Tryngolza®
(olezarsen) 80 mg injection

For your adult patients with familial chylomicronemia syndrome (FCS), it's time to

CELEBRATE

significant reductions in triglycerides[1]*

Introducing TRYNGOLZA: the first and only FDA-approved therapy that is proven to significantly reduce triglyceride levels in adults with FCS when used as an adjunct to diet.

*In the *Balance* clinical trial, TRYNGOLZA demonstrated a significant mean change of −42.5% in fasting triglycerides from baseline to Month 6 compared with placebo (P=0.0084).[1]

Not a real patient; actor portrayal.

TRYNGOLZA is a once-monthly subcutaneous injection, self-administered via autoinjector.[1]

INDICATION

TRYNGOLZA (olezarsen) is indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS).

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

TRYNGOLZA is contraindicated in patients with a history of serious hypersensitivity to TRYNGOLZA or any of the excipients in TRYNGOLZA. Hypersensitivity reactions requiring medical treatment have occurred.

Please see Important Safety Information throughout and full Prescribing Information for TRYNGOLZA.

Familial chylomicronemia syndrome (FCS) is an underdiagnosed genetic form of severe hypertriglyceridemia (sHTG)[2]

- FCS is an underdiagnosed condition caused by loss-of-function pathogenic variants in the lipoprotein lipase (*LPL*) gene and in other genes encoding proteins required for LPL activity[3]
  - LPL is an enzyme that breaks down triglycerides in chylomicrons and in very-low-density lipoprotein (VLDL) particles[3]
- The lack of LPL activity leads to the accumulation of VLDL and chylomicrons, leaving individuals with severely elevated triglyceride levels and an increased risk of pancreatitis[4]
- There are several methods to diagnose FCS, including clinical scoring tools (Moulin et al and North American FCS [NAFCS]) and genetic testing[5,6]

Patients with FCS can have triglyceride levels 10 to 100 times the normal level, leading to potentially **life-threatening pancreatitis**[3]

Patient case: Gus

Gus, aged 31, presents with persistently elevated triglyceride levels and a medical history that prompts further evaluation.

He complains of lethargy and brain fog, and continues to experience severe abdominal pain despite having seen multiple gastroenterologists and receiving a diagnosis of irritable bowel syndrome. For the past 2 years, he estimates that he's missed about 3 days of work each month.

Key findings:

- Diagnosed with sHTG at age 9
- Fasting triglyceride levels >1500 mg/dL that have been consistently refractory to lipid-lowering treatments
- History of recurrent abdominal pain
- No known secondary causes of sHTG (eg, certain medications, alcohol use, metabolic syndrome)
- Body mass index (BMI) of 21.3
- Total cholesterol=175 mg/dL
- Apolipoprotein B (apoB)=85 mg/dL

Hypothetical patient case; actor portrayal.

Based on a clinical assessment and genetic testing, Gus is diagnosed with FCS.

Indeterminate genetic testing results can support a clinical FCS diagnosis, as not all genetic variants associated with FCS have been identified.[5]

Tryngolza® (olezarsen) 80 mg injection

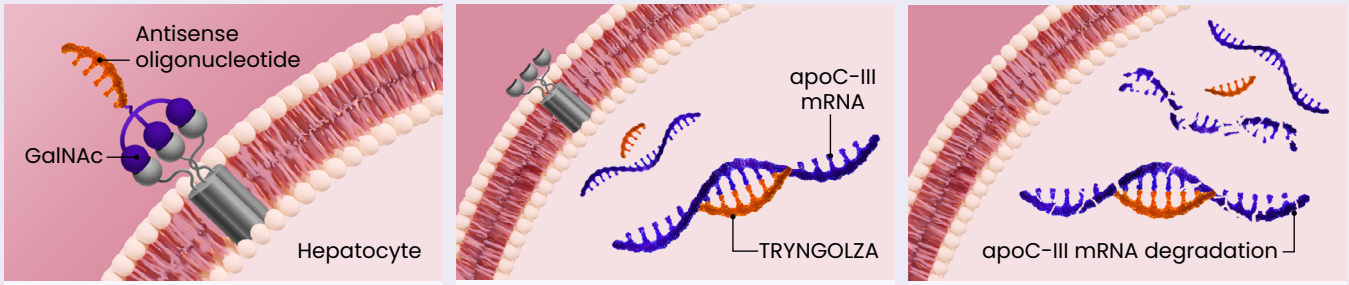
TRYNGOLZA is a GalNAc-conjugated antisense oligonucleotide inhibitor of apolipoprotein C-III (apoC-III) production[1]

GalNAc enables targeted delivery to the liver, where apoC-III mRNA is generated[1,7]

ApoC-III acts on the[3]:

- **LPL-independent pathways by inhibiting hepatic clearance** of triglyceride-rich lipoproteins, which play an important role in patients with FCS because of the substantial deficit in LPL activity
- **LPL-dependent pathway by inhibiting lipoprotein lipase (LPL) activity,** the primary mechanism by which plasma triglycerides are hydrolyzed

TRYNGOLZA is designed to work by[1]:



1 **Targeting hepatocytes**

2 **Selectively binding to apoC-III mRNA**

3 **Degrading apoC-III mRNA**

This process results in reduced serum apoC-III protein and reduced triglyceride levels.

TRYNGOLZA reduces apoC-III, which is a key regulator of triglyceride metabolism in both the LPL-dependent and LPL-independent pathways.[1,3]

FCS=familial chylomicronemia syndrome; GalNAc=triantennary N-acetylgalactosamine; mRNA=messenger ribonucleic acid.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions (including symptoms of bronchospasm, diffuse erythema, facial swelling, urticaria, chills, and myalgias) have been reported in patients treated with TRYNGOLZA. 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.

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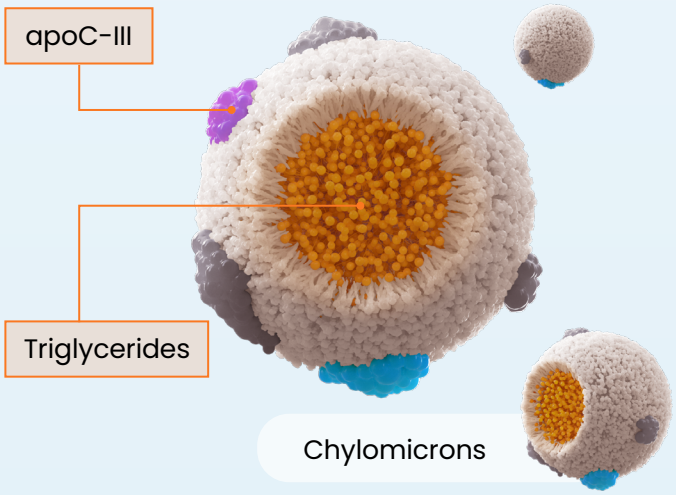
Pharmacodynamics: sustained reductions observed in fasting apoC-III from baseline over 1 year[1]

ApoC-III is a regulator of triglyceride metabolism.[3]

Fasting apoC-III placebo-corrected mean percent change from baseline[1]			
Month 1	**Month 3**	**Month 6**	**Month 12**
-57%	**-69%**	**-72%**	**-80%**



apoC-III=apolipoprotein C-III.

SELECT IMPORTANT SAFETY INFORMATION

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.

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Tryngolza® (olezarsen) 80 mg injection

TRYNGOLZA was evaluated in 45 adults with FCS in the *Balance* trial: a randomized, placebo-controlled, double-blind phase 3 clinical trial[1]

Participants were randomized to receive TRYNGOLZA or placebo once every 4 weeks for 6 months* for the primary analysis, and were continued over a 12-month† treatment period.[1,8]

The efficacy of TRYNGOLZA was evaluated in 45 adults with familial chylomicronemia syndrome (FCS)[1]

Criteria for the trial included:

- Fasting triglyceride levels ≥880 mg/dL[1]
- Genetically identified FCS based on variants in genes known to cause complete or partial deficiency in LPL function.‡ Participants with **indeterminate** genetic test results were confirmed to have FCS through adjudication by subject matter expert[1,7]
- ≥4-week run-in period where patients followed a low-fat diet of ≤20 grams of fat per day[1]

Primary endpoint:

- **Mean percent change in fasting triglycerides** from baseline to Month 6* compared with placebo[1]

*Average of Weeks 23, 25, and 27.[1]

†Average of Weeks 51 and 53.[8]

‡Variants were *LPL, APOA5, GPIHBP1, LMF1,* or *APOC2*.[7]

APOA5=apolipoprotein A5; *APOC2*=apolipoprotein C2; *GPIHBP1*=glycosylphosphatidylinositol-anchored high-density lipoprotein binding protein 1; *LMF1*=lipase maturation factor 1; *LPL*=lipoprotein lipase.

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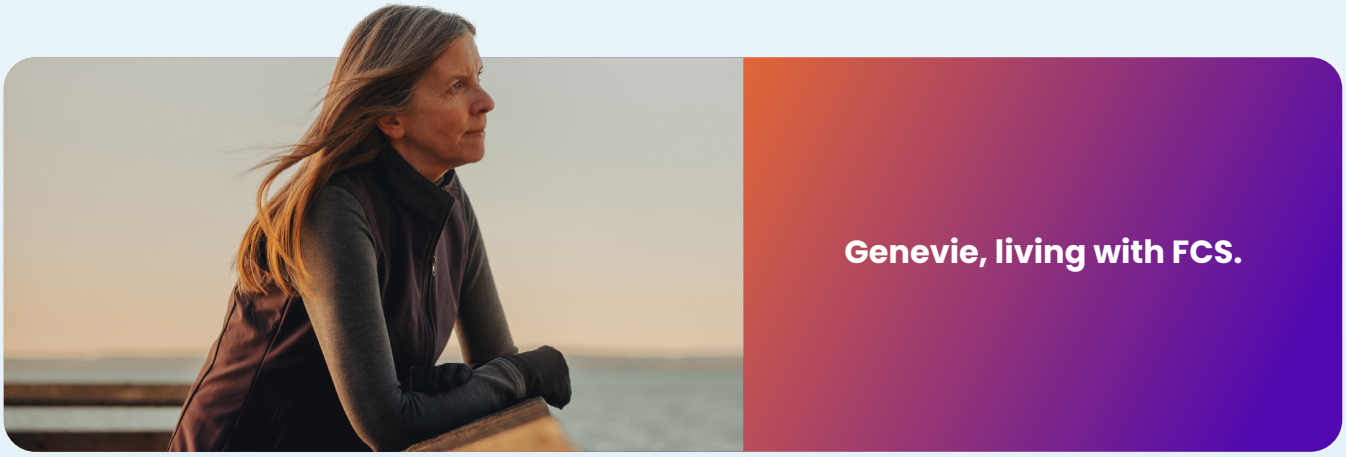
Select secondary and additional endpoints[1,4,8,9]

Select secondary and additional endpoints:

- Mean percent change in fasting triglycerides from baseline to Month 12 compared with placebo[9]
- Mean percent changes from baseline at Month 6 compared with placebo in fasting:
  - Total apoB[1]
  - apoB-48 (the only specific marker of intestinal chylomicrons)[1,4]
  - Non–HDL cholesterol[1]
  - LDL cholesterol[1]
- Adjudicated pancreatitis events and number of participants affected during treatment period[1,8]



apoB=apolipoprotein B; apoB-48=apolipoprotein B-48; FCS=familial chylomicronemia syndrome; LDL cholesterol=low-density lipoprotein cholesterol; non–HDL cholesterol=non–high-density lipoprotein cholesterol.

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WARNINGS AND PRECAUTIONS

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Tryngolza® (olezarsen) 80 mg injection

Participant demographic and baseline characteristics were generally similar across treatment groups[1]*

Participants were generally representative of the FCS population.[7]

Across all treatment groups, most participants were on stable background lipid-lowering therapy, such as statins, omega-3 fatty acids, and fibrates[1,8,10]

Baseline characteristic[7]	TRYNGOLZA 80 mg (n=22)[7]	Placebo (n=23)[7]
Body mass index (kg/m^2; mean±SD)	25.1±6.0	24.2±4.1
History of acute pancreatitis in the prior 10 years	17 (77%)	15 (65%)
Type 1 or 2 diabetes	7 (32%)	6 (26%)
Hypertension	4 (18%)	6 (26%)
Triglyceride level (mean±SD)	2613±1499	2596±1256
apoC-III level (mean±SD)	27.5±11.6	27.7±11.7
Non–HDL cholesterol level (mean±SD)	262.9±100.4	271.3±113.3

*Abbreviated baseline characteristics table.[7]

apoC-III=apolipoprotein C-III; non–HDL cholesterol=non–high-density lipoprotein cholesterol; SD=standard deviation.

SELECT IMPORTANT SAFETY INFORMATION

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.

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Tryngolza® (olezarsen) 80 mg injection

Significant reduction in fasting triglycerides at Month 6 with continued reductions observed at 1 year compared with placebo[1,9]

Primary endpoint*:

-42.5% at Month 6

significant mean change in fasting triglycerides compared with placebo
(95% CI, -74.1 to -10.9; *P*=0.0084)[1†]

Select secondary endpoint‡:

-56.9% at Month 12 mean change in fasting triglycerides compared with placebo (95% CI, -103.4 to -10.5)[9†§]

*Average of Weeks 23, 25, and 27.[1]
†Difference from baseline mean fasting triglyceride levels of 2604 mg/dL.[1]
‡Average of Weeks 51 and 53.[8]
§Missing data were imputed using placebo washout imputation. The 95% CIs of treatment differences were calculated using a robust variance estimator.[1]

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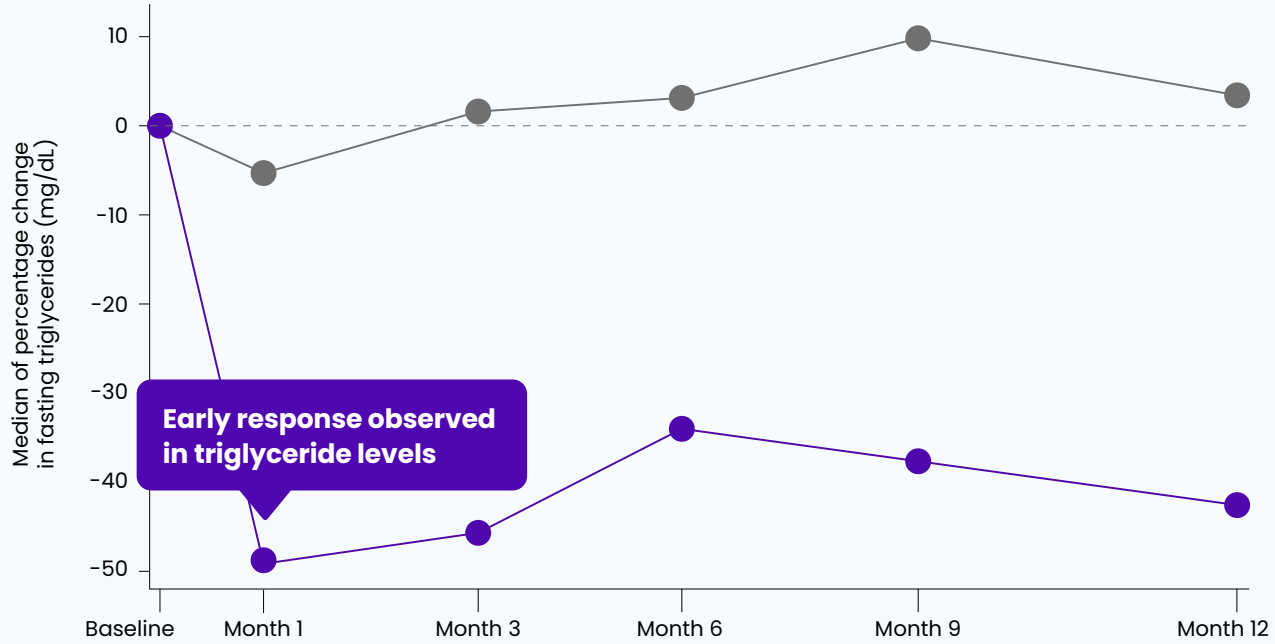
Tryngolza® (olezarsen) 80 mg injection

Rapid triglyceride reductions with consistent control over 1 year[1]

Median change in fasting triglyceride levels over 1 year[1]*



	Baseline	Month 1	Month 3	Month 6	Month 9	Month 12
Placebo	23	23	23	23	23	23
TRYNGOLZA 80 mg	22	22	22	22	22	22

Placebo TRYNGOLZA 80 mg

*Baseline median fasting triglyceride levels were 2303 mg/dL.[1]

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ADVERSE REACTIONS

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Tryngolza® (olezarsen) 80 mg injection

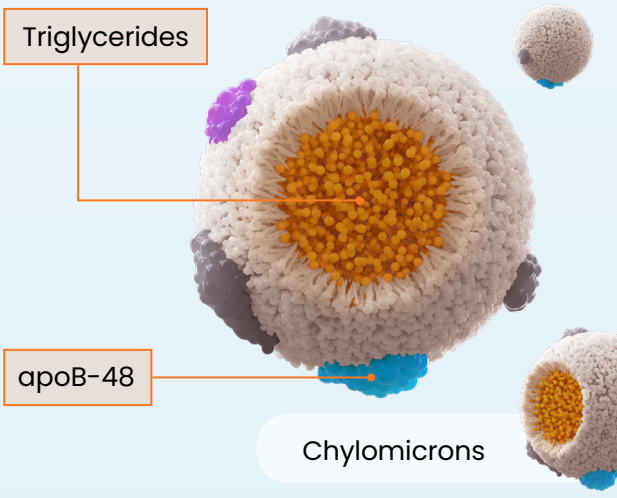
Changes observed in lipid/ lipoprotein parameters[1]

Mean LDL cholesterol levels increased but remained within normal range (ie, <70 mg/dL) for 74% of participants treated with TRYNGOLZA.[1]

Select secondary and additional endpoints: TRYNGOLZA vs placebo mean percent change from baseline (95% CI)[1]

Parameter (mg/dL)	Month 6
Total apoB	11.7% (-12.6 to 35.9)
apoB-48 (marker of intestinal chylomicrons[4])	-75.9% (-149.8 to -2.0)
Non–HDL cholesterol	-23.4% (-45.3 to -1.5)
LDL cholesterol*	55.0% (0.7 to 109.4)

Reductions observed
in apoB-48 and non–HDL cholesterol continued over 1 year.[11,12†]



*Baseline LDL cholesterol levels were 22.8±14.1 mg/dL in the TRYNGOLZA arm vs 16.7±8.4 mg/dL in the placebo arm.[7]

†Missing data were imputed using placebo washout imputation. The 95% CIs of treatment differences were calculated using a robust variance estimator.[1]

‡Reached statistical significance ($P<0.05$).[1]

apoB=apolipoprotein B; apoB-48=apolipoprotein B-48; LDL cholesterol=low-density lipoprotein cholesterol; non–HDL cholesterol=non–high-density lipoprotein cholesterol.

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WARNINGS AND PRECAUTIONS

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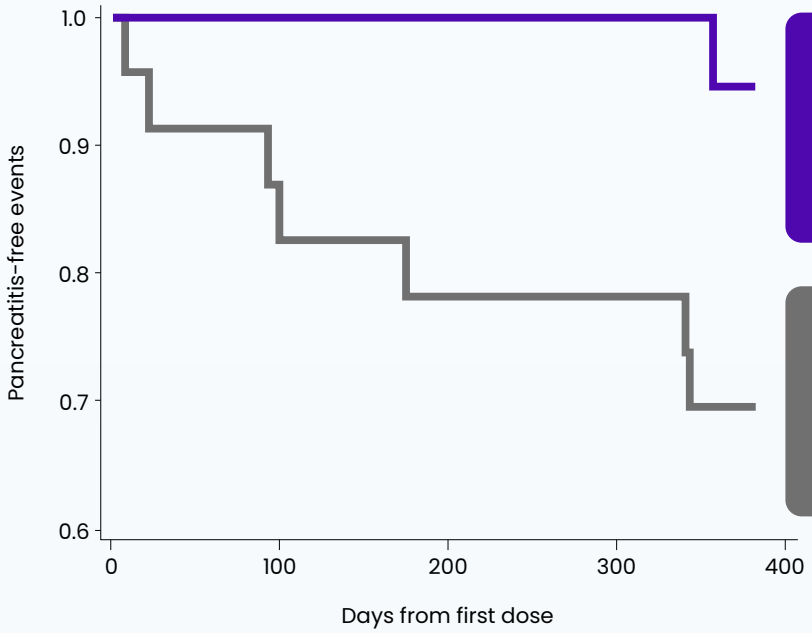
Tryngolza® (olezarsen) 80 mg injection

Lower incidence of acute pancreatitis (AP) with TRYNGOLZA[1,8]

The numerical incidence of AP in participants treated with TRYNGOLZA was lower compared with placebo.[8]

Select secondary endpoint: AP events over 1 year[1,8]*



TRYNGOLZA
1 AP event
experienced by 1 participant
First event at Day 357†

Placebo
11 AP events
experienced by 7 participants
First event at Day 9†

*Adjudication based on Atlanta classification; if serum and/or amylase activity was less than 3 times the upper limit of normal, imaging (preferably contrast-enhanced computed tomography) was considered to confirm the diagnosis of acute pancreatitis.[8]

†Time to first AP event was an ad hoc analysis.

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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.

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Tryngolza® (olezarsen) 80 mg injection

TRYNGOLZA demonstrated a well-tolerated safety profile[1]

Mean platelet counts remained within normal limits during the study, and no participant treated with TRYNGOLZA with FCS had a platelet count <50,000/mm^3. There were no major bleeding events associated with a low platelet count.[1]

Adverse reactions led to discontinuation of treatment in 3 participants (7%) treated with TRYNGOLZA and 0% of patients treated with placebo. Two participants in the 80 mg TRYNGOLZA arm and 1 in the 50 mg TRYNGOLZA arm reported adverse events (diarrhea, vomiting, chest discomfort, chills, myalgia, trismus, and flushing) that led to treatment discontinuation.[1,7]

Adverse reactions that occurred in >5% of participants treated with TRYNGOLZA and at >3% higher frequency than placebo[1]*

	Total TRYNGOLZA (n=43)	**Placebo** (n=23)
Injection-site reactions	8 (19%)	2 (9%)
Decreased platelet count	5 (12%)	1 (4%)
Arthralgia	4 (9%)	0

Please see "Laboratory Tests" in the TRYNGOLZA full Prescribing Information for additional safety information.

*The safety of TRYNGOLZA was evaluated in 66 participants with FCS enrolled in the *Balance* trial. In this trial, 43 participants received at least 1 dose of TRYNGOLZA, 50 mg (n=21) or 80 mg (n=22), and 23 participants received placebo. TRYNGOLZA 50 mg is not an approved dosing regimen for FCS.[1]

FCS=familial chylomicronemia syndrome.

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Tryngolza® (olezarsen) 80 mg injection

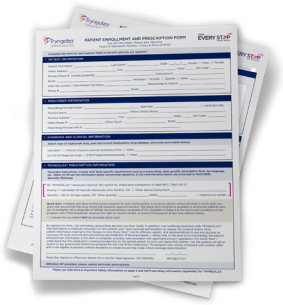
We're by your side at Ionis Every Step™

The Ionis Every Step team has been trained on familial chylomicronemia syndrome (FCS). We understand FCS, and that is why we offer patients prescribed TRYNGOLZA:

- Personal support from a dedicated Patient Education Manager*
- Help navigating the insurance process†
- Financial support offerings‡
- Nutritional tools and resources

IONIS EVERY STEP™ SUPPORT SERVICES

For more information about Ionis Every Step, call **1-844-789-8744 (Monday to Friday, 8 AM to 8 PM ET)**.



Click to download and complete the Patient Enrollment and Prescription Form, then fax to 1-877-914-0660.

*Patient Education Managers do not provide clinical recommendations and will refer patients back to their HCP as necessary.
†Insurance approval is not guaranteed. Ionis Every Step offers financial assistance programs for patients who are uninsured or denied coverage for their Ionis medication.
‡Subject to program terms, conditions, and limits.

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ADVERSE REACTIONS

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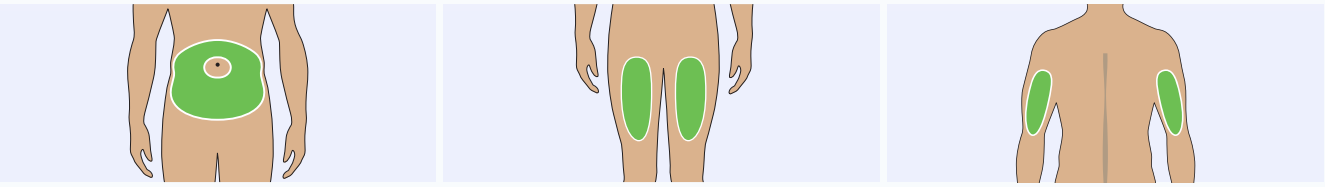
Please see Important Safety Information throughout and full Prescribing Information for TRYNGOLZA.

Tryngolza® (olezarsen) 80 mg injection

TRYNGOLZA is a monthly subcutaneous injection delivered via a convenient autoinjector[1,13]

TRYNGOLZA is self-administered once monthly into 1 of the following locations[1]:

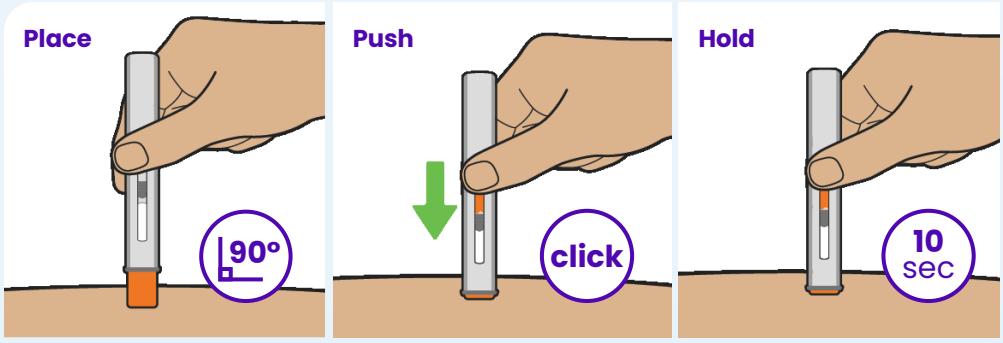


Abdomen
Appropriate for self-injection

Front of the thigh
Appropriate for self-injection

Back of the upper arm
If a healthcare professional or caregiver administers the injection

Three easy steps for injecting TRYNGOLZA[1]



Remove the clear cap and place the orange needle shield at a 90-degree angle against the skin. **Make sure you can see the viewing window.**

Push firmly against the skin. **You may or may not hear 2 clicks. This is normal. The procedure is not finished.**

Hold the autoinjector against the skin **and continue pressing down for 10 seconds.**

Do not lift the autoinjector until after holding for 10 seconds and checking that the orange plunger rod has filled the entire viewing window. Remove by lifting straight up, and throw away in a sharps container.

For additional information, please see complete Instructions for Use for TRYNGOLZA.

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Tryngolza® (olezarsen) 80 mg injection

Take TRYNGOLZA on the go[1]

Store the TRYNGOLZA autoinjector in the refrigerator between 36 °F and 46 °F (2-8 °C) in the original carton.[1]

When removed from the refrigerator, the TRYNGOLZA autoinjector can be stored at **room temperature** between 59 °F and 86 °F (15-30 °C) in its original carton for **up to 6 weeks**[1]*

This allows patients to administer their once-monthly dose **at home or away from home** if necessary[1]

*If not used within the 6 weeks stored at room temperature, discard TRYNGOLZA.[1]

Missed dose[1]

If a dose is missed:

- It should be administered as soon as possible after the missed dose
- Resume dosing at monthly intervals from the date of the most recently administered dose

Watch the TRYNGOLZA injection training video
A step-by-step instructional video explaining the self-administration process to patients with FCS, demonstrated by an Ionis Patient Education Manager.[1] **For full details on administration and storage, see the Instructions for Use and the injection training video on TRYNGOLZAHCP.com.**

SELECT IMPORTANT SAFETY INFORMATION

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.

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Tryngolza® (olezarsen) 80 mg injection

Genevie,
living with FCS.

Learn more about TRYNGOLZA: the first and only FDA-approved therapy for adults with FCS[1]

Visit TRYNGOLZAHCP.com

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INDICATION

TRYNGOLZA (olezarsen) is indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS).

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References: 1. TRYNGOLZA. Prescribing information. Ionis Pharmaceuticals; 2025. **2.** Davidson M, Stevenson M, Hsieh A, et al. The burden of familial chylomicronemia syndrome: results from the global IN-FOCUS study. *J Clin Lipidol*. 2018;12(4):898-907.e2. **3.** Gaudet D, Brisson D, Tremblay K, et al. Targeting APOC3 in the familial chylomicronemia syndrome. *N Engl J Med*. 2014;371(23):2200-2206. **4.** Ginsberg HN, Packard CJ, Chapman MJ, et al. Triglyceride-rich lipoproteins and their remnants: metabolic insights, role in atherosclerotic cardiovascular disease, and emerging therapeutic strategies—a consensus statement from the European Atherosclerosis Society. *Eur Heart J*. 2021;42(47):4791-4806. **5.** Moulin P, Dufour R, Averna M, et al. Identification and diagnosis of patients with familial chylomicronaemia syndrome (FCS): expert panel recommendations and proposal of an "FCS score". *Atherosclerosis*. 2018;275:265-272. **6.** Hegele RA, Ahmad Z, Ashraf A, et al. Development and validation of clinical criteria to identify familial chylomicronemia syndrome (FCS) in North America. *J Clin Lipidol*. 2025;19(1):83-94. **7.** Stroes ESG, Alexander VJ, Karwatowska-Prokopczuk E, et al; Balance Investigators. Olezarsen, acute pancreatitis, and familial chylomicronemia syndrome. *N Engl J Med*. 2024;390(19):1781-1792. **8.** Stroes ESG, Alexander VJ, Karwatowska-Prokopczuk E, et al; Balance Investigators. Olezarsen, acute pancreatitis, and familial chylomicronemia syndrome. *N Engl J Med*. 2024;390(19)(supplementary appendix):1781-1792. **9.** Data on file. REF-01848. Ionis Pharmaceuticals; 2024. **10.** Data on file. *Balance* clinical study report. Ionis Pharmaceuticals; 2024. **11.** Data on file. REF-01852. Ionis Pharmaceuticals; 2024. **12.** Data on file. REF-01850. Ionis Pharmaceuticals; 2024. **13.** Data on file. Human factors assessment. Ionis Pharmaceuticals; 2024.

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