

TRYNGOLZA (olezarsen)

DRAFT

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use TRYNGOLZA safely and effectively. See full prescribing information for TRYNGOLZA.

TRYNGOLZA (olezarsen) injection, for subcutaneous use
Initial U.S. Approval: 2024

INDICATIONS AND USAGE

TRYNGOLZA is an *APOC-III*-directed antisense oligonucleotide (ASO) indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS). (1)

DOSAGE AND ADMINISTRATION

- The recommended dosage of TRYNGOLZA is 80 mg administered subcutaneously once monthly. (2.1)
- Administer TRYNGOLZA 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. (2.2)

DOSAGE FORMS AND STRENGTHS

Injection: 80 mg/0.8 mL in a single-dose autoinjector. (3)

CONTRAINDICATIONS

History of serious hypersensitivity reactions to olezarsen or any of the excipients in TRYNGOLZA. (4)

WARNINGS AND PRECAUTIONS

Hypersensitivity reactions have been reported in patients treated with olezarsen. Advise patients on the signs and symptoms of hypersensitivity reactions and instruct patients to promptly seek medical attention and discontinue use of TRYNGOLZA if hypersensitivity reactions occur. (5.1)

ADVERSE REACTIONS

Most common adverse reactions (incidence >5% of TRYNGOLZA-treated patients and >3% higher frequency than placebo) were injection site reactions, decreased platelet count, and arthralgia. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Ionis Pharmaceuticals Inc. at toll free number 1-833-644-6647 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 1/2025

<https://ionis.com/sites/default/files/2025-03/TRYNGOLZA-olezarsen-FPI.pdf>

Current Criteria:

- Minimum age = 18
- Maximum quantity = 1 autoinjector per 28 days

Draft Criteria Considered to be Added:

- Diagnosis of Familial Chylomicronemia Syndrome
- Fasting triglycerides \geq 880 mg/dL within past 90 days
- Used in combination with a low-fat diet \leq 20 gm fat per day