

Desmopressin Melt 120 micrograms oral lyophilisate

Desmopressin Melt 240 micrograms oral lyophilisate

PATIENT INFORMATION

desmopressin acetate

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet, you may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Important things that you need to know:

- Desmopressin Melt is used to treat primary nocturnal enuresis (bedwetting) in children (from 5 years of age) and adults (up to 65 years of age).
- You should avoid drinking large amounts of fluid while you are being treated with Desmopressin Melt, 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.
- If you experience unusually bad or prolonged head ache, confusion, unexplained weight gain, ankle swelling, nausea or vomiting STOP USING Desmopressin Melt. You should tell your doctor immediately or go to the casualty department at your nearest hospital.

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine.

In this leaflet:

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

1. What Desmopressin Melt is and what it is used for

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

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

Desmopressin Melt is used:

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

2. Before you take Desmopressin Melt

There are general restrictions, precautions and warnings which apply to all patients using Desmopressin Melt.

General restrictions:

Do not take Desmopressin Melt if you:

- have a serious heart or kidney disease
- are taking diuretics (water tablets)
- are allergic to any of the ingredients listed in section 6 of this leaflet
- drink unusually large quantities of fluids, including alcohol
- are under 5 or over 65 years old
- are taking medication for high blood pressure or have been told that your blood pressure is abnormal

You should avoid drinking large amounts of fluid while you are being treated with Desmopressin Melt, 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.

General precautions and warnings:

Please consult your doctor before taking Desmopressin Melt if you:

- have an illness causing fluid and/or salt imbalance e.g. vomiting, diarrhoea, systemic infections, fever or gastroenteritis
- 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
- have cystic fibrosis

While taking Desmopressin Melt:

- 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.

Taking/using other medicines:

Please inform your doctor or pharmacist if you:

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

Pregnancy:

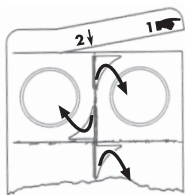
If you are pregnant or planning a pregnancy, please inform your doctor before you take Desmopressin Melt, as blood pressure monitoring is recommended due to the increased risk of pre-eclampsia (a condition in pregnant women that can cause serious complications).

Symptoms of pre-eclampsia include high blood pressure, oedema (swelling due to the build up of fluid).

3. How to take Desmopressin Melt

PATIENT INSTRUCTION

It is important to use your medicine as directed by your doctor. Desmopressin Melt is intended for sublingual use (to be placed under the tongue where it will dissolve completely).



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 completely.**
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 Desmopressin Melt is too strong or too weak, talk to your doctor or pharmacist.

The usual dose:

The usual starting dose is one Desmopressin Melt 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 Desmopressin Melts 120 micrograms or one Desmopressin Melt 240 micrograms sublingually (under the tongue) at bedtime. The need for continued treatment is normally checked every three months.

If you take more of this medicine than you should:

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

If you forget to take this medicine:

Do not take double doses to make up for forgotten doses. Take the next dose at the usual time.

4. Possible side effects

Like all medicines Desmopressin Melt can have side effects.

You should avoid drinking large amounts of fluid while you are being treated with Desmopressin Melt, 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 USING Desmopressin Melt if you experience:

- unusually bad or prolonged headache, confusion, unexplained weight gain, ankle swelling, nausea or vomiting
- itching, skin rashes, swelling of the face, lips or throat, difficulty in breathing, wheeziness, chest tightness or coughing (signs of allergic reactions)

If you experience one or more of these side effects or any other undesirable effects, please inform your doctor or pharmacist.

Most people using Desmopressin Melt find it causes them no problems. However, common side effects can include:

- headache
- stomach pain

Very rare cases of emotional disorders including aggression in children have also been reported.

If you experience one or more of these side effects or any other undesirable effects, please inform your doctor or pharmacist.

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 (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 Desmopressin Melt

Keep Desmopressin Melt out of the sight and reach of children.

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.

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 Desmopressin Melt contains

- This medicine contains the active ingredient, desmopressin (acetate). It is available in two strengths: 120 or 240 micrograms of desmopressin (as acetate).
- Other ingredients are gelatin, mannitol and citric acid.

What Desmopressin Melt looks like and contents of the pack

The melts 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 blister strips of 10 melts per strip. Pack size: 10, 30 or 100 oral lyophilisates.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

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

Distributor:

Aspire Pharma Ltd
Unit 4, Rotherbrook Court, Bedford Road,
Petersfield, Hampshire, GU32 3QG, UK

Manufacturer:

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