Prescribing Information: DesmoMelt® 120 and 240 micrograms oral lyophilisate.

Please consult the full Summaries of Product Characteristics before prescribing.

Name of Product: DesmoMelt 120 micrograms oral lyophilisate; DesmoMelt 240 micrograms oral lyophilisate; **Composition:** 120 or 240 micrograms of desmopressin (lyophilisate as acetate). **Indications:** Treatment of primary nocturnal enuresis (5 to 65 years of age). **Dosage and administration:** Children and adults (5–65 years of age) with normal urine concentrating ability: Initial dose of 120 micrograms sublingually at bedtime and if this dose is not sufficiently effective, the dose may be increased up to 240 micrograms, administered sublingually. Fluid restriction should be observed. DesmoMelt is intended for treatment periods of up to 3 months. The need for continued treatment should be reassessed by means of a period of at least 1 week without desmopressin. If adequate clinical effect is not achieved within 4 weeks following dose titration the medication should be discontinued. In the event of signs or symptoms of water retention and/or hyponatraemia treatment should be interrupted until the patient has fully recovered. When re-starting treatment fluid restriction should be enforced. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Known or suspected cardiac insufficiency and conditions requiring treatment with diuretics, moderate and severe renal insufficiency. DesmoMelt should only be used in patients with normal blood pressure and they should not be used in patients with known hyponatraemia, syndrome of inappropriate ADH secretion or patients (SIADH) over the age of 65. Exclude diagnosis of psychogenic polydipsia (resulting in urine production exceeding 40 ml/kg/24 hours). **Side Effects:** Common; headache. Please consult the full Summary of product characteristics for further information about side effects. **Special Warnings:** Take care in patients with reduced renal function and/or cardiovascular disease or cystic fibrosis. In chronic renal disease the antidiuretic effect of DesmoMelt would be less than normal. Fluid intake must be limited to a minimum from 1 hour before until the next morning (at least) 8 hours after administration. Treatment without concomitant reduction of fluid intake may lead to water retention and/or hyponatraemia with or without accompanying signs and symptoms. All patients and, when applicable, their guardians should be carefully instructed to adhere to the fluid restrictions. **Precautions**: Severe bladder dysfunction and outlet obstruction should be considered before starting treatment. Elderly patients and patients with serum sodium levels in the lower range of normal 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). Caution should be used in: illnesses characterized by fluid and/or electrolyte imbalance; patients at risk for increased intracranial pressure. Hyponatraemia should be avoided by careful attention

to fluid restriction and frequent sodium monitoring in case of concomitant treatment with drugs known to induce SIADH, treatment with NSAIDs and some antidiabetics of the sulfonylurea group particularly chlorpropamide. **Special precautions for storage:** None. **Presentation**: Carton containing 30 oral lyophilisates in blister strips. **Marketing Authorisation Number:**120 micrograms 03194/0094. 240 micrograms 03194/0095. **Marketing Authorisation Holder:** Ferring Pharmaceuticals Ltd., Drayton Hall, Church Road, West Drayton, UB7 7PS. **Legal Category:** POM. **Basic NHS Prices:** 30 x 120 micrograms £30.34. 30 x 240 micrograms £60.68. **Date of Preparation:** March 2023. All trademarks registered to Ferring. **PI approval code:** UK-MN-2300008

Adverse events should be reported. Reporting forms and information can be found at **www.mhra.gov.uk/yellowcard.**
Adverse events should also be reported to Ferring Pharmaceuticals Ltd.
Tel: 0800 111 4126.Email: **medical.uk@ferring.com**