

Desmotabs® 0.2mg

Desmopressin acetate

PATIENT INFORMATION

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

- Keep this leaflet, you may need to use 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.

Your medicine is called Desmotabs 0.2mg. They are tablets for oral use only.

- they are presented in plastic bottles containing 30 tablets
- each tablet contains 0.2mg of the active ingredient, Desmopressin acetate
- other ingredients in Desmotabs 0.2mg are lactose monohydrate, potato starch, povidone and magnesium stearate.

Marketing Authorisation Holder:
Ferring Pharmaceuticals Ltd.,
The Courtyard, Waterside Drive,
Langley, Berkshire SL3 6EZ (UK).

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

1. What Desmotabs 0.2mg are and what are they used for

Desmotabs 0.2mg are tablets for oral use only. They are white, round, convex tablets, scored on one side and engraved '0.2' on the other side. They contain Desmopressin acetate, an antidiuretic (reduces urine production).

Desmotabs 0.2mg are 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 Desmotabs 0.2mg

Do not take Desmotabs 0.2mg:

- if you have a serious heart or kidney disease
- if you are taking diuretics (water tablets)
- 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 drink unusually large quantities of fluids, including alcohol
- if you are allergic to any of the ingredients listed

Please consult your doctor before taking Desmotabs 0.2mg:

- if you have cystic fibrosis
- if you are on medication for depression or epilepsy
- 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
- if you have a medical condition causing fluid and/or electrolyte imbalance
- if you have a medical condition that could be made worse by fluid and/or electrolyte disturbance.

While you are on treatment with Desmotabs 0.2mg, avoid excessive fluid intake as this may lead to a build up of water in the body. In addition:

- 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 Desmotabs when suffering from vomiting and/or diarrhoea until you are better
- avoid swallowing water while swimming to prevent a build up of water in the body.

Pregnancy:

If you are pregnant or planning a pregnancy, please inform your doctor before you take Desmotabs 0.2mg as blood pressure monitoring is recommended due to the increased risk of pre-eclampsia.

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 Desmotabs 0.2mg.

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.

3. How to take Desmotabs 0.2mg

It is important that you do not take more than the prescribed dose in any 24 hour period.

Bedwetting from the age of 5 years:

Your usual starting dose is one tablet taken at bedtime. Your doctor may increase the dose to two tablets at bedtime depending on how well the bedwetting is controlled. The need for continued treatment is normally checked every three months.

If you have the impression that the effect of Desmotabs 0.2mg is too strong or too weak, talk to your doctor or pharmacist.

If you take more Desmotabs 0.2mg than you should:

If you take more Desmotabs 0.2mg than you should, talk to your doctor or pharmacist immediately.

If you forget to take Desmotabs 0.2mg:

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, Desmotabs 0.2mg can have side effects. Excessive fluid intake may 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 an unusually bad or prolonged headache, confusion, unexplained weight gain, nausea or vomiting, stop taking Desmotabs 0.2mg and tell your doctor immediately or go to the casualty department at your nearest hospital.

Most people taking Desmotabs 0.2mg find it causes them no problems. Side effects include headache, stomach pain and nausea. Isolated cases of allergic skin reactions and more severe general allergic reactions have been reported. Very rare cases of emotional disorders including aggression in children have 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 Desmotabs 0.2mg

Keep Desmotabs 0.2mg out of the reach and sight of children.

Do not store above 25°C. Keep the container tightly closed.

Do not remove the silica gel insert from the bottle top.

Use by date: Do NOT take Desmotabs 0.2mg past 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.

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This leaflet was revised in May 2008.

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