Prescribing Information

Redemplo (plozasiran) 25 mg solution for injection in pre-filled syringe
▼ This product is subject to additional monitoring.
Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Each single-dose pre-filled syringe contains plozasiran sodium equivalent to 25 mg plozasiran in 0.5 mL solution.

Indication: adjunct to diet to reduce triglyceride levels in adult patients with familial chylomicronaemia syndrome (FCS).

Dosage and Administration: Treatment should be initiated and supervised by a physician experienced in the treatment of patients with FCS.
Recommended dose: 25 mg administered as a single subcutaneous injection every 3 months. Sites for injection: upper arm, thigh, and abdomen (except for a 5 cm area around the navel). Do not inject in the same area where other medicines are injected. It is important that FCS diagnosis is established by either genetic testing, or by the presence of the following clinical criteria: fasting triglyceride (TG) levels ≥ 10 mmol/L (≥ 880 mg/dL) that are refractory to standard lipid-lowering therapy and at least one of the following: prior history of acute pancreatitis not caused by alcohol or cholelithiasis, history of recurrent hospitalisations for severe abdominal pain without other explainable cause, history of childhood pancreatitis, or family history of hypertriglyceridaemia-induced pancreatitis.
Special Populations: *Elderly (≥ 65 years of age)*: no dose adjustment is required. *Renal impairment*: no dose adjustment is required for patients with mild or moderate renal impairment. Plozasiran has not been studied in patients with severe renal impairment or end-stage renal disease (eGFR < 30 mL/min) and should only be used in these patients if the anticipated clinical benefit outweighs the potential risk. *Hepatic impairment:* No dose adjustment is required for patients with elevation of aspartate aminotransferase (AST) > upper limit of normal (ULN) and total bilirubin ≤ ULN, or total bilirubin > 1.0 to 1.5 × ULN and any AST. Plozasiran has not been studied in patients with moderate or severe hepatic impairment and should only be used in these patients if the anticipated clinical benefit outweighs the potential risk. *Paediatric patients*: safety and efficacy have not yet been established.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Special warnings and precautions for use: Hyperglycaemia as may increase blood glucose levels in some patients. Some patients with diabetes or at increased risk of developing diabetes may develop a degree of hyperglycaemia. These patients should be monitored both clinically and biochemically, in accordance with national guidelines.

Interaction with other medicinal products: no clinical interaction studies have been conducted. In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Fertility, pregnancy, and lactation: *pregnancy*: no data from the use in pregnant women therefore preferable to avoid use during pregnancy. *Lactation*: a risk to newborns/infants cannot be excluded. Assess the benefit of breastfeeding for the child versus the benefit of therapy for the woman. *Fertility*: no clinical data available.

Possible Side Effects: very common (≥ 1/10): hyperglycaemia (12.8%); common (≥ 1/100 to < 1/10): headache (6.8%), nausea (4.7%), and injection site reaction (4.7%); uncommon (≥ 1/1 000 to < 1/100): liver disorder (ALT increased, AST increased). Adverse events leading to discontinuation of treatment were hyperglycaemia (0.7%) and urticaria (0.7%).

Legal Category: POM
Package Quantities and Prices: Single-dose, pre-filled syringe - £74,315

Marketing Authorisation Holder: Arrowhead Pharmaceuticals Ireland Limited, One Spencer Dock, North Wall Quay, Dublin 1, D01 X9R7, Ireland

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Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/. Adverse events should also be reported to Arrowhead Pharmaceuticals Ireland Limited. Phone: +44 (0) 203 949 6480; e-mail: safety@arrowheadpharma.com