Prescribing Information: Noqdirna® 25 and 50 micrograms oral lyophilisate.

Please consult the full Summary of Product Characteristics before prescribing.

Name of Product: Noqdirna 25 micrograms oral lyophilisate; Noqdirna 50 micrograms oral lyophilisate. **Composition:** 25 or 50 micrograms of desmopressin (lyophilisate as acetate). **Indications:** Symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults. **Dosage and administration:** Women 25 microgram daily, men 50 microgram, daily one hour before bedtime administered sublingually without water. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients, habitual or psychogenic polydipsia, known or suspected cardiac insufficiency or other conditions associated with fluid overload, moderate and severe renal insufficiency, known history of hyponatremia, syndrome of inappropriate ADH secretion (SIADH). **Side Effects:** *Very common:* Dry mouth. *Common*: hyponatraemia, headache, dizziness, diarrhoea, nausea. *Uncommon*: constipation, abdominal discomfort, fatigue, peripheral oedema. Treatment with desmopressin without concomitant reduction of fluid intake may lead to water retention/hyponatraemia with or without accompanying warning symptoms of headache, nausea/vomiting, decreased serum sodium, weight gain and in serious cases convulsions. Consult the full Summary of Product Characteristics for further information about side effects. **Special Warnings and Precautions:** Not recommended in patients with cardiovascular or medical conditions associated with fluid overload. Fluid intake must be limited from 1 hour before until 8 hours after administration. Patients 65 years and older should have serum sodium monitored before initiation, in the first week of treatment and at one month post initiation. Discontinue Noqdirna if serum sodium falls below the lower limit of normal. Use with caution in conditions characterized by fluid and/or electrolyte imbalance. Fluid restriction and more frequent serum sodium monitoring must be taken with concomitant treatment with drugs known to induce SIADH. Exercise caution in patients taking thiazide or loop diuretics and in cases of cystic fibrosis, coronary heart disease, hypertensions, chronic renal disease and pre-eclampsia. Severe bladder dysfunction and outlet obstruction should be considered before treatment. Ensure patients taking lithium do not have early-stage lithium-induced nephrogenic diabetes insipidus. **Special precautions for storage:** None. Use immediately after opening individual tablet blister**. Presentation:** Perforated unit dose blisters in a carton. **Marketing Authorisation Number:** 50 micrograms 03194/0119. 25 micrograms 03194/0118. **Marketing Authorisation Holder:** Ferring Pharmaceuticals Ltd., Drayton Hall, Church Road, West Drayton, UB7 7PS. **Legal Category:** POM. **Basic NHS Prices:** 30 x 25 micrograms £15.16. 30 x 50 micrograms £15.16. **Date of Preparation:** July 2018. All trademarks registered to Ferring. **PI approval code:** NOQ/2109/2016/UK(1)

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., Drayton Hall, Church Road, West Drayton, UB7 7PS. Telephone: 0800 111 4126. Email: medical@ferring.com