WHY BEDWETTING CAN AND SHOULD BE TREATED

Dry nights mean good mornings

Higher levels of compliance and efficacy with MINIRIN Melt *than MINIRIN tablet* [1]

Reference: 1.Juul KV *et al.* Eur J Pediatr 2013;**172**:1235-1242

Abbreviated Prescribing Information: Prescribing information and indications may vary from country to country. Contact the local Ferring representative for country specific prescribing information. **Presentation:** MINIRIN® Melt is presented as oral lyophilisates containing 60 µg, 120 µg or 240 µg desmopressin. The oral lyophilisates are white, round, and marked with one, two or three drop shaped figures on one side for the strengths 60 µg, 120 µg and 240 µg respectively. MINIRIN® Melt also contains gelatin, mannitol and citric acid, anhydrous. **Indications:** Central Diabetes Insipidus; Primary Nocturnal Enuresis in patients (from 5 years of age) with normal ability to concentrate urine; and symptomatic treatment of Nocturia in adults, associated with nocturnal polyuria (i.e. nocturnal urine production capacity exceeding bladder capacity). **Dosage and method of administration:** *Central diabetes insipidus:* The normal daily maintenance dose in adults and children is 60 µg - 120 µg administered sublingual three times daily. *Primary nocturnal enuresis:* The recommended dose is 120 µg - 240 µg administered sublingual at bedtime. *Nocturia:* The recommended initial dose is 60 µg administered sublingual at bedtime. The dose may be increased up to 120 µg and subsequently 240 µg by weekly dose escalations. The initiation of treatment in elderly (over 65 years old) is not recommended. **Contraindications:** Habitual or psychogenic polydipsia (resulting in a urine production exceeding 40 ml/kg/24 hours); A history of known or suspected cardiac insufficiency and other conditions requiring treatment with diuretics; Moderate and severe renal insufficiency (creatinine clearance below 50 ml/min); Known hyponatraemia; Syndrome of inappropriate ADH secretion; Hypersensitivity to desmopressin or the excipients. **Warnings:** When used for primary nocturnal enuresis and nocturia indications, the fluid intake must be limited to a minimum from 1 hour before until 8 hours after administration. Treatment without concomitant reduction of fluid intake may lead to water retention and/or hyponatraemia with or without accompanying warning signs and symptoms (headache, nausea/vomiting, weight gain, and, in severe cases, convulsions). **Precautions:** Severe bladder dysfunction and outlet obstruction should be considered before starting treatment. Elderly patients and patients with low serum sodium levels may have an increased risk of hyponatraemia. Treatment with desmopressin should be interrupted during acute intercurrent illnesses characterised by fluid and/or electrolyte imbalance (such as systemic infections, fever, gastroenteritis). Precautions to avoid hyponatraemia including careful attention to fluid restriction and more frequent monitoring of serum sodium must be taken in case of concomitant treatment with drugs, which are known to induce SIADH, e.g. tricyclic antidepressants, selective serotonine reuptake inhibitors, chlorpromazine and carbamazepine, case of concomitant treatment with NSAIDs. **Side effects:** Primary nocturnal enuresis & diabetes insipidus: *Common:* Headache, abdominal pain and nausea. *Very rare:* Hyponatraemia. Nocturia: The most frequent during dosetitration: Headache, nausea, abdominal pain, hyponatraemia, dizziness, and dry mouth. *The most frequent in long-term treatment:* Headache, dizziness, peripheral oedema, micturition frequency, nausea, and weight increase. **Pregnancy and lactation:** Caution should be exercised when prescribing to pregnant women. The amounts of desmopressin that may be transferred to the child are considerably less than the amounts required to influence diuresis. **Overdose:** An overdose leads to a prolonged duration of action with an increased risk of water retention and/or hyponatremia. **Special precautions for storage:** Store in the original package in order to protect from moisture and light. **Marketing authorization holder:** Ferring-Léčiva, a.s., K Rybníku 475, 252 42 Jesenice u Prahy, Czech Rep. **Marketing authorization numbers:** MINIRIN Melt 60 µg: 56/358/05-C; MINIRIN Melt 120 µg: 56/359/05-C. MINIRIN Melt 240 µg: 56/360/05-C. **Date of revision of the text:** MINIRIN Melt 60 µg/120 µg/240 µg: 22. 8. 2012. On medical prescription. Reimbursed from Healthcare insurance. **Legal category:** POM. Ferring International Center S.A.Chemin de la Vergognausaz 50, 1162 Saint-Prex, Switzerland / Ferring Pharmaceuticals CZ, s.r.o., K Rybníku 475, 252 42 Jesenice u Prahy, Czech Rep., Phone: +420 241 041 111.

MINIRIN Melt 240 µg is not on a market in the Czech Republic. For full Product Information please contact: Ferring Pharmaceuticals CZ, s.r.o., K Rybníku 475, 252 42 Jesenice u Prahy, Czech Rep., Phone: +420 241 041 111.

Date of preparation June 2015
MN/518/2014/CH3a

FERRING
PHARMACEUTICALS