. 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(R)

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking MINIRIN(R).

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you become ill whilst taking Minirin, tell your doctor, who may wish to monitor your condition.

Things you must not do

Do not take MINIRIN(R) Tablets to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen.

Things to be careful of

It is very important when using MINIRIN(R) Tablets for primary nocturnal enuresis 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(R) Tablets.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MINIRIN(R).

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.

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:

- * headache
- * 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 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 due to a build up of water in the body,
- * convulsions

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(R)

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25 degrees C. Keep the container tightly closed and do not remove the dessicant capsule from the cap.

Do not store MINIRIN(R) tablets 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 taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

MINIRIN(R) Tablets are supplied in bottles of 30 tablets.

MINIRIN(R) Tablets 100 are white, oval and convex tablets with a single score and marked '0.1' on one side. (Not currently available in Australia).

MINIRIN(R) Tablets 200 are white, round and convex tablets with a single score and marked '0.2' on one side.

Do not use this product if the packaging appears damaged in any way. Do not take the tablets if they appear different from the descriptions above or if they look unusual in any way.

Ingredients

MINIRIN(R) Tablets 100 and 200 contain 100 micrograms and 200 micrograms of desmopressin acetate, respectively, as the active ingredient. They also contain:

- * povidone
- * lactose
- * potato starch

* magnesium stearate

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

Distributor

MINIRIN(R) Tablets are distributed in Australia by
Ferring Pharmaceuticals Pty Ltd
Suite 2B, Level 2,
802 Pacific Highway,
Gordon, NSW, 2072

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AUST R 93678 MINIRIN(R)100
AUST R 93731 MINIRIN(R) 200