PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

MINIRIN ® Melt 60 µg sublingual tablet

MINIRIN ® Melt 120 µg sublingual tablet

MINIRIN ® Melt 240 µg sublingual tablet

Desmopressin (as acetate)

Contains sugar alcohol (mannitol 10,25 mg per dosage unit).

Sugar free

Read all of this leaflet carefully before you start taking MINIRIN® Melt or before you give MINIRIN® Melt sublingual tablets to your child

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- MINIRIN® Melt has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MINIRIN® Melt is and what it is used for
2. What you need to know before you take MINIRIN® Melt or give MINIRIN® Melt to your child
3. How to take MINIRIN® Melt or give MINIRIN® Melt to your child
4. Possible side effects
5. How to store MINIRIN® Melt
6. Contents of the pack and other information

1. What MINIRIN® Melt is and what it is used for

MINIRIN® Melt is intended for sublingual use (under the tongue) as an antidiuretic (reduces urine production).

MINIRIN® Melt is used to treat:

- Central diabetes insipidus (extreme thirst and the continuous production of large volumes of dilute urine). IMPORTANT: This should not be confused with diabetes mellitus (sugar diabetes).
- Primary nocturnal enuresis (bedwetting) in patients (from 5 years of age) with normal ability to concentrate urine.

2. What you need to know before you take MINIRIN® Melt or give MINIRIN® Melt to your child

Do not take MINIRIN® Melt:

- if you are hypersensitive (allergic) to desmopressin acetate or to any of the other ingredients of MINIRIN® Melt (listed in section 6)
- if you have a serious heart or kidney disease
- if you are taking diuretics (water tablets)
- if you suffer from moderate or severe kidney impairment
- if you have an abnormal intense thirst
- if you have a medical condition causing fluid and/or electrolyte imbalance
- if you have low serum sodium levels (hyponatraemia)

Warnings and precautions

Before you commence treatment with MINIRIN® Melt, you should have received appropriate advice concerning fluid intake, from your doctor. Excessive fluid and water intake may lead to a harmful build-up of water in the body.

When your child is using MINIRIN® Melt for bedwetting you must make sure that your child does not drink too much fluid in the evening. He/she must drink fluid only to satisfy thirst from 1 hour before until 8 hours after the intake of MINIRIN ® Melt. If the fluid intake is not controlled it may lead to headache, nausea, vomiting, and weight gain caused by too much fluid and/or electrolyte imbalance.

Tell your doctor or health care provider before taking MINIRIN® Melt:

- If you are taking a medicine for pain and/or inflammation containing non-steroidal anti-inflammatory drugs (also known as NSAIDs)
- If you are taking a medicine containing loperamide, for diarrhoea
- If you suffer from severe bladder dysfunction or bladder outlet obstruction
- If you have a medical condition that could be made worse by fluid and/or electrolyte disturbance e.g. heart or kidney problems
- If you are 65 years of age or older, have low serum sodium or a constant high urine volume

Other medicines and MINIRIN® Melt

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Certain medicines, taken concomitantly with MINIRIN® Melt, may cause an additive antidiuretic effect leading to an increased risk of water retention and electrolyte imbalance. Please tell your doctor if you are taking any of the following medicines:

- antidepressants (tricyclic antidepressants and selective serotonin reuptake inhibitors);
- chlorpromazine used to treat mental illness;
- anti-epileptic medicine carbamazepine;
- antidiabetic medicines of the sulfonylurea group;

- non-steroid anti-inflammatory drugs (NSAIDs);
- medicines used to treat high and low blood pressure;
- loperamide, used for diarrhoea.

MINIRIN® Melt with food or drink

Concomitant intake of food and fluid may reduce the effect of MINIRIN® Melt.

Pregnancy, breastfeeding and fertility

Safety of MINIRIN® Melt during pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking MINIRIN® Melt.

Blood pressure monitoring is recommended due to the increased risk of high blood pressure.

There is no information on how this medicine affects the ability to have children.

Driving and using machines

MINIRIN® Melt may cause drowsiness and dizziness and may affect your ability to drive and use machines.

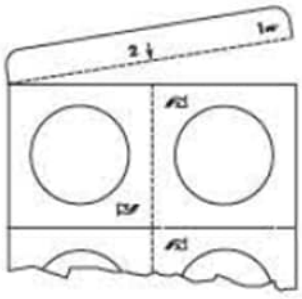
It is not always possible to predict to what extent MINIRIN® Melt may interfere with the daily activities of a patient. Patients should ensure that they do not engage in driving a vehicle or use machines until they are aware of the measure to which MINIRIN® Melt affects them.

3. How to take MINIRIN® Melt or give MINIRIN® Melt to your child

Do not share medicines prescribed for you with any other person.

Always take MINIRIN® Melt exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

It is important that you do not take more than the prescribed dose in any 24 hour period. If you have the impression that the effect of MINIRIN® Melt is too strong or too weak, talk to your doctor or pharmacist.



1. Completely remove the end tab of a blister strip by tearing along the perforations, starting from the corner with the hand symbol.
2. Now remove one blister from the strip by tearing along the perforations.
3. Remove the foil on each blister, starting at the corner with the printed arrow, by peeling off the foil in the direction of the arrow.
4. Carefully take a melt out of its blister. Place the melt under the tongue and allow it to dissolve.
5. If a melt breaks into more than two pieces while you are taking it out of its blister, do not take the broken pieces. Take a melt from another blister.

Treatment of diabetes insipidus

Your doctor will prescribe the dose most suitable for you. The total daily dose normally lies in the range of 120 micrograms to 720 micrograms. A suitable starting dose in adults and children is one MINIRIN® Melt 60 micrograms taken sublingually (under the tongue) three times a day. The most common doses in adults and children are either one MINIRIN® Melt 60 micrograms or one MINIRIN® Melt 120 micrograms taken sublingually (under the tongue) three times a day.

Primary nocturnal enuresis (bedwetting)

The recommended initial dose is 120 µg at bedtime, administered sublingually (under the tongue). If this is not sufficiently effective, your doctor may increase the dose up to 240 µg sublingually (under the tongue). Fluid restriction should be observed.

If the patient receiving MINIRIN® Melt displays signs or symptoms of water toxicity and/or hyponatraemia (headache, nausea/vomiting, weight gain, and in severe cases, convulsions) treatment should be interrupted until the patient has fully recovered. Your healthcare professional should be consulted.

MINIRIN® Melt is intended for treatment periods of up to 8 weeks. Your doctor will reassess the need for continued treatment by means of a period of at least one week without MINIRIN® Melt.

If you take more MINIRIN® Melt or give more MINIRIN® Melt to your child than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take MINIRIN® Melt or if you forget to give MINIRIN® Melt to your child

Do not take or give a double dose to make up for forgotten individual doses. If you forget to take MINIRIN® Melt, please consult your doctor or pharmacist for advice.

4. Possible side effects

MINIRIN® Melt can have side effects.

Not all side effects reported for MINIRIN® Melt are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MINIRIN® Melt, please consult your health care provider for advice.

If any of the following happens, stop taking MINIRIN® Melt and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to MINIRIN® Melt. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Hyponatraemia or low sodium levels in the blood may have the following signs or symptoms:
  - convulsions (seizures/ fits),
  - unusually bad or prolonged headache,
  - confusion,
  - unexplained weight gain,
  - nausea or vomiting.

If you experience one or more of these symptoms, stop taking MINIRIN® Melt.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

Adults:

- headache

- high blood pressure
- nausea, vomiting, stomach pain, diarrhoea and constipation
- dizziness
- urinary symptoms
- fatigue
- swelling due to the build up of fluid

Children and Adolescents:

- headache

Less frequent side effects:

Adults:

- trouble sleeping, sleepiness
- generalised physical weakness and/or a lack of energy and strength

Children and Adolescents:

- emotional disorder
- aggression
- symptoms of anxiety
- nightmares
- mood swings
- sleepiness
- high blood pressure
- stomach pain, nausea, vomiting, diarrhoea

- urinary symptoms
- irritability
- fatigue
- swelling due to a build up of fluid

Side effects with unknown frequency:

Adults:

- convulsions
- coma
- dehydration
- *Diabetes Insipidus indication only*: high blood sodium, weakness

Children and Adolescents:

- abnormal behaviour
- emotional disorder
- depression
- hallucination
- trouble sleeping
- disturbance in attention
- increased restlessness and movement
- convulsions
- nose bleeds
- allergic skin reactions, rash, sweating, hives

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of MINIRIN® Melt.

5. How to store MINIRIN® Melt

Store at or below 25 °C in the original package.

Protect from moisture and light.

Store all medicines out of reach of children.

Do not take MINIRIN® Melt after the expiry date on the packaging.

If you are unsure about the storage, ask your pharmacist. It is best to return all old and unused medicines to your pharmacist for safe disposal.

6. Contents of the pack and other information

What MINIRIN® Melt contains:

The active substance is desmopressin (as acetate).

MINIRIN® Melt 60 µg: Each unit contains 60 µg desmopressin (free base), added as desmopressin acetate.

MINIRIN® Melt 120 µg: Each unit contains 120 µg desmopressin (free base), added as desmopressin acetate.

MINIRIN® Melt 240 µg: Each unit contains 240 µg desmopressin (free base), added as desmopressin acetate.

The other ingredients are gelatine, mannitol and citric acid.

What MINIRIN® Melt looks like and contents of the pack

MINIRIN® Melt 60 µg: White, round, oral lyophilisate (freeze-dried sublingual tablet) marked with a drop shaped figure on one side.

MINIRIN® Melt 120 µg: White, round, oral lyophilisate (freeze-dried sublingual tablet) marked with two drop shaped figures on one side.

MINIRIN® Melt 240 µg: White, round, oral lyophilisate (freeze-dried sublingual tablet) marked with three drop shaped figures on one side.

MINIRIN® Melt sublingual tablets are packed in white oriented polyamide aluminium (bottom foil) and silver aluminium (top foil) blister strips containing 10 tablets per strip.

Pack sizes: 10, 30 and 100 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

FERRING (Pty) Ltd.

Route 21 Corporate Park

6 Regency Drive, Irene Ext 30, South Africa

Tel no: 012 345 6358

Manufactured by:

Catalent U.K Swindon Zydis Limited

Frankland Road

Blagrove, Swindon

Wiltshire, SN5 8RU, UK

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MINIRIN® Melt 60 µg: A42/18.2/0345

MINIRIN® Melt 120 µg: A42/18.2/0346

MINIRIN® Melt 240 µg: A42/18.2/0347

Namibia NS2	Reg. No/Nr: 18/18.2/0085 (60 microgram) Reg. No/Nr: 16/18/0156 (120 microgram) Reg. No/Nr: 16/18/0157 (240 microgram)