

Your Tryngolza treatment

This brochure is intended for patients who have been prescribed Tryngolza (olezarsen) and is not a substitute for professional medical advice. Always consult your doctor, pharmacist, or other qualified healthcare professional with any questions regarding your condition, your treatment, or the proper use of this medicine. This material does not contain all possible information about the medicine, its use, risks, or side effects. For complete information please refer to the package leaflet that accompanies the product.

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What is familial chylomicronemia syndrome?

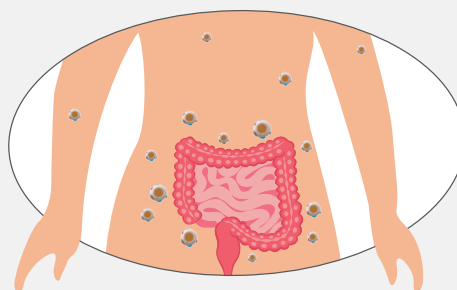
Familial chylomicronemia syndrome, or FCS, is a very rare genetic disorder that affects how the body handles fat.

FCS is caused by changes in certain genes that people are born with – and can usually be confirmed with a genetic test.

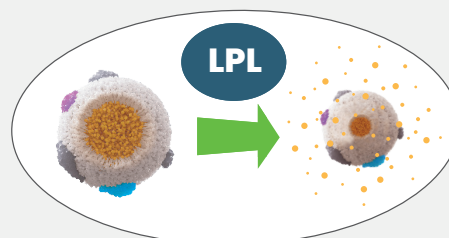
FCS affects between 1 and 13 of every 1 million people in Europe. So, you are one of the very few people who knows how tough it is to manage life with FCS.

How FCS affects fat breakdown

After a meal, the body makes tiny particles called **chylomicrons** that carry a certain form of fat, known as triglycerides, from the intestines to the rest of the body, where they can be used for energy or stored for later.



To do this, the body needs a **special enzyme called lipoprotein lipase (LPL)**, which helps break down these fats transported in the chylomicrons.



In people with FCS, the gene changes **stop LPL from working properly**, so the body can't break down fat in the usual way. As a result, too much fat and chylomicrons build up in the blood, which can lead to health problems over time.



Common signs and symptoms of FCS include:

- Very high triglyceride levels
- Acute pancreatitis (inflammation of the pancreas)
- Abdominal pain
- Nausea
- Fatigue
- Small yellowish skin bumps (called xanthomas)
- Milky appearance of the eye's blood vessels.

*Image is for illustrative purposes only
– not an actual patient.*

What is Tryngolza?

Tryngolza is a medicine containing the active substance **olezarsen**, which is designed to treat FCS.

Together with a controlled, very low-fat diet, Tryngolza may help lower the triglyceride levels in your blood and reduce the occurrence of acute pancreatitis episodes.

How Tryngolza works in people living with FCS



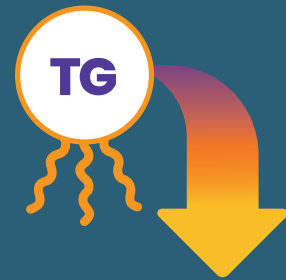
1.

There is a protein called apolipoprotein C-III (apoC-III), made in the liver, that slows down the clearance of fat from the bloodstream.



2.

Tryngolza reduces the production of this protein, so triglycerides can be cleared more easily.



3.

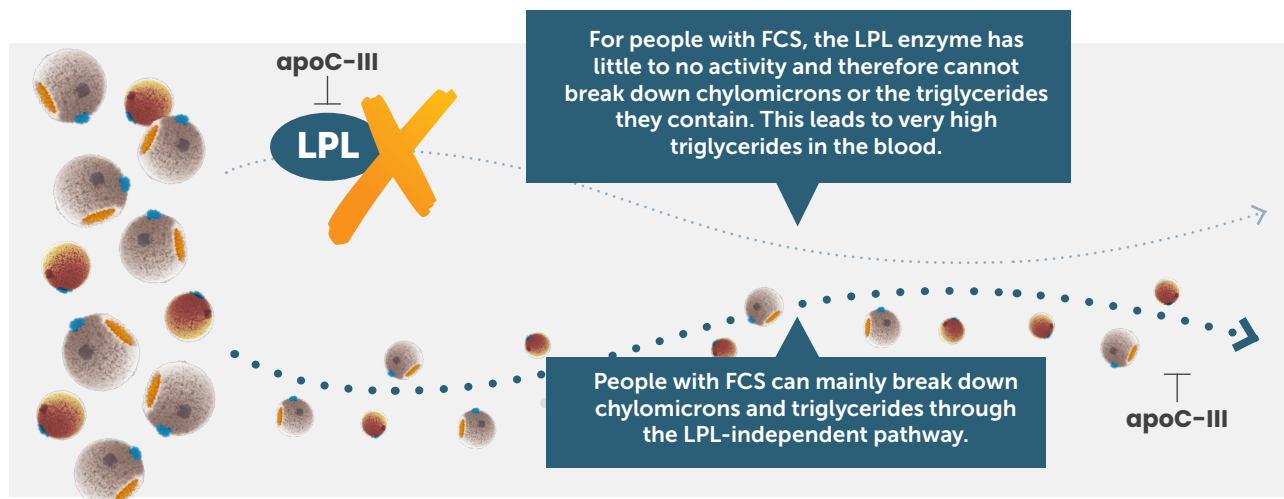
This helps to lower the triglyceride levels in your blood.



Why is a low-fat diet still needed?

There are two main pathways for removing fats from the bloodstream.

The major pathway needs the LPL enzyme, which helps break down these fats – this is called the **LPL-dependent** pathway. The second pathway works mostly through the liver, which can take up fat particles – this is called the **LPL-independent** pathway.



Because there is little or no LPL activity at all in FCS, Tryngolza can predominantly help the weaker, LPL-independent pathway by reducing apoC-III. While that is enough to make triglycerides go down a lot, the body still cannot handle a high-fat diet. A low-fat diet keeps the level of new chylomicrons low, so that the liver, with the help of Tryngolza, can remove them.



The FCS diet

Apart from your Tryngolza treatment, managing FCS involves maintaining an extremely low-fat diet.

The FCS diet is limited to 10–20 grams of fat per day. That is equivalent to approximately one tablespoon of olive oil or half an avocado. It also means restricting simple and refined carbohydrates and foods with added sugars, and abstaining from alcohol.

Quick tips:

- Eat smaller, more frequent meals. Being hungry can lead to poor eating choices. Try eating something every 2–3 hours to avoid hunger.
- Carry a suitable snack with you at all times to avoid being stranded somewhere with nothing appropriate to eat.
- Take a packed lunch with you if you're out and about for the day.
- Consult a registered dietitian for nutrition counselling.
- Learn to read food labels to manage your fat and calorie intake.
- Keep a food diary to monitor your eating habits.
- Use a medium chain triglyceride (MCT) oil – such as coconut oil – for cooking. MCT molecules are smaller than those in most other fats (long-chain triglycerides or LCTs). This makes them easier to digest.

Introducing Tryngolza

Tryngolza is provided in a pack as a single-dose pre-filled pen, which contains a clear, colourless to yellow solution.

Tryngolza is designed to be given once monthly. The dose should be given on the same day each month.

Always use Tryngolza exactly as your doctor has told you – and check with your doctor if you are not sure.

Before using this medicine, it is important that you read, understand and closely follow the instructions for use.

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See section 4 of the package leaflet for how to report side effects.

IMPORTANT!

Read the package leaflet carefully before you start using Tryngolza.



How to handle Tryngolza

- Keep this medicine out of the sight and reach of children.
- Do not use after the expiry date, which is stated on the carton and pre-filled pen label after 'EXP'.
- Please note that the expiry date refers to the last day of the month.
- Store in a fridge (between 2° and 8°C) and in the original package to protect from light.
- Tryngolza can be kept at room temperature (up to 30°C) in the original carton for up to 6 weeks after removing from the fridge.
- Do not use if the solution appears frozen, is cloudy, or contains particles; it should be a clear and colourless to yellow liquid.
- Do not throw away any medicines via wastewater or household waste.
- Ask your pharmacist how to throw away medicines you no longer use.

How to inject Tryngolza

Easy-to-use autoinjector

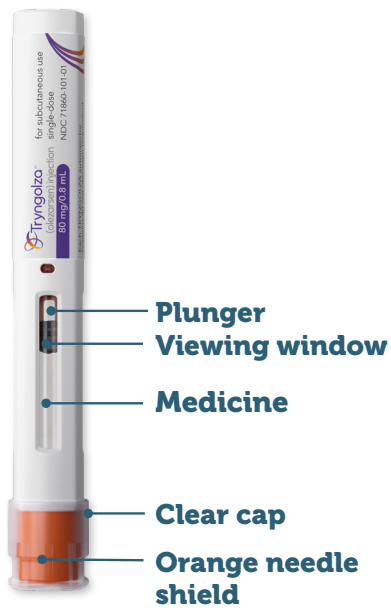
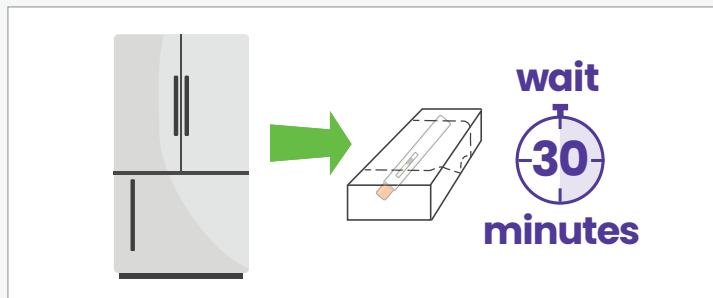


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1. Prepare

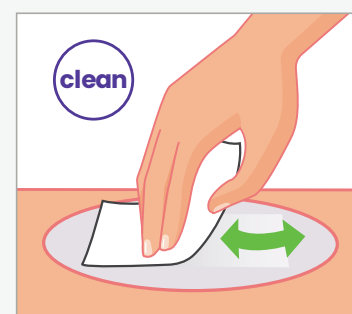
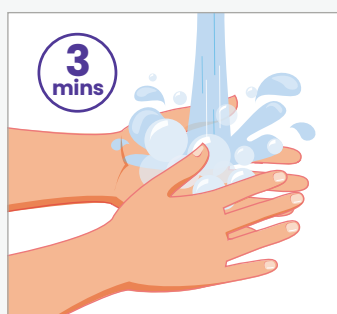
Take your pre-filled pen out of the fridge at least 30 minutes before your injection to allow it to come to room temperature. This will allow for a more comfortable injection experience. Set a timer to keep track of the time.



Gather supplies on a clean surface:

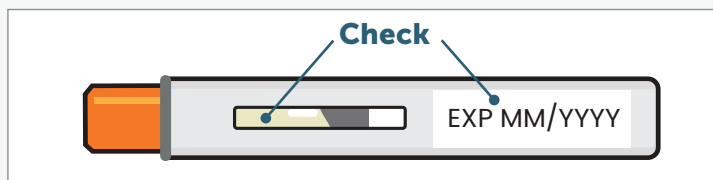
- Alcohol pad
- Tryngolza pre-filled pen
- Sharps container
- Cotton ball/gauze pad (optional)
- Bandage (optional)
- Ice or ice pack (optional)

Wash your hands for 3 minutes with soap and dry them well, then clean the injection site with the alcohol pad. Do not touch the injection site after cleaning.



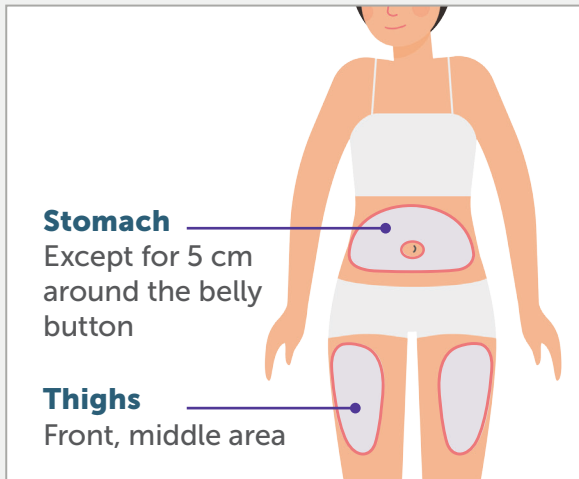
Check the expiry date

Make sure you check the expiry date on the packaging and the appearance of the medicine before injecting. It should be clear and colourless or yellow.

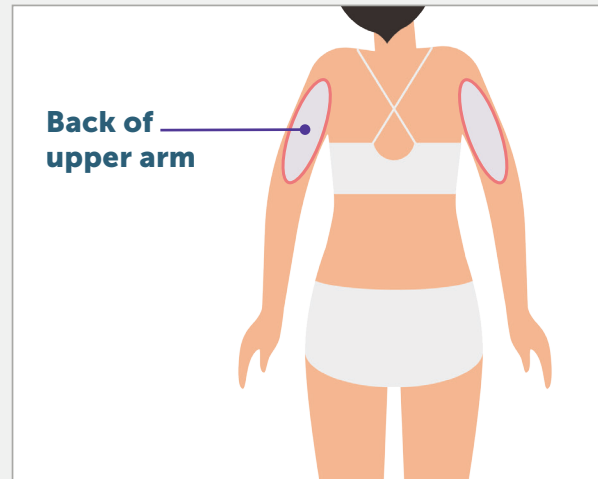


2. Select an injection site

If you are injecting Tryngolza yourself



If someone else is injecting Tryngolza (another option in addition to the other sites)



Sites for injection include the stomach, upper thigh region, or outer area of the upper arm. Injection into the upper arm should only be performed by another person, such as a carer or healthcare professional.

Do not inject Tryngolza into skin that is bruised, tender, red or hard, or into scars or damaged skin. The area around the belly button should be avoided.

Change the place on your body where you inject Tryngolza with each dose to avoid hardening of the skin.

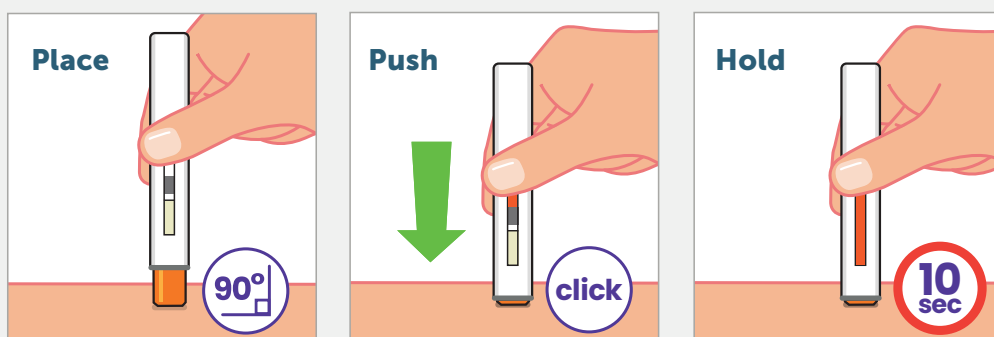
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3. Inject

Please see the package leaflet for full instructions on how to inject Tryngolza.

1. Make sure the injection site is clean before beginning.
2. Remove the clear cap. Hold the pre-filled pen in one hand and **place** the orange needle shield at a 90-degree angle against your skin.
3. **Push** firmly and hold the pre-filled pen straight against the skin. You will hear a click as the injection starts. You may hear a second click. This is normal. The procedure is not finished.
4. **Hold** the pre-filled pen against the skin for **10 seconds** to make sure the full dose has been given.



5. Remove the pre-filled pen by lifting it straight up.
6. Dispose of used pre-filled pen in an approved sharps disposal container.
7. If needed, press lightly with a sterile cotton ball or gauze if there are drops of blood.

IMPORTANT!

- Do not use the pre-filled pen if the clear cap is missing or not attached.
- Do not use the pre-filled pen if it appears damaged.
- Do not freeze the pre-filled pen.
- If any of the above happens, throw away the pre-filled pen in a puncture-resistant (sharps) container and use a new one.
- Do not reuse the pre-filled pen or clear cap.

If you use more Tryngolza than you should or if the full dose is not received (i.e. the plunger rod does not fill the viewing window) – contact your doctor or pharmacist, or attend a hospital emergency department immediately, even if there are no symptoms. Bring the medicine's carton or pen with you.

Do not stop using Tryngolza unless you have discussed stopping your treatment with your doctor.

If you have any further questions on using this medicine, ask your doctor, pharmacist or nurse.

Ask your doctor or nurse if there is an instruction video showing how to administer Tryngolza.

Side effects

Like all medicines, Tryngolza may cause side effects, so some people may get them. You can learn more about possible side effects in the package leaflet.

The most common side effect of Tryngolza is allergic (hypersensitivity) reactions. Other very common side effects are: headache, pain, soreness, or stiffness in your joints (arthralgia), redness (erythema) at the site of injection, and being sick (vomiting).

Contact your doctor immediately if you experience any of the following side effects, as they may be life-threatening:



- **Difficulty breathing**
- **Throat tightening**
- **Swelling of the face, lips, mouth, tongue and/or throat**
- **Redness of the skin**
- **Chills**

Other possible side effects include muscle pain (myalgia), change in skin colour at the site of injection, shivering (chills), pain at the site of injection, and swelling at the site of injection.

IMPORTANT!

If you get any side effects, talk to your doctor, pharmacist or nurse about them. This includes any possible side effects not listed in this brochure. You can also report side effects directly via the national reporting system listed in the package leaflet.



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Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Tryngolza if you have or have had any of the following medical problems:

- Any liver or kidney problem
- A low number of platelets in your blood.

Do not use Tryngolza if any of the following apply to you:

- You are allergic to olezarsen or any of the other ingredients in this medicine listed in the package leaflet
- You are less than 18 years of age.

Tryngolza has not been studied in pregnant women. As a precautionary measure, Tryngolza should be avoided during pregnancy, and women of child-bearing age should use effective contraception if they are taking Tryngolza.

If any of the above apply to you, or you are not sure, talk to your doctor before using Tryngolza.

Tell your doctor if you are breast-feeding or planning to breast-feed.

Other medicines and Tryngolza

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

Tryngolza can be used with other lipid-lowering medicines – for example, statins and fibrates.



Treatment routines

The *Tryngolza treatment journal* is a tool that will help you keep a record of your injections, important contact numbers, and other notes about your experience with Tryngolza. Share this information with your doctor to better manage your treatment and disease.

Ask your doctor or nurse if they can provide you with the Tryngolza treatment journal.

Schedule

Make sure to follow your dosing schedule. If you need to change your dosing schedules, make sure to discuss this with your doctor.

A missed dose

If you miss a dose, inject your next dose as soon as possible, and continue your monthly injections from then on. If you have questions about your dosing schedule, contact your doctor, pharmacist or nurse.



TIP

Complete the *Tryngolza treatment journal* after each injection; it will help you remember where you injected the last time.

A vertical rectangular graphic with a gradient from orange at the top to purple at the bottom. It has a white border and the text 'My journal' in white. There are small orange and purple corner tabs on the right side.

My
journal

Notes

A series of horizontal dotted lines for writing notes.

Notes

A series of horizontal dotted lines for writing notes.

Notes

A series of horizontal dotted lines for writing notes.

**Light the way forward
for life with FCS**

Learn more about FCS at

<https://pro.sobi.com/en/therapeutic-areas-diseases/specialty-care/fcs>



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 **Tryngolza**[®]
(olezarsen) 80 mg
injection