

MINIRIN(R) Melt

DESMOPRESSIN

Sublingual (under the tongue) Wafer

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MINIRIN Melt.

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

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

The active ingredient in MINIRIN Melt 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 Melt 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 Melt

When you must not take it

Do not take MINIRIN Melt 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

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 date printed on the pack (expiry date), 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).

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

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

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

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 Melt may interfere with each other. These include:

- * loperamide, a medicine used to stop diarrhoea
- * medications which are known to release antidiuretic hormone (eg tricyclic antidepressants, selective serotonin reuptake inhibitors, chlorpromazine or carbamazepine) as they can increase the risk of fluid build up in the body.
- * Non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain and inflammation. NSAIDs may induce water retention/low sodium levels in the blood (hyponatraemia)

These medicines may be affected by MINIRIN Melt 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 Melt

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 pack, ask your doctor or pharmacist for help.

Some of the details for MINIRIN Melt will vary depending on the purpose for which it is used.

How to use

Do not push MINIRIN Melt through the foil.

Peel back the foil covering the

MINIRIN Melt and push up gently from below to remove the 'Melt'.

Place MINIRIN Melt under the tongue (sublingual). It will dissolve in seconds without the need for water.

How much to take

Bedwetting (nocturnal enuresis)

The starting dose is 120 micrograms at bedtime. If this dose is inadequate, your doctor may recommend that you increase the dose to 240 micrograms at bedtime. Fluid intake should be limited. (see Things to be careful of).

Cranial diabetes insipidus

The dose you receive will be adjusted to suit your personal requirements. A suitable starting dose in adults and children is 60 micrograms three times daily and for the majority of patients the maintenance dose is 60 to 120 micrograms three times daily. Your doctor will advise you further regarding the dose most suitable for you.

When to take it

Bedwetting (nocturnal enuresis)

Just before you go to bed

Cranial diabetes insipidus

At times specified by your doctor

You can take MINIRIN Melt with or without food.

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

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.

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 Melt. 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 Melt

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 Melt

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.

Things you must not do

Do not take MINIRIN Melt 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 Melt for bedwetting (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 Melt.

Side effects

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

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 Melt

Storage

Keep MINIRIN Melt in the blister pack until it is time to take it.

If you store them out of the blister pack they may not keep well.

Keep MINIRIN Melt in a cool dry place where the temperature stays below 25 degrees C.

Do not store MINIRIN Melt, 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 Melt 60 microgram is a white, round, sublingual (under the tongue) wafer, marked with a drop shaped figure on one side (Not currently available in Australia).

MINIRIN Melt 120 microgram is a white, round, sublingual (under the tongue) wafer, marked with two drop shaped figures on one side.

MINIRIN Melt 240 microgram is a white, round, sublingual (under the tongue) wafer, marked with three drop shaped figures on one side (Not currently available in Australia).

MINIRIN Melt comes in boxes of 10*, 30 or 100* wafers (*Not currently available in Australia).

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

Ingredients

MINIRIN Melt wafers contain either 60*, 120 or 240* micrograms of desmopressin (free base), as the active ingredient (*Not currently available in Australia).

They also contain:

- * gelatin
- * mannitol
- * citric acid

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

Distributor

MINIRIN Melt is distributed in Australia by Ferring Pharmaceuticals Pty Ltd

Suite 2B, Level 2, 802 Pacific Highway, Gordon, NSW, 2072

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AUST R 121721 MINIRIN(R) Melt 120

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