

MINIRIN[®] Melt

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking MINIRIN Melt?

MINIRIN Melt contains the active ingredient desmopressin, which is a synthetic version of a naturally occurring substance produced in the brain called vasopressin. It is used for several conditions including **primary nocturnal enuresis (bedwetting)** in patients over 6 years of age and **cranial diabetes insipidus**.

For more information, see Section [1. Why am I taking MINIRIN Melt?](#) in the full CMI.

2. What should I know before I take MINIRIN Melt?

Do not take if you have ever had an allergic reaction to desmopressin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take MINIRIN Melt?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MINIRIN Melt and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take MINIRIN Melt?

- MINIRIN Melt is placed under the tongue (sublingual). It will dissolve in seconds without the need for water.
- Bedwetting (nocturnal enuresis) - one (120 mcg) to two (240 mcg) wafers under the tongue at bedtime
- Cranial diabetes insipidus - doses up to 120 micrograms three times daily are often used.

More instructions can be found in Section [4. How do I take MINIRIN Melt?](#) in the full CMI.

5. What should I know while taking MINIRIN Melt?

Things you should do	<ul style="list-style-type: none">● Remind any doctor, dentist or pharmacist you visit that you are taking MINIRIN Melt.● 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.
Things you should not do	<ul style="list-style-type: none">● Do not take MINIRIN Melt to treat any other complaints unless your doctor tells you to do so.● 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.
Driving or using machines	<ul style="list-style-type: none">● This medicine is not expected to affect your ability to drive a car or operate machinery.

Looking after your medicine

- Keep MINIRIN Melt in the original container to protect from moisture and light until it is time to take it.
- Store it in a cool dry place, where the temperature stays below 25°C, away from moisture, heat or sunlight.

For more information, see Section [5. What should I know while taking MINIRIN Melt?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Most of them are minor and temporary but some may need medical attention.

Tell your doctor if you experience any side effects, including headache, stomach pain, nausea or vomiting, rapid weight gain, confusion or drowsiness. These are signs and symptoms of hyponatraemia (low sodium levels in the blood), a rare, but serious possible side effect of MINIRIN Melt. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

MINIRIN[®] Melt

Active ingredient: *desmopressin*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking MINIRIN Melt. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking MINIRIN Melt.**

Where to find information in this leaflet:

- [1. Why am I taking MINIRIN Melt?](#)
- [2. What should I know before I take MINIRIN Melt?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take MINIRIN Melt?](#)
- [5. What should I know while taking MINIRIN Melt?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking MINIRIN Melt?

MINIRIN Melt contains the active ingredient desmopressin, which is a synthetic version of a naturally occurring substance produced in the brain called vasopressin.

MINIRIN Melt has a few different actions on the body including on the kidney to reduce the amount of urine produced.

MINIRIN Melt is used for several 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).

2. What should I know before I take MINIRIN Melt?

Warnings

Do not take MINIRIN Melt if:

- you are allergic to desmopressin, or any of the ingredients listed at the end of this leaflet
- you are in the habit of drinking large amounts of fluid
- you have cardiac insufficiency (shortness of breath, swelling of the feet or legs due to fluid build-up)
- you have kidney disease where you pass little or no urine
- you have low levels of sodium in your bloodstream
- you have a disease which causes excessive release of anti-diuretic hormone

- you are breast-feeding
- you are a child under the age of 6 years. Safety and effectiveness in children younger than 6 years have not been established
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

Always check the ingredients to make sure you can take this medicine.

Check with your doctor if you:

- have any other medical conditions especially the following:
 - a known allergy to anti-diuretic hormone
 - 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
 - raised pressure within your head (increased intracranial pressure)
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

MINIRIN Melt should only be taken by a pregnant woman if necessary. Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is recommended that you do not breastfeed while taking MINIRIN Melt.

3. What if I am taking other medicines?

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

Some medicines may interfere with MINIRIN Melt and affect how it works.

Medicines that may increase the effect of MINIRIN Melt include:

- loperamide, a medicine used to stop diarrhoea

- medications which are known to release antidiuretic hormone (e.g. tricyclic antidepressants, selective serotonin reuptake inhibitors, chlorpromazine or carbamazepine) or some medications which are known to treat high blood sugar (diabetes), as they can increase the risk of fluid buildup 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 affect how well MINIRIN Melt works. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MINIRIN Melt.

4. How do I take MINIRIN Melt?

How much to take

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

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 (two 120 micrograms wafers, OR one 240 micrograms wafer) at bedtime.

- if after four weeks of MINIRIN Melt treatment there has been no resolution of the bedwetting, treatment should be stopped.
- 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.

Follow the instructions provided and take MINIRIN Melt until your doctor tells you to stop.

When to take MINIRIN Melt

- **Bedwetting (nocturnal enuresis)**
- take MINIRIN Melt at bedtime.

Cranial diabetes insipidus

- take MINIRIN Melt at times specified by your doctor.

How long to take MINIRIN Melt

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. Your doctor will decide whether continued treatment with MINIRIN is needed.
- **Cranial diabetes insipidus**
- Your doctor will advise you.

How to take MINIRIN Melt

- 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.

If you forget to take MINIRIN Melt

MINIRIN Melt should be taken regularly at the same time each day.

Bedwetting (nocturnal enuresis)

If you miss your dose at the usual time, 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 to make up for the dose you missed.

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 MINIRIN Melt

If you think that you have taken too much MINIRIN Melt, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include confusion, drowsiness, continuing headache, nausea or vomiting, rapid weight gain due to a buildup of water in the body, or, in severe cases, convulsions.

5. What should I know while taking MINIRIN Melt?

Things you should do

If you are about to be started on any new medicine, remind any doctor, dentist or pharmacist you visit that you are taking MINIRIN Melt.

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 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 should 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 the next morning (at least eight hours).
- 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 during daytime.

Cranial diabetes insipidus

- Carefully follow your doctor's instruction about fluid intake.
- It is very important to keep your body water in balance.

Driving or using machines

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

Looking after your medicine

- **Keep MINIRIN Melt in the original container 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.

Store it in a cool dry place, where the temperature stays below 25°C, away from moisture, heat or sunlight.

For example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.
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- Heat and dampness can destroy some medicines.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date. The expiry date refers to the last day of that month.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

If you are over 65 years of age, commencing MINIRIN Melt treatment is not recommended.

The elderly may be at an increased risk of some side effects.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

Side effects

Side effects	What to do
Hyponatraemia or low sodium levels in the blood may have the	These side effects are not usually serious but can become serious.

Side effects	What to do
<p>following signs or symptoms:</p> <ul style="list-style-type: none"> • headache • stomach pain • nausea. <p>Hyponatraemia can potentially become a serious side effect, see below.</p> <p>Uncommon side effects (affect less than 1 in 100 users):</p> <ul style="list-style-type: none"> • fatigue • diarrhoea. <p>Rare side effects (affect less than 1 in 1000 users):</p> <ul style="list-style-type: none"> • sleepiness <p>Side effects (unknown frequency):</p> <ul style="list-style-type: none"> • sweating • nosebleed. 	<p>Speak to your doctor if you have any of these side effects and they bother or worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • high blood pressure • bladder problems • emotional or behavioural disturbances • hallucinations. <p>*Hypersensitivity or allergic reactions (uncommon side effects - affect less than 1 in 100 users):</p> <ul style="list-style-type: none"> • 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. <p>*Hyponatraemia or low sodium levels in the blood may have the following serious signs or symptoms:</p> <ul style="list-style-type: none"> • confusion or drowsiness 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● continuing headache ● nausea or vomiting ● rapid weight gain or swelling of hands, ankles or feet, which may be due to a buildup of water in your body ● convulsions, fitting and blackouts (including coma) <p>*These side effects are rare.</p>	

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What MINIRIN Melt contains

Active ingredient (main ingredient)	desmopressin (free base)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• gelatin• mannitol• citric acid.
Potential allergens	contains sulfites and fish products

MINIRIN Melt 120 mcg: Contains desmopressin (free base) 120 mcg (equivalent to 136 mcg desmopressin (acetate)).

MINIRIN Melt 240 mcg: Contains desmopressin (free base) 240 mcg (equivalent to 272 mcg desmopressin (acetate)).

Do not take this medicine if you are allergic to any of these ingredients.

What MINIRIN Melt 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. (AUST R 121721)

Minirin Melt 240 micrograms is a white, round, sublingual (under the tongue) wafer, marked with three drop shaped figures on one side. (AUST R 121722)

Who distributes MINIRIN Melt

Ferring Pharmaceuticals Pty Ltd

Suite 2, Level 1, Building 1

20 Bridge Street

Pymble, NSW 2073

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