

## Package Leaflet: Information for the user

### Tryngolza 80 mg solution for injection in pre-filled pen olezarsen

▼ 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 the end of section 4 for how to report side effects.

#### **Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Tryngolza is and what it is used for
2. What you need to know before you use Tryngolza
3. How to use Tryngolza
4. Possible side effects
5. How to store Tryngolza
6. Contents of the pack and other information

#### **1. What Tryngolza is and what it is used for**

Tryngolza is a medicine that changes the way in which the body breaks down fats (a so-called lipid-lowering medicine). It contains the active substance olezarsen.

It is used together with dietary restrictions to help treat people aged 18 years and above with familial chylomicronemia syndrome (FCS). FCS is an inherited disease that gives rise to abnormally high levels of fats called triglycerides in the blood. This can lead to inflammation of the pancreas, causing severe pain, lasting damage to the pancreas, and can be life threatening.

Olezarsen works by blocking the production of the molecule that slows the removal of triglycerides. By doing so, it helps to lower the levels of triglycerides in the blood and can help to reduce the occurrence of acute pancreatitis (inflammation of the pancreas).

You will only be given Tryngolza if genetic testing has confirmed you have FCS.

Tryngolza may be given after you have already received other medicines used to lower the levels of triglycerides in blood and have maintained a low fat diet without having much effect.

#### **2. What you need to know before you use Tryngolza**

##### **Do not use Tryngolza**

- if you are allergic to olezarsen or any of the other ingredients of this medicine (listed in section 6).

### **Warnings and precautions**

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

- Any liver or kidney problems.
- A low number of platelets in your blood. Platelets are a type of blood cell which clump together to help blood clot.

### Allergic reactions

Tryngolza can cause serious allergic reactions. Stop using Tryngolza and contact your doctor immediately if you develop symptoms of a serious allergic reaction (see section 4).

### **Children and adolescents**

Do not use Tryngolza if you are under 18 years old. Olezarsen has not been studied in patients under 18 years old and it is not known how this medicine will affect them.

### **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.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

It is not known if this medicine can harm the unborn baby. It is preferable to avoid using Tryngolza if you are pregnant, think you may be pregnant, or are planning to have a baby. Women who are able to become pregnant should use effective contraception.

It is not known if olezarsen passes into breast milk. It is not known if this medicine can affect a breast-feeding newborn/infant. Tell your doctor if you are breast-feeding or planning to breast-feed; your doctor will decide if you should take this medicine or breast-feed based on what is best for you and your baby.

### **Driving and using machines**

Tryngolza has no or negligible effect on your ability to drive or use machines.

### **Sodium**

This medicine contains less than 1 mmol sodium (23 mg) per 80 mg dose, that is to say essentially 'sodium-free'.

## **3. How to use Tryngolza**

Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor or pharmacist if you are not sure.

You should continue the very low-fat diet that your doctor has recommended during treatment with Tryngolza.

The recommended dose is 80 mg once a month; the dose should be given on the same day each month.

Tryngolza should be injected under the skin (subcutaneous administration) of your belly (abdomen), the front of your upper legs, or the back of your upper arms. You or your caregiver will be trained how to use Tryngolza according to the instructions for use provided at the end of this leaflet. When injecting this medicine yourself, you can only inject it under the skin of your belly or upper legs. Only a healthcare provider or caregiver may give you an injection in the back of your upper arm.

Each single-dose pre-filled pen of this medicine gives you a dose of 80 mg in 0.8 mL. The pen can only be used once and should be disposed after use.

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

Do not use this medicine if the solution appears frozen, is cloudy, or contains particles; it should be a clear and colourless to yellow liquid. You may see air bubbles in the solution, this is normal.

**Do not inject:**

- within 2 inches (5 cm) of the belly button.
- into skin that is bruised, tender, red or hard.
- into scars or damaged skin.

#### **If you use more Tryngolza than you should**

If you inject too much Tryngolza, contact your doctor or pharmacist, or attend a hospital emergency department immediately, even if there are no symptoms. You will be monitored and given supportive care if needed. Bring the medicine's carton or pen with you.

#### **If you forget to use Tryngolza**

If you miss your dose of Tryngolza, 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.

#### **If you stop using Tryngolza**

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

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

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

#### **Serious side effects**

**Common** (may affect up to 1 in 10 people)

If you get any of the following side effects, contact your doctor immediately:

- allergic (hypersensitivity) reactions. These may be life-threatening. Symptoms of an allergic reaction may include difficulty breathing, throat tightening, swelling of the face, lips, mouth, tongue and/or throat, redness of skin, and chills.

#### **Other side effects**

**Very common** (may affect more than 1 in 10 people)

- headache
- pain, soreness, or stiffness in your joints (arthralgia)
- redness (erythema) at the site of injection
- being sick (vomiting).

**Common** (may affect up to 1 in 10 people)

- muscle pain (myalgia)
- change in skin colour at the site of injection
- shivering (chills)
- pain at the site of injection
- swelling at the site of injection.

## Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard), or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Tryngolza

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and pre-filled pen label after 'EXP'. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C).

Store in the original package in order to protect from light.

Tryngolza can also be stored in the original package outside the refrigerator (up to 30 °C) for up to 6 weeks. If storing Tryngolza outside the refrigerator, write the disposal date on the outer carton. The disposal date is maximally 6 weeks after taking the medicine out of the refrigerator, and should be noted in the space indicated for storage up to 30 °C. If the expiry date on the pre-filled pen label or disposal date on the carton has passed, do not use the pre-filled pen and discard it.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Tryngolza contains

- The active substance is olezarsen. Each single-dose pre-filled pen contains 80 mg olezarsen in 0.8 mL solution.
- The other ingredients are sodium dihydrogen phosphate (E339), disodium hydrogen phosphate (E339), sodium chloride, water for injections, sodium hydroxide (E524), hydrochloric acid (E507) (see section 2 under 'Sodium').

### What Tryngolza looks like and contents of the pack

Tryngolza is a clear, colourless to yellow solution for injection in a disposable single-dose pre-filled pen. Each pre-filled pen contains 0.8 mL solution.

Pack size of one pre-filled pen.

### Marketing Authorisation Holder

Swedish Orphan Biovitrum AB (publ)  
SE-112 76  
Stockholm  
Sweden

### Manufacturer

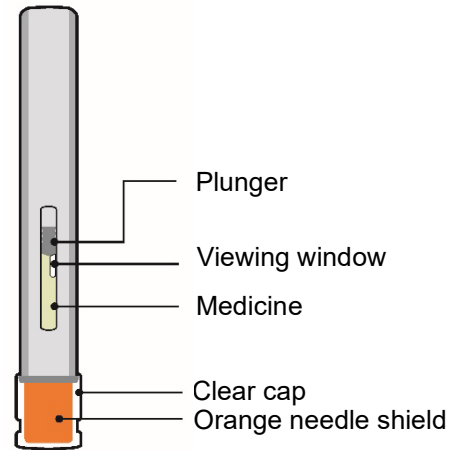
Swedish Orphan Biovitrum AB (publ)  
Norra Stationsgatan 93  
113 64 Stockholm  
Sweden

**This leaflet was last revised in 03/2026.**

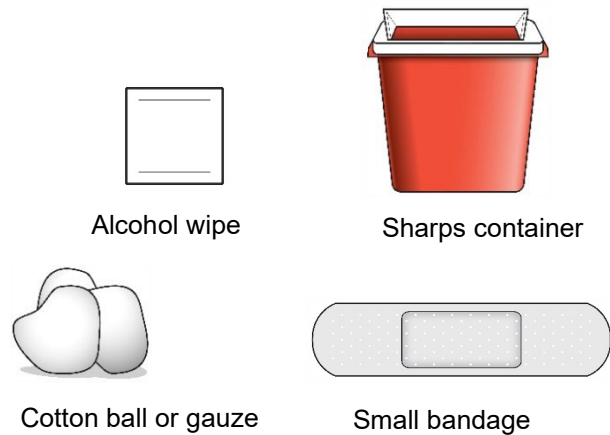
## INSTRUCTIONS FOR USE

Tryngolza is an injection given under the skin with a disposable single-dose pre-filled pen. Do not use Tryngolza until you completely understand the procedure described below. If you have any questions about how to use Tryngolza, please contact your doctor, pharmacist or nurse.

### Single-dose pre-filled pen



### Other supplies (not included)



## Get ready to inject Tryngolza

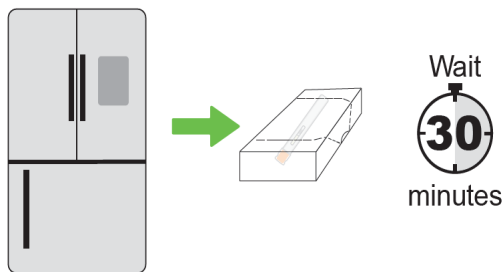
### Step 1 Remove from the refrigerator

a) Remove the pre-filled pen from the refrigerator (2 °C – 8 °C).

b) **Keep the pre-filled pen in the original carton** and let the pre-filled pen reach room temperature (up to 30 °C) for 30 minutes before injecting.

**Do not** try to speed up the warming process using other heat sources, such as a microwave or hot water.

If you store Tryngolza outside the refrigerator, write the disposal date on the outer carton. The disposal date is maximally 6 weeks after you take the medicine out of the refrigerator, and should be noted in the space indicated for storage up to 30 °C.



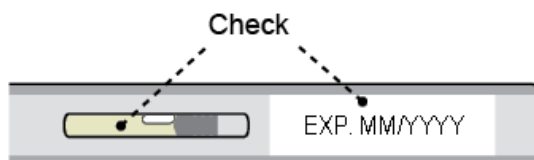
### Step 2 Inspect the medicine

a) Check the expiry ('EXP') date. Do not use Tryngolza if the 'EXP' date or disposal date on the carton has passed.

b) Check the medicine through the viewing window. The medicine should be a clear and colorless to yellow liquid. There should be no particles. It is normal to see air bubbles in the solution.

**Do not** use the pre-filled pen if:

- the clear cap is missing or not attached.
- the expiry ('EXP') date or disposal date has passed.
- the medicine looks frozen, cloudy, or has particles.
- the pre-filled pen appears damaged.



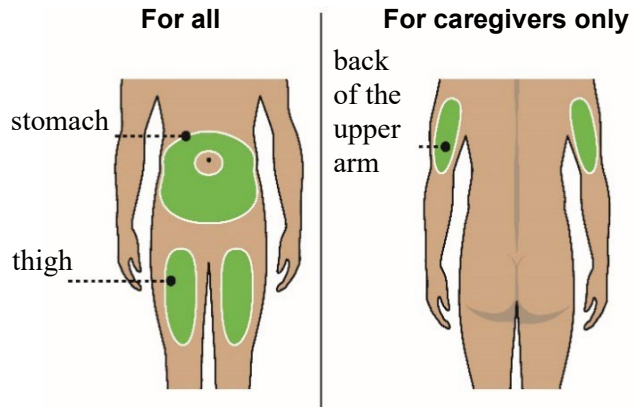
### Step 3 Choose the injection site

a) Choose an injection site on the stomach or the front of the thigh.

b) Only caregivers may inject in the back of upper arm.

**Do not** inject:

- within 2 inches (5 cm) of the belly button.
- into skin that is bruised, tender, red, or hard.
- into scars or damaged skin.



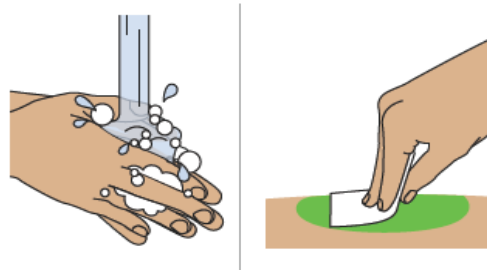
### Step 4 Wash hands and clean the injection site

The person administering the injection should:

a) Wash their hands with soap and water.

b) Clean the injection site with an alcohol wipe in a circular motion. Let the skin air dry.

**Do not** touch the cleaned skin before injecting.



### Injecting Tryngolza

#### Step 5 Remove and throw away the clear cap

a) Hold the pre-filled pen by the middle with the clear cap facing away from you.

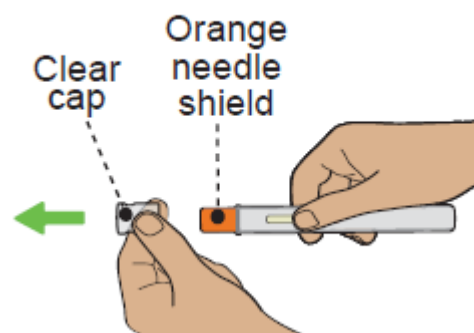
b) Remove the clear cap by pulling it straight off. **Do not** twist it off. The needle is inside the orange needle shield.

c) Throw away the clear cap in the trash or sharps container.

**Do not** remove the clear cap until right before you inject.

**Do not** recap the pre-filled pen.

**Do not** push the orange needle shield against the hand or finger.



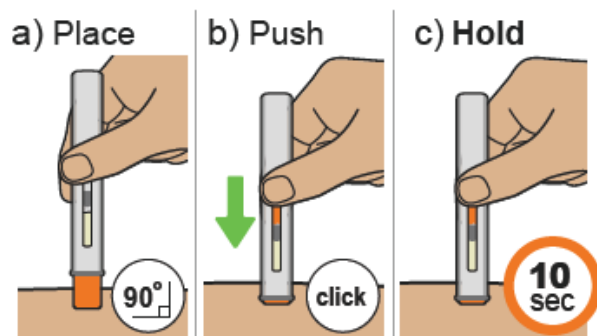
### Step 6 Begin injection

a) Hold the pre-filled pen in one hand. Place the orange needle shield at a 90-degree angle against your skin. Make sure you can see the viewing window.

b) 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.**

c) Hold the pre-filled pen against the skin for 10 seconds to make sure the full dose has been given.



**Do not** move, turn, or change the angle of the pre-filled pen during the injection.

### Step 7 Finish injection

a) Check that the orange plunger rod has moved down to fill the entire viewing window. If the orange plunger rod does not fill the viewing window, you may not have received the full dose.

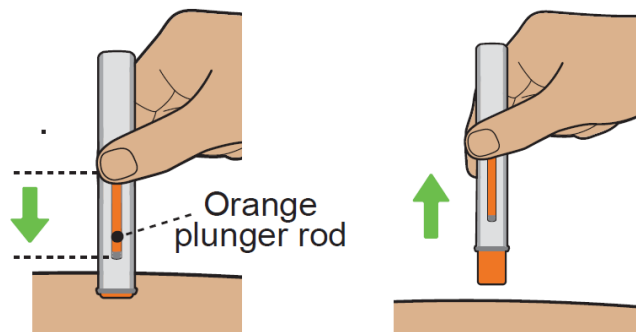
If this happens or if you have other concerns, contact your healthcare provider.

b) Remove the pre-filled pen by lifting it straight up. After removal from the skin, the orange needle shield locks into place and covers the needle.

c) There may be a small amount of blood or liquid where you injected. This is normal.

If needed, press a cotton ball or gauze on the area and apply a small bandage.

**Do not** reuse the pre-filled pen.



## Throwing away Tryngolza

### Step 8 Throw away the pre-filled pen

Put the used pre-filled pen in a sharps container right away after use.

**Do not** throw away the pre-filled pen in your household waste.

**Do not** recycle your used sharps disposal container.

**Do not** reuse the pre-filled pen or clear cap.

If you do not have a sharps container, you may use a household container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labelled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be local laws about how you should throw away used pre-filled pens. Ask your pharmacist or see your local public health government website (where available) for more details on how you should dispose of sharps in your location.

