TRYNGOLZA® ▼ (olezarsen) - Prescribing Information for United Kingdom

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

Composition: Each pre-filled pen contains 80 mg olezarsen (as olezarsen sodium) in 0.8 mL solution.

Indications: Tryngolza® is indicated as an adjunct to diet in adult patients for the treatment of genetically confirmed familial chylomicronemia syndrome (FCS).

Dosage and administration: The recommended dose of Tryngolza® is 80 mg administered by subcutaneous injection once monthly. This medicinal product is intended for subcutaneous use only. It should not be administered intramuscularly. If a dose is missed, Tryngolza® should be administered as soon as possible. Dosing at monthly intervals should be resumed from the date of the most recently administered dose. This medicinal product should be administered into the abdomen or front of the thigh. The back of the upper arm can also be used as an injection site if a healthcare provider or caregiver administers the injection. It should not be injected into skin that is bruised, tender, red, or hard, into scars or damaged skin; the area around the navel should be avoided. Some patients might not be responsive to the treatment after 6 months, in such a case the discontinuation of Tryngolza® should be considered on an individual basis by the prescribing physician. For instructions on handling of the medicinal product before administration, see section 6.6 of the SmPC. Paediatric population: The safety and efficacy of this medicinal product in children and adolescents below 18 years of age have not yet been established. For further information, see section 5.1 of the SmPC. Elderly population: No dose adjustment is required in patients ≥ 65 years of age, see section 5.2 of the SmPC. Hepatic impairment: No dose adjustment is necessary in patients with mild hepatic impairment. Tryngolza® 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 risk. Renal impairment: No dose adjustment is necessary in patients with mild or moderate renal impairment. Tryngolza® has not been studied in patients with severe renal impairment or end-stage renal disease and should only be used in these patients if the anticipated clinical benefit outweighs the risk.

Contraindications: Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the SmPC.

Special warnings and precautions for use: General: While no serious risks of thrombocytopenia, hepatotoxicity, or renal toxicity were identified during clinical development, these adverse reactions have been observed with some antisense oligonucleotides and cannot be completely excluded. Hypersensitivity reactions: Hypersensitivity reactions (including symptoms of diffuse erythema and chills) have been reported in patients treated with Tryngolza®. If a serious hypersensitivity reaction occurs, Tryngolza® must be discontinued immediately and appropriate therapy initiated. Use in patients with low platelet counts: Some patients with FCS are susceptible to platelet count variability over time as part of the natural history and progression of the disease. There are limited data available on the use of olezarsen in FCS patients with platelet count <100 000/mm^3. Excipients: This medicinal product contains less than 1 mmol sodium (23 mg) per 80 mg dose, which is to say essentially 'sodium-free'.

Interactions: No interaction studies have been performed. In vitro studies show that olezarsen is not a substrate or inhibitor of transporters, does not interact with highly plasma protein bound medicines, and is not an inhibitor or inducer of cytochrome P450 (CYP) enzymes. Oligonucleotide therapeutics, including olezarsen, are not typically substrates of CYP enzymes. Therefore, olezarsen is not expected to cause or be affected by interactions mediated through transporters, plasma protein binding or CYP enzymes. Tryngolza® can be used with other lipid-lowering medicines, for example statins and fibrates.

Fertility, pregnancy, and lactation: Fertility: No clinical data on the effect of this medicinal product on human fertility are available. Pregnancy: There are no data from the use of olezarsen in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of Tryngolza® during pregnancy and women of child-bearing potential should practice effective contraception. Lactation: There is no information on the excretion of olezarsen/metabolites in human milk, the effects of olezarsen on breastfed newborns/infants, or the effects of olezarsen on milk production in treated women. A risk to the newborns/infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Undesirable effects: Please consult SmPC section 4.8 for the full list of possible adverse reactions. The adverse reactions at least possibly related to treatment are listed below as very common (≥1/10) and

common (≥1/100 to <1/10). In patients with FCS, the most commonly reported adverse reactions during treatment with olezarsen were injection site erythema (17%), headache (16%), arthralgia (15%), and vomiting (10%). Very common adverse reactions: Headache, Vomiting, Arthralgia, Injection site erythema. Common adverse reactions: Hypersensitivity, Myalgia, Injection site discolouration, Chills, Injection site pain, Injection site swelling. Injection site reactions: Injection site reactions occurred in olezarsen-treated patients with FCS. These local reactions were mostly mild and consisted of injection site erythema (17%), discolouration (9%), pain (6%), and swelling (5%). These events are either self-limiting or can usually be managed using symptomatic treatment. Hypersensitivity: Hypersensitivity has been observed with olezarsen. Severe hypersensitivity reactions (including symptoms of bronchospasm, diffuse erythema, facial swelling, urticaria, chills, and myalgias) have been observed in 2 patients in clinical trials. In both patients the event was acute, required treatment, and resulted in treatment discontinuation.

Legal Category: Prescription Only Medicine (POM)

Marketing Authorisation No.: PL30941/0031

Pack size: Pack size of one pre-filled pen

Price: NHS list price £24,722 per pack.

Marketing Authorisation Holder: Swedish Orphan Biovitrum AB (publ), SE-112 76 Stockholm, Sweden.

Further information available from: Swedish Orphan Biovitrum (UK) Ltd, Suite 2, Riverside 3, Cambridgeshire, CB21 6AD

Date of Preparation: May 2026

Company Reference: PP-33099

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Swedish Orphan Biovitrum Ltd by email at medical.info.uk@sobi.com or by calling +44 (0) 800 111 4754.