

MINIRIN[®] Melt

Desmopressin

Sublingual (under the tongue) wafers

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, desmopressin in Minirin Melt 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 Melt 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 whom an enuresis alarm is contraindicated or inappropriate

- cranial diabetes insipidus (large amounts of urine being produced day and night and constant thirst).

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.

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 Minirin Melt if you:

- are in the habit of drinking large amounts of fluid
- have cardiac insufficiency (shortness of breath, swelling of

the feet or legs due to fluid build-up)

- have kidney disease where you pass little or no urine
- have low levels of sodium in your bloodstream
- have a disease which causes excessive release of anti-diuretic hormone (ADH).

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

Minirin Melt 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 take this medicine after the 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.

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

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:

- a known allergy to anti-diuretic hormone (ADH)
- too little or too much fluid in the body

- heart or blood vessel disease or any other disease for which you take diuretics
- low blood pressure
- cystic fibrosis or any other disease which causes fluid or salt imbalance
- any disease of the blood clotting cells (platelets)
- serious problems with bladder function or with passing urine.

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

Minirin Melt should only be used in a pregnant woman if necessary. 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 following details for Minirin Melt will vary depending on the purpose for which it is used.

How to use it

When it is time for your dose, peel off the back of the foil on one of the blisters starting in the corner with the arrow.

Carefully push on the foil to remove the wafer. Do not try to push Minirin Melt through the blister foil.

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

Please read the detailed instruction leaflet in the box of Minirin Melt carefully.

How much to take

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

Bedwetting (nocturnal enuresis)

The usual starting dose for treatment of bedwetting is one wafer (120 micrograms) under the tongue at bedtime. If this dose does not adequately help resolve the

bedwetting, your doctor may recommend that you increase the dose to 240 micrograms under the tongue at bedtime (two 120 micrograms wafers, OR one 240 micrograms wafer).

Fluid intake should be limited in preparation for your dose of Minirin Melt (see 'Things to be careful of').

Cranial diabetes insipidus

The dose you need will be adjusted to suit your personal requirements. Doses up to 120 micrograms three times daily are often used. Your doctor will advise you about the dose most suitable for you.

When to take it

Bedwetting (nocturnal enuresis)

- take Minirin Melt at bedtime.

Cranial diabetes insipidus

- take Minirin Melt at times specified by your doctor.

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.

Bedwetting (nocturnal enuresis)

Minirin Melt for bedwetting is usually taken for periods up to 3 months.

After this period you should have at least one week without Minirin Melt to check if your bedwetting has stopped. If not, continue for another three months.

Cranial diabetes insipidus

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.

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 taking 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.

If you are about to have any blood tests, tell your doctor that you are taking 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 take Minirin Melt 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 taking 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

Bedwetting (nocturnal enuresis)

You must avoid drinking fluids from one hour before taking Minirin Melt until at least eight hours after administration.

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.

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.

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:

- 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, behavioural and 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 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 taking Minirin Melt

Storage

Keep Minirin Melt in the original container in order to protect from moisture and light until it is time to take it.

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

Keep Minirin Melt in a cool dry place where the temperature stays below 25°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 Melts are supplied in packs of 30s.

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

Minirin Melt 240 micrograms is a white, round, sublingual (under the tongue) wafer, marked with three drop shaped figures on one side.

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 sublingual wafers contain either 120 micrograms or 240 micrograms of desmopressin (free base), as the active ingredient.

They also contain:

- gelatin
- mannitol
- citric acid.

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

Sponsor

Minirin Melt is supplied in Australia by:

Ferring Pharmaceuticals Pty Ltd

Suite 2, Level 1, Building 1

20 Bridge Street

Pymble, NSW 2073

AUST R 121721

Minirin Melt desmopressin 120 micrograms sublingual wafers blister pack

AUST R 121722

Minirin Melt desmopressin 240 micrograms sublingual wafers blister pack

This leaflet was prepared in November 2012.