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Package leaflet: Information for the user

DesmoMelt® 120 micrograms oral lyophilisate DesmoMelt® 240 micrograms oral lyophilisate Desmopressin (as acetate)

Drawing
E-MS-3053

Size A
210x297mm

Fiber direction
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Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet, you may need to read it again
- If you have further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What DesmoMelt is and what it is used for
2. What you need to know before you take DesmoMelt
3. How to take DesmoMelt
4. Possible side effects
5. How to store DesmoMelt
6. Contents of the pack and other information

1. What DesmoMelt is what it is used for

DesmoMelt are oral lyophilisates, they look like tables but are much softer and lighter. Intended for sublingual use (to be placed under the tongue where it will dissolve completely). They are referred to as DesmoMelt or melt(s) in this leaflet.

DesmoMelt is available in two strengths: 120 or 240 micrograms. It contains Desmopressin acetate, an antidiuretic which reduces urine production.

DesmoMelt is used to treat:

- **Primary nocturnal enuresis** (bedwetting) in children (from 5 years of age) and adults (up to 65 years of age).

2. What you need to know before you take DesmoMelt

Do not take DesmoMelt:

- if you are allergic to desmopressin or any of the other ingredients of this medicine (listed in section 6)
- if you have a serious heart or kidney disease
- if you are taking diuretics (water tablets)
- if you drink unusually large quantities of fluids, including alcohol
- if you are under 5 or over 65 years old
- if you are taking medication for high blood pressure or have been told that your blood pressure is abnormal
- if you are suffering from habitual polydipsia (habitually increased fluid intake) or psychogenic polydipsia (mentally caused increased thirst and increased fluid intake)
- if you have low sodium levels in your blood (hyponatraemia)
- if you have conditions with increased ADH secretion (syndrome of inadequate ADH secretion)

You should avoid drinking large amounts of fluid while you are being treated with DesmoMelt, as this could lead to a build up of water which dilutes the salt in the body. This may lead to headaches, nausea/vomiting, weight gain and in severe cases convulsions.

Warnings and precautions:

Talk to your doctor or pharmacist before taking DesmoMelt.

Take special care with DesmoMelt:

- if you have an illness causing fluid and/or electrolyte imbalance e.g. vomiting, diarrhoea, systemic infections, fever or gastroenteritis
- if you have a medical condition that could be made worse by fluid and/or electrolyte disturbance. Condition where your blood sodium levels are too low or you are likely to build up too much water in your body
- if you have cystic fibrosis
- if you have difficulty in passing water (severe bladder dysfunction)

While taking DesmoMelt:

- fluid intake must be limited to a minimum from 1 hour before taking the dose at bedtime until the following morning (and, in any case, for at least 8 hours)
- stop taking this medicine when suffering from vomiting and/or diarrhoea until you are better
- swallowing water while swimming should be avoided because it could lead to a build up of water in the body.

DesmoMelt with food and drink:

DesmoMelt is taken together with food, the intensity and duration of effect may be reduced.

All patients, in case of children their parents and, where applicable, responsible nursing staff should be carefully instructed to adhere to the fluid restrictions.

Other medicines and DesmoMelt:

Please inform your doctor or pharmacist:

- if you are taking or have recently taken or used any other medicines, even those not prescribed
- if you are on medication for depression, epilepsy or type II diabetes
- if you are taking a medicine for pain and/or inflammation containing non-steroidal anti-inflammatory drugs (also known as NSAIDs) e.g. indometacin
- if you are taking a medicine containing loperamide for diarrhoea

Pregnancy, breast-feeding and fertility:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Blood pressure monitoring is recommended due to the increased risk of pre-eclampsia (a condition in pregnant women that can cause serious complications). Symptoms of pre-eclampsia include high blood pressure, oedema (swelling due to the build up of fluid).

3. How to take DesmoMelt

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

The usual starting dose is one DesmoMelt 120 micrograms sublingually (under the tongue) at bedtime. Depending on how well the bedwetting is controlled, your doctor may increase the dose to either two DesmoMelts 120 micrograms or one DesmoMelt 240 micrograms sublingually (under the tongue) at bedtime. The need for continued treatment is normally checked every three months.



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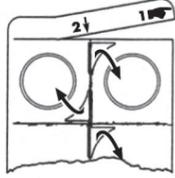
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PATIENT INSTRUCTION

DesmoMelt is intended for sublingual use, to be placed under the tongue where it will dissolve completely without the need for water.



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. **Do not put the melt through the foil.**
4. Carefully take a melt out of its blister. Place the melt under the tongue and allow it to dissolve completely. **Do not swallow or chew.**
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.

Do NOT take more than the prescribed dose in any 24 hour period.

If you have the impression that the effect of DesmoMelt is too strong or too weak, talk to your doctor or pharmacist.

If you take more DesmoMelt than you should:

If you take more DesmoMelt than you should, talk to your doctor or pharmacist immediately.

If you forget to take DesmoMelt:

Do not use a double dose to make up for a forgotten dose. If you forget to take this medicine please consult your doctor or pharmacist for advice.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You should avoid drinking large amounts of fluid while you are being treated with DesmoMelt, as this could lead to a build up of water which dilutes the salt in the body. This is a serious problem and may lead to convulsions.

STOP TAKING DesmoMelt if you experience:

- unusually bad or prolonged headache, confusion, unexplained weight gain, ankle swelling, nausea, vomiting, dizziness, feeling of general discomfort, memory impairment, feel a whirling or spinning (vertigo) or falls
- allergic reactions including itching, skin rashes, swelling of the face, lips or throat, difficulty in breathing, wheeziness, chest tightness or coughing

If you experience any of the above side effects, you should contact your doctor or go to the nearest casualty department immediately.

Common side effects may affect up to 1 in 10 people:

- headache

Uncommon side effects may affect up to 1 in 100 people:

- aggression
- emotional instability
- stomach pain
- nausea
- vomiting
- diarrhoea
- urinary symptoms
- swelling of the tissue in the lower limbs (Oedema peripheral)
- tiredness (Fatigue)

Rare side effects may affect up to 1 in 1,000 people:

- symptoms of anxiety
- nightmares
- mood swings
- sleepiness (somnolence)
- high blood pressure
- irritability

Other side effects:

- anaphylactic reactions (severe allergic reactions)
- low levels of sodium in the blood (hyponatraemia)
- abnormal behaviour
- emotional disorder
- depression
- hallucination
- trouble sleeping (Insomnia)
- increased restlessness and movement (psychomotor hyperactivity)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store DesmoMelt

Keep DesmoMelt out of the sight and reach of children.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture and light.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What DesmoMelt contains

- The active substance is desmopressin added as desmopressin acetate. Each oral lyophilisate contains 120 or 240 micrograms of desmopressin.
- The other ingredients are gelatin, mannitol (E421) and citric acid, anhydrous.

What DesmoMelt looks like and contents of the pack

The DesmoMelt oral lyophilisates are flat, round and white. Each melt is marked on one side with two or three drops, indicating a strength of 120 or 240 micrograms respectively.

Each carton contains 30 melts in blister strips of 10 melts per strip.

Marketing Authorisation Holder:

Ferring Pharmaceuticals Ltd.
Drayton Hall, Church Road., West Drayton, UB7 7PS, (UK).

Manufacturer:

Ferring GmbH, Wittland 11, D-24109 Kiel, Germany.

DesmoMelt 120 micrograms oral lyophilisate
PL 03194/0094

DesmoMelt 240 micrograms oral lyophilisate
PL 03194/0095

This leaflet was last revised in December 2018.

DesmoMelt is a registered trademark of Ferring BV.