

=No print area



=Folding Line



=Perforation

Pharmacode
75 mm from
top and
bottom.

Drawing
E-MS-3053

Size
210x297 mm

Fiber direction

DDAVP[®] Melt 60 micrograms oral lyophilisate

DDAVP[®] Melt 120 micrograms oral lyophilisate

DDAVP[®] 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:

- DDAVP Melt is used to treat
 - diabetes insipidus (a condition that causes extreme thirst and the continuous production of large volumes of dilute urine)
 - post-hypophysectomy polyuria/polydipsia (extreme thirst and the continuous production of large volumes of dilute urine following surgical removal of the pituitary gland).
- You should avoid drinking large amounts of fluid while you are being treated with DDAVP 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 headache, confusion, unexplained weight gain, ankle swelling, nausea or vomiting, STOP USING DDAVP Melt. You should tell your doctor or immediately 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 DDAVP Melt is and what it is used for
2. Before you take DDAVP Melt
3. How to take DDAVP Melt
4. Possible side effects
5. How to store DDAVP Melt
6. Further information

1. What DDAVP Melt is what it is used for

DDAVP 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 it will dissolve completely). They are referred to as DDAVP Melt or melt(s) in this leaflet.

DDAVP Melt is available in three strengths: 60, 120 or 240 micrograms. It contains Desmopressin acetate, an antidiuretic (reduces urine production). It is used:

- to treat diabetes insipidus (a condition that causes extreme thirst and the continuous production of large volumes of dilute urine). *IMPORTANT: This should not be confused with diabetes mellitus (sugar diabetes)*
- to treat post-hypophysectomy polyuria/polydipsia (extreme thirst and the continuous production of large volumes of dilute urine following surgical removal of the pituitary gland).

2. Before you take DDAVP Melt

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

General restrictions:

Do not take DDAVP 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

You should avoid drinking large amounts of fluid while you are being treated with DDAVP 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 DDAVP 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.

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 DDAVP 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) and proteinuria (protein in the urine).

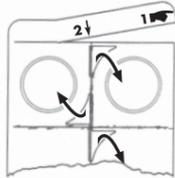
Breast-feeding:

If you are breast-feeding ask your doctor or pharmacist for advice before taking DDAVP Melt.

3. How to take DDAVP Melt

PATIENT INSTRUCTIONS

It is important to use your medicine as directed by your doctor. DDAVP 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 DDAVP Melt is too strong or too weak, talk to your doctor or pharmacist.

The usual doses are:

Treatment of diabetes insipidus:

Your doctor will prescribe the dose most suitable for you. The most common doses in adults and children are either one DDAVP Melt 60 micrograms or one DDAVP Melt 120 micrograms three times a day.

Treatment of extreme thirst and the continuous production of large volumes of dilute urine following surgical removal of the pituitary gland:

Your doctor will prescribe the most suitable dose for you based on the concentration of your urine.

If you take more of this medicine than you should:

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

If you forget to take this medicine:

Do not use a double dose to make up for a forgotten dose. If you are a patient with diabetes insipidus, please consult your doctor or pharmacist for advice.

4. Possible side effects

Like all medicines DDAVP Melt can have side effects.

You should avoid drinking large amounts of fluid while you are being treated with DDAVP 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 DDAVP 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 any of the above side effects, you should contact your doctor or go to the nearest casualty department immediately.

Most people using DDAVP 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.

5. Storing DDAVP Melt

Keep DDAVP Melt out of the reach and sight 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. Further information

- Each carton contains 100 melts in blister strips of 10 melts per strip.
- This medicine contains the active ingredient, desmopressin (as acetate). It is available in three strengths: 60, 120 or 240 micrograms of desmopressin (as acetate).
- Other ingredients in this medicine are gelatin, mannitol and citric acid.
- The melts are flat, round and white. Each melt is marked on one side with one, two or three drops, indicating a strength of 60, 120 or 240 micrograms respectively.

Marketing Authorisation Holder:

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

Manufacturer:

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

DDAVP Melt 60 micrograms oral lyophilisate
PL 03194/0091

DDAVP Melt 120 micrograms oral lyophilisate
PL 03194/0092

DDAVP Melt 240 micrograms oral lyophilisate
PL 03194/0093

This leaflet was last revised in February 2013.

DDAVP is a trademark of Ferring BV.

FERRING

PHARMACEUTICALS

1162 St-Prex

Switzerland

Nathalie Chateau

Item No : 2009052593

Title :

Leaflet DDAVP MELT tab oral blis GB

E-MS No : 3053

Barcode : 1735

Date : 2014-04-08

Proof version : 2

Braille Perforation vignette other

Format (mm) : 210x297 mm

Colours : Black

Variable data line 1 (eng) :

Variable data line 2 (eng) :

Variable data line 3 (eng) :

Country :

Name :

Date :

Signature :

E-2009052593.01