IRISH MEDICINES BOARD

# Notice Information: Human Medicines - 3rd Party Publications 30 June 2007

## Part 1. Product Information

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| a) | Title: | Desmopressin Nasal Spray Formulation |
| b) | Product Name/Type: | Desmopressin - MIMS Advisory |
| c) | Reference: | MIMS Publication June 2007 |
| d) | Prescription Required: | Yes |

## Part 2. Target Audience

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| a) | Target Audience: | Healthcare Professionals |

## Part 3. Problem/Issue

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| a) | Problem/Issue: | Desmopressin is an anti-diuretic authorised in Ireland for the diagnosis and treatment of cranial diabetes insipidus including post-hypophysectomy polyuria/ polydipsia and for the measurement of urine concentration capacity. Desmopressin tablets are also authorised for use in the short term management of nocturnal enuresis. Desmopressin is a synthetic analogue of the natural anti-diuretic peptide vasopressin with an increased anti-diuretic activity and a prolonged duration of action in comparison with the natural peptide. Hyponatraemia is a rare but serious adverse reaction known to occur in association with the use of desmopressin. It has been reported at a rate of approximately 15 cases per 100,000 patient years of exposure for nasal formulations and has been predominantly associated with overdose, excessive fluid intake or inappropriate use. It is not known whether these adverse effects are dose-related but there is strong evidence of a relationship to the nasal formulation, since the majority of cases of hyponatraemia occurred with the nasal formulation in the PNE indication. As such, and following review by European regulatory authorities including the IMB, the indication for the treatment of primary nocturnal enuresis (PNE) has been removed from all desmopressin nasal spray preparations . The decision to remove the PNE indication was taken because, in comparison with oral formulations of desmopressin [5 cases per 100,000 patient years], nasal forms were associated with the majority of suspected serious adverse reactions in patients with PNE, including in particular hyponatraemia, water intoxication and convulsions. As the risk benefit profile of the oral formulations is more favourable than the nasal spray, the nasal form should no longer be used for the treatment of PNE in adults and children. Prescribers should also be aware that there is a possible risk of severe hyponatraemia when nasal desmopressin is used to treat patients with cranial diabetes insipidus. |

## Part 4. Action to be taken

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| a) | Action to be taken: | Healthcare professionals are advised that the oral and injectable formulations of desmopressin remain authorised, with oral treatment recommended for the following indications only: 1. For the short term treatment of primary nocturnal enuresis in patients (from 5 to 65 years of age) with normal ability to concentrate urine. 2. For the diagnosis and treatment of cranial diabetes insipidus including posthypophysectomy polyuria/ polydipsia. 3. For the symptomatic treatment of nocturia in adults up to 65 years only, associated with nocturnal polyuria, i.e. nocturnal urine production exceeding bladder capacity. The risk of hyponatraemia occurring with oral desmopressin can be reduced by closely following the advice in the approved product information. Healthcare professionals are reminded to report any cases of suspected adverse reactions in association with the use of desmopressin to the IMB in the usual way. |

## Part 5. Keywords

a) Keywords: desmopressin