Prescribing Information UK and ROI
Aqumeldi 0.25mg and 1mg orodispersible tablets

Please refer to the full Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Enalapril maleate orodispersible tablets in a bottle containing 50, 100 or 200 tablets. Depending upon product strength, each orodispersible tablet contains either 0.25mg or 1mg of enalapril maleate.

Indication: Treatment of heart failure in children from birth to less than 18 years.

Dosage: The SmPC should be referred to for full dosing details. For oral use only.

Starting/test dose: Before giving a test dose, blood pressure (BP) and renal function should be checked. 0.01 to 0.04 mg/kg (max. 2mg) as a single initial dose. BP should be monitored at intervals for 1 – 2 hours after the initial dose.

Target/maintenance dose: 0.15 to 0.3 mg/kg (max. 20mg) per day in one or two divided doses, 8 hours after test dose. The dose should be titrated according to BP, serum creatinine and potassium response.

If GFR ≥30 - <50ml/min/1.73m^2: Start with 50% of the single dose and dose at 12 hourly intervals. For dialysis: Start with 25% of the normal single dose at 12 hourly intervals. Aqumeldi may be administered via enteral feeding tubes; flush enteral tubes with at least 3ml of water post-dose.

Contraindications: Hypersensitivity to enalapril, excipients or any other angiotensin converting enzyme inhibitor (ACEi); history of angioedema with ACEi therapy; hereditary or idiopathic angioedema; second and third trimesters of pregnancy; concomitant use of aliskiren-containing medicines in patients with diabetes mellitus or renal impairment (GFR <60ml/min/1.73m^2); combination with sacubitril/valsartan (a medicinal product containing a neprilysin inhibitor); severe renal impairment.

Special warnings and precautions for use: Monitor for symptomatic hypotension. Use in pregnancy. Avoid in patients with cardiogenic shock and haemodynamically significant obstruction. Use with caution in left ventricular valvular and outflow tract obstruction; renal disorders (impairment, renal artery stenosis, transplantation, haemodialysis); breast-feeding; hyperkalaemia and associated risk factors; neutropenia; agranulocytosis; in combination with: diuretics including potassium-sparing diuretics; lithium; angiotensin II receptor blockers or aliskiren, antihypertensives. Development of hepatic failure or hypersensitivity/angioedema

(including anaphylaxis) requires prompt discontinuation and appropriate treatment.

Undesirable effects: Common adverse reactions seen in children with heart failure treated with Aqumeldi include: postural dizziness, hypotension, cough, vomiting, hyperkalaemia, microalbuminuria. Serious adverse reactions seen in adults treated with enalapril tablets include: angioedema, bone marrow suppression, neutropenia, thrombocytopenia, pancytopenia, agranulocytosis, myocardial infarction, cerebrovascular accident, Stevens-Johnson syndrome, Toxic epidermal necrolysis, severe skin reactions, aplastic anaemia, liver disorders, lower levels of haemoglobin and/or haematocrit. Please refer to the SmPC for full details of adverse reactions.

Marketing Authorisation Holder (MAH): Proveca Pharma Ltd., 2 Dublin Landings, North Wall Quay, Dublin 1, Ireland. **Legal Classification:** POM.

Further prescribing information can be obtained from the MAH.

Date of last revision: April 2025

For the United Kingdom

MA numbers: 0.25mg: PLGB 51785/0001, 1mg: PLGB 51785/0002

Basic NHS Price: 0.25mg 50-tablet pack, £34.25; 0.25mg 100-tablet pack, £68.48; 1mg 50-tablet pack, £68.48; 1mg 100-tablet pack, £136.97.

Adverse events should be reported. Reporting forms and information can be found at: yellowcard.mhra.gov.uk

Adverse events should also be reported to Proveca Limited.

Phone: +44 333 200 1866 E-mail: medinfo@proveca.com

For the Republic of Ireland

MA numbers: 0.25mg 50-tablet pack, EU/1/23/1717/001; 0.25mg 100-tablet pack, EU/1/23/1717/002; 1mg 50-tablet pack, EU/1/23/1717/004; 1mg 100-tablet pack, EU/1/23/1717/005

Adverse events should be reported. Reporting forms and information can be found at: www.hpra.ie

Adverse events should also be reported to Proveca Limited.

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