

Desmopressin

Product:

DESMOPRESSIN oral disintegrating tablet (DDAVP Melt®), 60mcg, 120mcg

Class of drugs:

Antidiuretic

Indication:

Treatment of nocturnal enuresis (bedwetting) and central diabetes insipidus

Manufacturer:

Ferring Inc.

CED Recommendation

The CED recommended that desmopressin oral disintegrating tablet (DDAVP Melt) be listed on the Ontario Drug Benefit (ODB) Formulary, on the condition that concerns regarding its costs and appropriate dosage conversion are addressed.

Executive Officer Decision

Taking into consideration the CED's recommendation and based on a subsequent listing agreement, the Executive Officer decided to list desmopressin oral disintegrating tablets (DDAVP Melt) on the Ontario Drug Benefit (ODB) Formulary.

Status

Funding available through the Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Desmopressin is an antidiuretic hormone used to treat enuresis (bedwetting). It is also used to treat central diabetes insipidus.
- ◆ Desmopressin oral disintegrating tablet (DDAVP Melt) dissolves when placed under the tongue. This is a line extension product of other desmopressin dosage forms (e.g. regular tablet, nasal spray) that are already listed on the Formulary.
- ◆ A study in children and adolescent patients with enuresis showed that desmopressin oral disintegrating tablet (DDAVP Melt) provided similar clinical efficacy and safety as desmopressin regular tablet.
- ◆ Appropriate dose conversion is required when switching from the regular tablet to the Melt form of the medication.
- ◆ Desmopressin oral disintegrating tablet is more expensive than generic forms of desmopressin regular tablets.
- ◆ **Overall, the Committee acknowledged that desmopressin oral disintegrating tablet (DDAVP Melt) provides an additional choice to patients who require desmopressin. Therefore, the CED recommended that this product be listed on the Ontario Drug Benefit (ODB) Formulary, on the condition that an educational program be put in place to ensure appropriate dose conversion and that it be priced proportionately to generic desmopressin tablet.**

Background:

When it is not associated with related problems (such as a daytime increase in urinary urgency or incontinence), uncontrollable night-time urination leading to bedwetting is called nocturnal enuresis. This condition is considered a problem if it persists after a child is more than five years old. Some 14-16 percent of these cases resolve on their own in any given year, and for most people the incidence will decline with age. Treatment generally begins with an alarm system to alert a child to a nighttime urinary accident. If an alarm system is not effective, drug therapy can be tried.

Central diabetes insipidus occurs when the body has too little of the hormone vasopressin. Vasopressin normally limits the amount of urine the body produces. The lack of vasopressin results in a rapid loss of water from the body in the form of dilute urine.

Desmopressin is a synthetic replacement hormone that increases urine concentration and decreases urine production.

continued...

Detailed Discussion:

- ◆ Desmopressin oral disintegrating tablet (DDAVP Melt) dissolves when placed under the tongue. This is a line extension product of other desmopressin dosage forms (e.g. regular tablet, nasal spray) that are already listed on the Formulary.
- ◆ The Committee reviewed a randomized, 6 week, open label, cross-over study in 221 children and adolescent patients with primary nocturnal enuresis.
- ◆ The study found no statistically significant difference between desmopressin oral disintegrating tablet (DDAVP Melt) and desmopressin regular tablet, in terms of clinical efficacy or safety.
- ◆ A higher proportion of subjects preferred the disintegrating tablet to the regular tablet (55.7% vs. 53.8%); however, this difference was not statistically significant. A post hoc analysis was performed, and subjects aged less than 12 years old were shown to have a statistically significant preference for the disintegrating tablet formulation. Compliance was similar for both treatment arms. Because the trial was not blinded, a bias favouring the oral disintegrating tablet may have been introduced.
- ◆ A dosage adjustment is required when switching between the different desmopressin formulations. The Committee noted there may be confusion by physicians and patients on the appropriate dose conversion. Inappropriate dose substitution may lead to unwarranted adverse events, such as headache, nausea, and abdominal pain.
- ◆ At equivalent doses, desmopressin oral disintegrating tablet (DDAVP Melt) is twice as expensive as generic forms of desmopressin regular tablets.
- ◆ Overall, the Committee acknowledged that desmopressin oral disintegrating tablet (DDAVP Melt) provides an additional choice to patients who require desmopressin. Therefore, the CED recommended that this product be listed on the Ontario Drug Benefit (ODB) Formulary, on the condition that an educational program be put in place to ensure appropriate dose conversion and that it be priced proportionately to generic desmopressin tablet.

CEDAC Recommendation:

(<http://www.cadth.ca/index.php/en/cdr/recommendations>)

The Canadian Expert Advisory Committee (CEDAC) did not review desmopressin oral disintegrating tablets (DDAVP Melt).



Ministry of
Health and Long-Term Care
Ontario Public Drug Programs

For more information, please contact:

Ministry of Health and Long-Term Care
Ontario Public Drug Programs
Hepburn Block, 9th Floor
80 Grosvenor Street, Queen's Park
Toronto, Ontario M7A 1R3
or click: http://www.health.gov.on.ca/english/providers/program/drugs/ced_rec_table.html