

Important safety information

Dear Pharmaceutical Advisor,

Desmopressin Nasal Spray: Removal of the Primary Nocturnal Enuresis Indication

With immediate effect the indication for the treatment of Primary Nocturnal Enuresis (PNE) has been removed from all desmopressin nasal spray products, including Desmospray. The accompanying 'Dear Doctor' letter has been sent to GPs, relevant hospital doctors and pharmacists on 16th April 2007.

This communication provides you with a resource pack to help manage patients moving from desmopressin sprays to oral formulations and to help you respond appropriately to any enquiries from local clinicians.

Prescribing Advice

Patients may complete their current course of treatment with desmopressin nasal spray. At their next routine review, patients needing continued treatment should only be prescribed an oral form of desmopressin. Regardless of the dose of spray they have been taking, all patients starting treatment with oral desmopressin should start at the lower recommended dose, which should only be increased if necessary to achieve control of symptoms.

There are two oral formulations of desmopressin available for the treatment of PNE. DesmoMelt should be the medication of choice for the treatment of PNE in children, as fast dissolving melts are recommended in the EMEA Reflection Paper: *Formulations of Choice for the Paediatric Population*, which was adopted on the 21st September 2006. Desmotabs are also available for those patients who prefer to take conventional tablets.

DesmoMelt	Take 1 x 120 mcg melt at bedtime, only if necessary increasing to: 2 x 120 mcg or 1 x 240 mcg
Desmotabs	Take 1 x 0.2 mg tablet at bedtime, Only if necessary increasing to: 2 x 0.2 mg

The cost of treatment is the same for both DesmoMelt and Desmotabs.

PNE patients should be advised to limit fluid intake to a minimum from 1 hour before until at least 8 hours after taking desmopressin.



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Further Information

DesmoMelt, desmopressin oral lyophilisate is available in two strengths, 120 micrograms and 240 micrograms of desmopressin (as acetate). It is a presentation that has been formulated specifically with children in mind and there is evidence that children under 12 years prefer DesmoMelt to ordinary tablets (*Persson B-E et al. 15th European Urology Winter Forum, Davos, Switzerland, February 11-15 Poster 13*)

Additional information can be found on the CD ROM. Active review of patients is necessary to re-titrate patients to oral preparations. This is because some patients may respond differently to tablets as response to the spray may be technique dependent. We estimate that there is the equivalent of approximately two patients treated with spray per GP per year.

Desmospray remains available for the treatment of other indications and patients with cranial diabetes insipidus, or nocturia associated with multiple sclerosis can continue their current therapy as normal. Patients with cranial diabetes insipidus can also be treated with DDAVP tablets or DDAVP Melt.

Ferring has worked closely with the Medicines and Healthcare Products Regulatory Agency to ensure that the transfer from desmopressin spray formulations spray to DesmoMelt or Desmotabs is completed as smoothly as possible so that patients can continue to receive their treatment uninterrupted.

Ferring has also worked with stakeholders to develop materials which may be helpful in managing this change. The enclosed CD ROM contains copies of the following:

- A template letter for use by practices to notify patients
- An FAQ sheet
- A copy of the MHRA/Ferring 'Dear Doctor' Letter
- SPCs on Desmospray, Desmotabs and DesmoMelt.
- Prescribing bulletin summary.
- DesmoMelt pamphlet
- Desmopressin Treatment Review Flow Chart

Further information is available on request from Ferring Pharmaceuticals Limited and at www.urinecontrol.co.uk/news.php

If you have any further questions, please do not hesitate to contact me or my colleagues in the medical information department on 01753 214848 or email: medical@ferring.com

Yours faithfully



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