Prescribing Information UK
Aqumeldi 0.25mg orodispersible tablets

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

Active Ingredient: Enalapril maleate**. Presentation:** Enalapril maleate orodispersible tablets in a bottle containing 50, 100 or 200 tablets. Each orodispersible tablet contains 0.25mg 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.

MA number for Great Britain: PLGB 51785/0001. **MA number(s) for Northern Ireland:** EU/1/23/1717/001, EU/1/23/1717/002, EU/1/23/1717/003. **Legal Classification:** POM. **Basic NHS Price:** 50 tablet pack £34.25. 100 tablet pack £68.48. **Marketing Authorisation Holder (MAH):** Proveca Pharma Ltd., 2 Dublin Landings, North Wall Quay, Dublin 1, Ireland. Further prescribing information can be obtained from the MAH. **Date of last revision of prescribing information:** March 2024

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