

Package leaflet: Information for the patient

Rystiggo 140 mg/ml solution for injection rozanolixizumab

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

1. What Rystiggo is and what it is used for

What is Rystiggo

Rystiggo contains the active substance rozanolixizumab. Rozanolixizumab is a monoclonal antibody (a type of protein) designed to recognise and attach to FcRn, a protein that keeps the immunoglobulin G (IgG) antibodies in the body for longer.

Rystiggo is used together with standard therapy in adults to treat generalised myasthenia gravis (gMG), an autoimmune disease that causes muscle weakness which can affect multiple muscle groups throughout the body. The condition can also lead to shortness of breath, extreme fatigue and difficulties swallowing. Rystiggo is used in adults with gMG that produces IgG autoantibodies against acetylcholine receptors or muscle-specific kinase.

In generalised myasthenia gravis (gMG), these IgG autoantibodies (proteins of the immune system that attack parts of a person's own body) attack and damage proteins that are involved in communication between nerves and muscle, called acetylcholine receptors or muscle-specific kinase. By attaching to FcRn, Rystiggo reduces the level of IgG antibodies, including IgG autoantibodies, thereby helping to improve symptom of the disease.

2. What you need to know before you use Rystiggo

Do not use Rystiggo

- If you are allergic to rozanolixizumab 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 this medicine if any of the following applies to you:

Myasthenic crisis

Your doctor may not prescribe this medicine if you are, or are likely to be, on a ventilator due to gMG muscle weakness (myasthenic crisis).

Inflammation of the membranes that surround the brain and spinal cord (aseptic meningitis)

Aseptic meningitis has been observed in association with this medicine. Seek immediate medical attention if you develop symptoms of aseptic meningitis such as severe headache, fever, stiffness of the neck, nausea, vomiting and/or intolerance to bright light.

Infections

This medicine may reduce your natural resistance to infections. Before starting or during treatment with this medicine, inform your doctor if you have any symptoms of infection (feeling warm, fever, chills or shivering, cough, sore throat or fever blisters may be signs of an infection).

Hypersensitivity (allergic reactions)

This medicine contains a protein that can cause reactions such as rash, swelling or itching in some people. You will be monitored for signs of an infusion reaction during and for 15 minutes after treatment.

Immunisations (vaccinations)

Please inform your doctor if you have received a vaccine in the last 4 weeks, or if you plan to be vaccinated in the near future.

Children and adolescents

Do not give this medicine to children below the age of 18 years because the use of Rystiggo has not been studied in this age group.

Other medicines and Rystiggo

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Taking Rystiggo with other medicines may decrease the effectiveness of those medicines, including therapeutic antibodies (such as rituximab) or subcutaneous or intravenous immunoglobulins. Other medicines, including subcutaneous or intravenous immunoglobulins, or interventions such as plasmapheresis (a process in which the liquid part of the blood, or plasma, is separated from blood that has been drawn from a person), may impair the effect of Rystiggo. Tell your doctor if you are taking or planning to take other medicines.

Tell your doctor about your treatment with Rystiggo before you have a vaccination. This medicine may impair the effect of vaccines. Vaccination with so-called live-attenuated or live vaccines is not recommended during treatment with Rystiggo.

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 or pharmacist for advice before using this medicine.

The effects of this medicine in pregnancy are not known. You should not use this medicine if you are pregnant or think that you may be pregnant unless your doctor specifically recommends it.

It is not known whether this medicine passes into human milk. Your doctor will help you decide if you should breast-feed and use Rystiggo.

Driving and using machines

Rystiggo is not likely to affect your driving and use of machines.

Rystiggo contains proline

This medicine contains 29 mg of proline in each ml of medicine.

Proline may be harmful for patients with hyperprolinaemia, a rare genetic disorder in which an excess of the amino acid, proline, builds up in the body.

If you have hyperprolinaemia, tell your doctor and do not use this medicine unless your doctor has recommended it.

Rystiggo contains polysorbate 80

This medicine contains 0.3 mg of polysorbate 80 in each ml of medicine. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How to use Rystiggo

Treatment with Rystiggo will be initiated and supervised by a specialist physician experienced in the management of neuromuscular or neuro-inflammatory disorders.

How much Rystiggo is given and for how long

You will be given Rystiggo in cycles of 1 infusion per week for 6 weeks.

Your doctor will calculate the correct dose for you based on your weight:

- if you weigh at least 100 kg, the recommended dose is 840 mg per infusion (requiring 6 ml per administration)
- if you weigh from 70 kg to less than 100 kg, the recommended dose is 560 mg per infusion (requiring 4 ml per administration)
- if you weigh from 50 kg to less than 70 kg, the recommended dose is 420 mg per infusion (requiring 3 ml per administration)
- if you weigh from 35 kg to less than 50 kg, the recommended dose is 280 mg per infusion (requiring 2 ml per administration)

The frequency of treatment cycles varies for each patient and your doctor will consider if and when a new treatment cycle is appropriate for you.

Your doctor will advise you on how long you should be treated with this medicine.

How Rystiggo is given

Rystiggo will be given to you by a doctor or nurse.

Rystiggo can also be injected by yourself. You and your doctor or nurse will decide if, after training by a healthcare professional, you can inject this medicine yourself. Another person may also give your injections after they have been trained. Do not give yourself or someone else Rystiggo until you have been trained on how to do it.

If you or your caregiver inject Rystiggo, you or your caregiver must carefully read and follow the Instructions for administration at the end of this leaflet (see 'Instructions for use').

You will be given this medicine as an infusion under the skin (subcutaneous use). It is usually injected into the lower part of the tummy, below the belly button. Injections should not be given into areas where the skin is tender, bruised, red or hard.

The administration is done using an infusion pump set at a flow rate up to 20 ml/hr.
The administration can also be done manually (by manual push, this means without an infusion pump) at a flow rate that is comfortable for you.

If you receive more Rystiggo than you should

If you suspect that you have been accidentally administered a higher dose of Rystiggo than prescribed, please contact your doctor for advice.

If you forget or miss an appointment to receive Rystiggo

If you miss a dose, please contact your doctor immediately for advice and to schedule another appointment to receive Rystiggo within the next 4 days. Thereafter, the next dose should be given according to the original dosing schedule until the treatment cycle is completed.

If you stop using Rystiggo

Do not stop using this medicine without talking to your doctor first. Interrupting or stopping treatment with Rystiggo may cause your symptoms of generalised myasthenia gravis to come back.

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.

The below side effects, presented in order of decreasing frequency, have been observed with Rystiggo:

Very common: may affect more than 1 in 10 people

- Headache (including migraine)
- Diarrhoea
- Fever (pyrexia)

Common: may affect up to 1 in 10 people

- Rapid swelling under the skin in areas such as the face, throat, arms and legs (angioedema)
- Joint pain (arthralgia)
- Skin rash, sometimes with red bumps (rash papular)
- Injection site reaction including injection site rash, redness of the skin (erythema), inflammation, discomfort, and infusion site pain
- Nose and throat infections

Not known (frequency cannot be estimated from the available data) reversible non-infectious inflammation of the protective membranes that surround the brain and spinal cord (aseptic meningitis):

- headache
- fever
- stiffness of the neck
- nausea
- vomiting
- and/or intolerance to bright light

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:

Yellow Card Scheme

Website: 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 Rystiggo

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 vial label and outer carton after EXP. The expiry date refers to the last day of that month.

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

Do not freeze.

Keep the vial in the outer carton in order to protect from light.

Each vial of solution for injection must be used only once (single use). Any unused product or waste material should be disposed of in accordance with local requirements.

Do not use this medicine if you notice that the liquid looks cloudy, contains foreign particles, or has changed colour.

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 Rystiggo contains

- The **active substance** is rozanolixizumab. Each ml of solution contains 140 mg of rozanolixizumab. Each vial of 2 ml contains 280 mg rozanolixizumab. Each vial of 3 ml contains 420 mg of rozanolixizumab. Each vial of 4 ml contains 560 mg rozanolixizumab. Each vial of 6 ml contains 840 mg rozanolixizumab.
- The **other ingredients** are: histidine, histidine hydrochloride monohydrate, proline, polysorbate 80, and water for injections. See section 2 Rystiggo contains proline and Rystiggo contains polysorbate 80.

What Rystiggo looks like and contents of the pack

Rystiggo is a solution for injection. Each carton contains 1 vial of 2 ml, 3 ml, 4 ml or 6 ml solution for injection.

Not all vials may be marketed.

The solution is colourless to pale brownish-yellow, clear to slightly opalescent (pearly white). The devices used for administration should be procured separately.

Marketing Authorisation Holder

UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, SL1 3WE, United Kingdom

Manufacturer

UCB Pharma S.A., Chemin du Foriest, B-1420 Braine-l'Alleud, Belgium

This leaflet was last revised in February 2025.

INSTRUCTIONS FOR USE

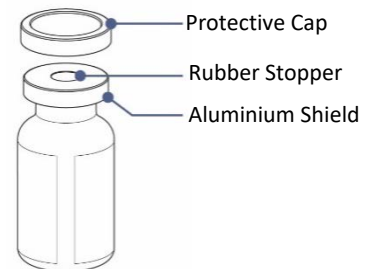
**Rystiggo (rozanolixizumab)
Rystiggo 140 mg/ml solution, for subcutaneous use
Single-Use Vial**

Read all of these instructions before using Rystiggo. A doctor or nurse will show you how to give yourself Rystiggo before you use it for the first time. Another person may also give your infusions after they have been trained. Do not give yourself or someone else Rystiggo until you have been shown how to do it. This information does not replace talking to your healthcare provider about your medical condition or treatment.

If you are using an infusion pump (also known as a syringe pump) to give yourself Rystiggo, please read the instructions provided by your doctor or nurse on how to set up the pump.

! Important information you need to know before giving yourself or someone else Rystiggo

- For under the skin (subcutaneous) use only.
- Use each vial only once.
- Check your dose – you may need more than 1 vial to prepare your prescribed dose.
- **Do not** use Rystiggo if the expiry date has passed.
- Before using Rystiggo, check if the dose on the box(es) is the same as your prescribed dose. **Do not** use if the dose is not the same as your prescription. Contact your doctor or nurse for next steps.
- **Do not** use the vial if the liquid has particles you can see. The medicine should be colourless to pale brownish-yellow, clear to slightly opalescent (pearly white).
- **Do not** shake the vial.
- **Do not** use the vial if the protective cap is missing or broken. If any of the vials are broken or do not have a cap, report and return them to the pharmacy.
- If you are using a non-programmable pump, please refer to the manufacturer’s instructions for use and your nurse’s guidance on how to fill the infusion line and set the dose.



How to store Rystiggo

- Store in a fridge (2 °C - 8 °C).
- **Do not** freeze.
- Keep Rystiggo in the original box to protect it from light.
- Remove the box from the fridge before your infusion. For a more comfortable infusion, let the vial reach room temperature before you use this medicine. This may take 30 to 120 minutes. Do not warm in any other way.



30 – 120 minutes

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

What is in the box

- 1 vial of Rystiggo - 2 ml, 3 ml, 4 ml or 6 ml depending on your prescribed dose.
- Rystiggo Package Leaflet which includes the Instructions for Use.

Step-by-step instructions

1. Get ready

Step 1: Gather all the supplies you will need on a clean and flat work surface:

- **Included** in the Rystiggo box(es):
 - Rystiggo vial.
 - Rystiggo Package Leaflet.

! Check your dose – you may need more than 1 vial to prepare your prescribed dose.

- **Not included** in the Rystiggo box:
 - Syringe (5 -10 ml depending on your prescribed dose).
 - Transfer needle with 18G needle or larger diameter (or a vented vial adaptor).
 - Infusion line with a 26G needle or larger diameter. The infusion line should be 61 cm in length or shorter.
 - Alcohol wipes.
 - Tape or see-through dressing.
 - Adhesive bandage.
 - Sharps container.
 - Bowl or paper towel to collect extra liquid when filling the infusion line.
 - Syringe pump – if you are using a pump.



! The supplies above are for illustration only. Your specific supplies may look different.

Step 2: Clean your work surface and hands

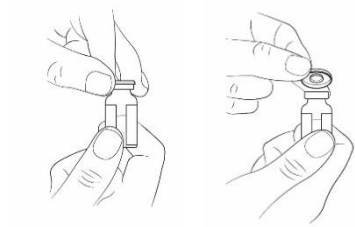
- Clean your work surface with disinfectant and wash your hands carefully with soap and water or use a hand sanitiser. Dry them on a clean towel.

2. Prepare the vial(s) and syringe

! Check your dose – you may need more than 1 vial to prepare your prescribed dose.

Step 3: Remove the protective cap from the vial(s)

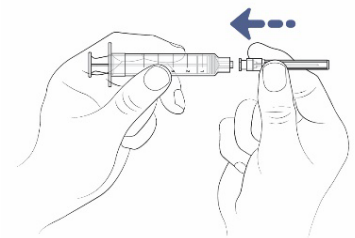
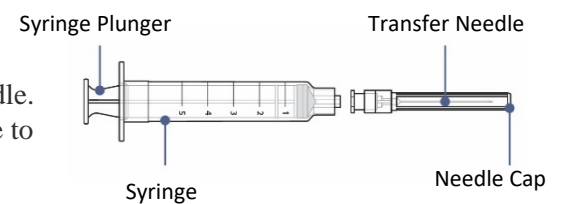
- Take the protective cap off the vial(s) by holding the edge and lifting upwards.
- Clean the rubber stopper with an alcohol wipe. Allow to air-dry.
- Leave the aluminium shield in place.
- Check your dose - if you need more than one vial to prepare your prescribed dose, remove all the caps and clean the stoppers.



! If you are using a vented vial adaptor instead of a transfer needle, you can skip directly to Step 7.

Step 4: Attach the transfer needle to the syringe

- Remove the plastic covers from the syringe and transfer needle. Do not touch the tip of the syringe or the base of the needle to avoid germs.
- With the needle cap still on, gently push or twist the transfer needle onto the syringe until it is firmly connected.



Step 5: Draw air into the syringe

- Slowly pull down on the syringe plunger to draw air into the syringe.
- Fill the syringe with about the same amount of air as the amount of medicine in the vial.
- Keep the needle cap on while you are doing this.



Step 6: Remove the needle cap from the transfer needle

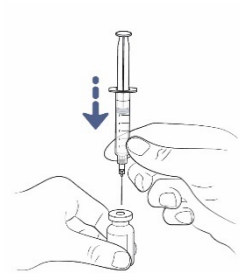
- Hold the syringe with one hand.
- With your other hand, hold the transfer needle cap and pull it straight off the needle
- Place the cap on the table to throw away later.
- **Do not** touch the needle tip.
- **Do not** let the needle tip touch anything after you remove the cap.

Step 7: Insert the transfer needle or vented vial adaptor directly into the vial

Follow the instructions for the infusion method you are using:

Using transfer needle

- Place the vial on the table and insert the transfer needle straight through the rubber stopper.



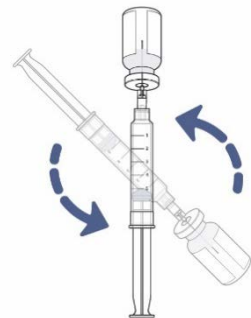
Using vial adaptor

- Place the vial on the table and insert the **vial adaptor** straight through the rubber stopper.
- Attach the syringe to the vented vial adaptor.



Step 8: Turn the vial and syringe

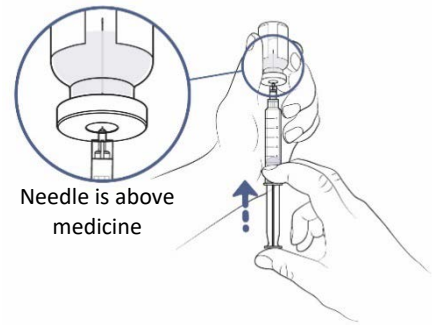
- Now turn the vial and syringe upside-down.
- Keep the transfer needle or vented vial adaptor inside the vial.



! If you are using a vented vial adaptor, you can skip directly to Step 11.

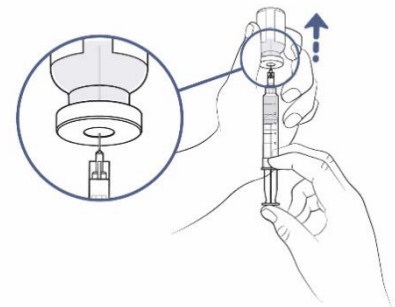
Step 9: Push air from the syringe into the vial

- Check that the transfer needle now points upwards and make sure the needle tip is in the space above the medicine.
- Slowly push the syringe plunger upwards to push all the air from the syringe into the vial. Keep your thumb pressed on the syringe plunger the whole time – so you do not let air into the syringe.
- Keep the needle tip in the space above the medicine the whole time.
- **Do not** push air into the medicine as this can create bubbles.



Step 10: Get ready to fill the syringe

- Keep your thumb pushed on the syringe plunger. With your other hand, pull the vial **slowly and carefully** upwards so the needle tip is fully covered by the liquid medicine.



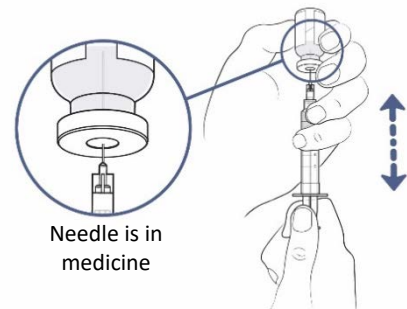
Step 11: Fill the syringe with as much medicine as possible

! Check your dose – you may need more than 1 vial to prepare your prescribed dose.

- Now slowly pull the syringe plunger down and fill the syringe with medicine.

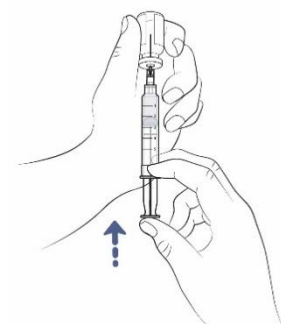
If you are using a transfer needle to fill the syringe, do the following:

- Keep pulling the vial slowly and carefully upwards to keep the tip of the needle fully covered by the liquid.
 - Adjust the needle tip to keep it in the liquid. This will help you to take as much medicine out of the vial(s) as possible.
- You should now have more medicine in the syringe than your prescribed dose. You will adjust this later.



! There will also be a very small amount of the medicine that you cannot take out of the vial. You will throw this away with the vial later.

! If you are using a vented vial adaptor, detach the syringe from the vented vial adaptor. Leave the vented vial adaptor in the vial. You can throw this away at the end of the infusion. You can now skip directly to Step 14.



Step 12: Remove air from the syringe

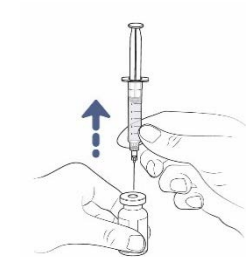
- If there is any space between the liquid in the syringe and the top of the syringe, slowly push the plunger to push air back into the vial.

- If you see air bubbles in the syringe, you can remove them by tapping gently on the syringe with your index finger. Now slowly push the plunger to push air back into the vial.

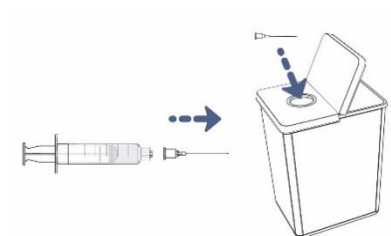


Step 13: Remove the transfer needle from the vial and the syringe

- Turn the vial and syringe over and put the vial on the work surface.
- Remove the transfer needle and syringe from the vial by pulling straight up on the syringe.



- Remove the transfer needle from the syringe by pulling or twisting carefully on the base of the needle.
- **Do not** touch the needle. **Do not** put the needle cap back on.
- Throw the needle away in the sharps container.
- If you are using a vented vial adaptor instead of a needle, it is not necessary to remove the vented vial adaptor from the vial before throwing them away.



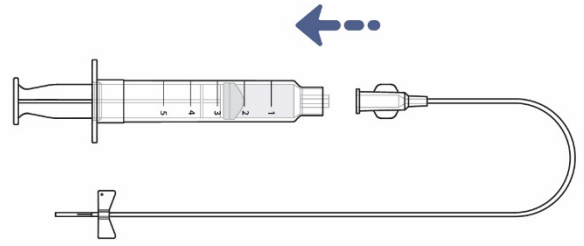
Step 14: Re-check your dose

- If you need to use another vial to prepare your prescribed dose, repeat Steps 4-13 with the same syringe and a new transfer needle or vented vial adaptor to avoid contamination.

3. Prepare for infusion

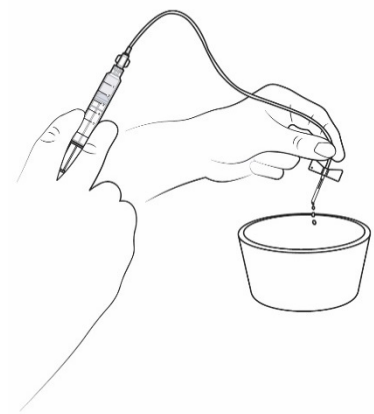
Step 15: Attach the infusion line onto the syringe

- Place the syringe on the clean work surface while you are preparing the infusion line.
- Remove the infusion line from the protective pouch.
- Remove the cap from the end of the infusion line by twisting it off. Place the cap on the work surface to throw away later.
- Attach the infusion line onto the syringe until firmly connected.
Do not touch the tip of the syringe or the base of the infusion line to avoid germs.
- **Do not** remove the needle cap from the infusion line needle.



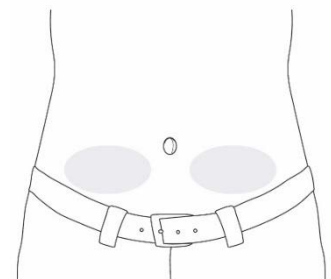
Step 16: Fill the infusion line with medicine

- Make sure you have a bowl or paper towel in front of you – you can use it to collect any medicine from the infusion line that is not needed.
- Keep the cap on the infusion line needle and hold it over the bowl. Now hold the syringe in a vertical position and fill the infusion line with medicine by pushing gently on the syringe plunger.
- **The amount of liquid left in the syringe must match your prescribed dose.**
- If you are using a syringe pump, please read the manufacturer's instructions on how to set up and operate the pump and fill the infusion line.



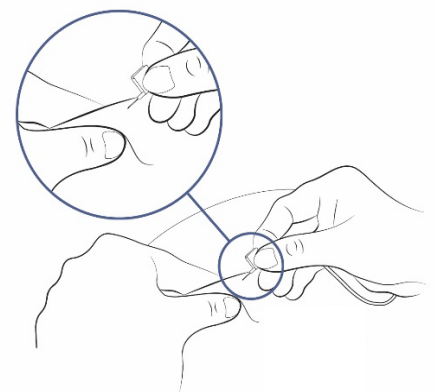
Step 17: Choose and prepare the infusion site

- Choose an infusion site to the lower left or lower right side of the tummy (abdomen), below the level of the belly button.
 - **Do not** use an area of skin which:
 - is tender, bruised, red or hard
 - has scars or stretch marks.
- Prepare the infusion site:
 - Clean the infusion area with an alcohol wipe and allow it to air-dry.



Step 18: Insert the infusion line needle

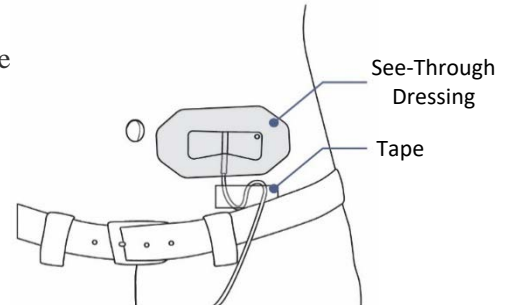
- Carefully remove the needle cap from the infusion line needle.
- Fold the butterfly wings together and hold them with your thumb and index finger of one hand.
- With your other hand, pinch the skin between 2 fingers to make a fold.
- Push the needle into the middle of the skin and push it under the skin.



- The needle should go in easily. If it is difficult, you can pull the needle out slightly.
- You may be using an infusion line without a butterfly-type needle at the end. Your nurse or doctor will explain to you how to insert the needle.

Step 19: Secure the infusion line needle

- Use a see-through dressing to hold the needle in place. Some infusion sets have a built-in adhesive.
- You can use tape to hold the infusion line on your skin.



4. Infuse and finish

Step 20: Start the infusion

Follow the instructions for the infusion method you are using:

Manual push

- Sit back comfortably and push firmly on the syringe plunger to infuse the medicine.
- You should infuse the medicine at a speed that feels comfortable to you. Keep pushing until there is no more medicine left in the syringe.
- Before and during the infusion, make sure that the infusion line does not twist or bend. If this happens, the flow of medicine can be interrupted. In this case, correct the bend in the infusion line and try again.
- If it feels uncomfortable or if any of the medicine flows back into the infusion line, you can push more slowly.

Syringe pump

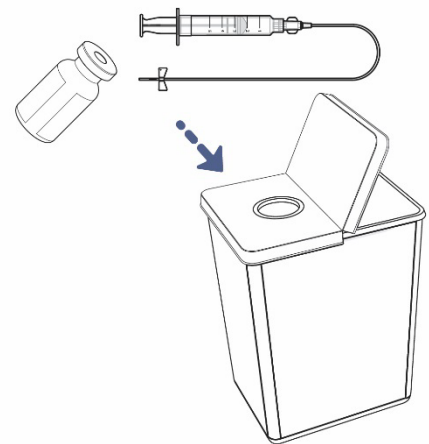
- Before you use a syringe pump, make sure that you understand the following:
 - How to set up your syringe pump (set an infusion rate of up to 20 ml per hour).
 - How to set the occlusion alarm to maximum setting.
 - How to start the syringe pump.
 - What the various syringe pump sounds and alarms mean and how to manage them.
 - How to stop the syringe pump.
- When you are ready to infuse:
 - Place the syringe in the syringe holder and start the pump by following the pump instructions.

- Sit back comfortably while the pump gives you the medicine.
- Before and during the infusion, make sure that the infusion line does not twist or bend. If this happens, the flow of medicine can be interrupted. In this case, correct the bend in the infusion line and try again.
- Once it has finished, stop the pump by following the pump instructions.
- Take the syringe out of the syringe pump.

! Note: There will be some medicine left in the infusion line. This is normal and you can throw it away in the sharps container.

Step 21: Finish the infusion and clean up

- After you finish the infusion, **do not** try to take the dressing off the needle. Remove them both from your skin together and throw them away with the syringe in the sharps container.
- There may be a drop or two of liquid at the infusion site after you take out the needle. This is normal.
- Throw away any used vial(s) and leftover medicine into the sharps container.
- Cover the infusion site with a clean dressing, such as an adhesive bandage.
- Throw away any other used supplies in your household waste.



! Always keep the sharps container out of the sight and reach of children.