

Package leaflet: Information for the user

DESMOTABSMELT 120 micrograms oral lyophilisate desmopressin (as acetate)

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 use it again.
- If you have any 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 you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

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

1. What Desmotabs Melt is and what it is used for:

Desmotabs Melt is for sublingual use (placed under the tongue). Desmotabs Melt contain desmopressin (as acetate), an antidiuretic that reduces urine production.

Desmotabs Melt is used to treat:

- **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 from the age of 5)
- **Nocturia** in adults up to 65 years (night time urine production exceeding bladder capacity)

2. What you need to know before you take Desmotabs Melt

Do not take Desmotabs Melt

- 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.
- for Primary Nocturnal Enuresis and Nocturia: these tablets should not be used if you are under 5 years old or over 65 years old.
- if you have known hyponatraemia (serum sodium levels below normal range)
- if you have syndrome of inappropriate secretion of anti diuretic hormone, a hormone regulating urine production (SIADH)

Warnings and precautions

Talk to your doctor or pharmacist before taking Desmotabs Melt.

Take special care with Desmotabs Melt:

- if you have an illness causing fluid and/or electrolyte imbalance e.g. vomiting, diarrhoea, systemic infections, fever, gastroenteritis
- if you have a medical condition that could be made worse by fluid and/or electrolyte disturbance
- if you have cystic fibrosis
- if you have difficulty in passing water
- for Primary Nocturnal Enuresis and Nocturia: STOP using Desmotabs Melt when suffering from vomiting and diarrhoea until you are better.

If any of these apply to you, or if you are not sure, contact your doctor before taking Desmotabs Melt.

Other medicines and Desmotabs Melt:

Tell your doctor or pharmacist:

- if you are taking, have recently taken or might take any other medicines
- 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. indomethacin
- if you are taking a medicine containing loperamide, for diarrhoea

Desmotabs Melt with food or drink:

- for Primary Nocturnal Enuresis and Nocturia: 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)
- You should avoid drinking large amounts of fluid while you are being treated with Desmotabs 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.
- Food intake may reduce the intensity and duration at low doses.

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.

3. How to take Desmotabs Melt

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

Do NOT take more than the prescribed dose in any 24 hour period. If you have the impression that the effect of Desmotabs Melt is too strong or too weak, talk to your doctor or pharmacist. Remove the Melt from the blister strip. Place the Melt under the tongue and allow it to dissolve. Do not swallow or chew.

Diabetes Insipidus:

Your doctor will prescribe the dose most suitable for you. A suitable starting dose in adults and children is 60 micrograms three times daily administered sublingually (placed under the tongue). For the majority of patients the maintenance dose is 60 micrograms to 120 micrograms sublingually three times a day.

Bedwetting from the age of 5 years:

The recommended initial dose is 120 micrograms to be taken sublingually (placed under the tongue) at bedtime. The dose may be increased to 240 micrograms if the lower dose is not effective. Do not drink until morning. The need for continued treatment is usually reassessed every three months.

Nocturia

The initial dose is 60 micrograms taken sublingually (placed under the tongue) at bedtime.

This dose may be increased after one week to 120 micrograms and increased weekly thereafter to 240 micrograms as your doctor recommends. Fluid restriction should be observed.

If you take more Desmotabs Melt than you should

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

If you forget to take Desmotabs Melt

DO NOT TAKE A DOUBLE DOSE to make up for a forgotten dose.

If you are a patient being treated for Primary Nocturnal Enuresis or Nocturia, do not take Desmotabs Melt until the usual time for your next dose.

If you are a patient with diabetes insipidus, 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.

STOP USING DESMOTABSMELT if you experience:

- allergic reactions including itching, skin rashes, swelling of the face, lips or throat, difficulty in breathing, wheeziness, chest tightness or coughing.
- unusually bad or prolonged headache, abdominal pain, nausea, vomiting, unexplained weight gain, dizziness, confusion, feeling of

general discomfort, memory impairment, feel a whirling or spinning (vertigo) or falls.

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

Low levels of sodium in your blood can lead to fits. This is more likely to happen if you drink large amounts of fluid while receiving this medication.

Other side effects associated with Desmotabs Melt are listed below, starting with the most common.

The following common side effects may affect up to 1 in 10 people:

Adults:

- increased blood pressure
- diarrhoea, constipation
- urinary symptoms
- fatigue
- swelling due to the build up of fluid

The following uncommon side effects may affect up to 1 in 100 people: Adults:

- trouble sleeping, sleepiness
- numbness, tingling, burning or creeping on the skin (paresthesia)
- visual impairment
- feeling of abnormal heart beat (palpitations)
- low blood pressure
- shortness of breath (dyspnoea)
- upset stomach, indigestion, flatulence, bloating
- sweating, itchy, rash, hives
- muscle spasms, muscle pain
- chest pain
- influenza-like illness
- changes in liver function
- low blood potassium

Children and Adolescents:

- emotional instability
- aggression
- diarrhoea
- urinary symptoms
- fatigue
- swelling due to a build up of fluid

The following rare side effects may affect up to 1 in 1,000 people

Adults:

- allergic skin reactions

Children and Adolescents:

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

The frequency of the following side effects cannot be estimated from the available data:

Adults:

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

Children and Adolescents:

- anaphylactic reaction
- abnormal behaviour
- emotional disorder
- depression
- hallucination
- trouble sleeping
- disturbance in attention
- increased restlessness and movement
- convulsions

- nose bleeds

- allergic skin reactions, rash, sweating, hives

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 HPRC Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Desmotabs Melt

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

Store below 25°C. Store in the original package in order to protect from moisture and light.

Do not use Desmotabs Melt past the expiry date which is stated on the carton and blister after EXP. 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 Desmotabs Melt contain

The active substance is desmopressin acetate. Each Desmotabs Melt contains 120 micrograms of the active ingredient, desmopressin (as acetate).

The other ingredients are gelatin, mannitol and citric acid, anhydrous.

What Desmotabs Melt look like and contents of the pack

Desmotabs Melt oral lyophilisates are flat, round and white. The oral lyophilisates look like tablets but are much softer and lighter. They are intended for sublingual use (to be placed under the tongue where they will dissolve completely).

Each Desmotabs Melt is marked on one side with two drops, indicating a strength of 120 micrograms. Desmotabs Melts are presented in packs containing 30 Melts, with 10 Melts in each blister strip.

Parallel Product Authorisation holder:

IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

Manufactured by:

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

Repackaged by:

Cast Healthcare Ltd, Unit E, The Business Centre, 5-7 Tobermore Road, Draperstown, Magherafelt, BT45 7AG, UK(NI) or IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

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