

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is marketed upon physician's prescription only

WINREVAIR®

45 mg

Powder and solvent for solution for injection

Each vial contains:

45 mg of sotatercept (50 mg/mL after reconstitution)

WINREVAIR®

60 mg

Powder and solvent for solution for injection

Each vial contains:

60 mg of sotatercept (50 mg/mL after reconstitution)

For the list of inactive ingredients and allergens, see section 6 'FURTHER INFORMATION'. See also section 2.8 'Important information about some of the ingredients of the medicine'.

Read the entire leaflet carefully before you start using this medicine.

- This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT WINREVAIR IS INTENDED FOR?

WINREVAIR, in combination with other pulmonary arterial hypertension (PAH) therapies, is indicated for the treatment of PAH in adult patients with WHO Functional Class (FC) II to III, to improve exercise capacity.

Therapeutic group: Antihypertensive medicines for treatment of pulmonary arterial hypertension.

PAH is a type of high blood pressure in the arteries of your lungs. In PAH, these arteries get narrower, which makes it harder for the heart to pump blood through these vessels, and leads to symptoms like fatigue, dizziness, and difficulty breathing.

WINREVAIR acts on the causes of PAH responsible for the narrowing of the arteries of your lungs. This makes it easier for the heart to pump blood to your lungs and improves your ability to be physically active.

2. BEFORE USING WINREVAIR

2.1 Do not use WINREVAIR if:

- | |
|---|
| <ul style="list-style-type: none">- you are sensitive (allergic) to the active ingredient (sotatercept) or any of the other ingredients that this medicine contains. For the list of inactive ingredients, see section 6 'FURTHER INFORMATION'.- the number of platelets in your blood is repeatedly very low. |
|---|

2.2 Special warnings regarding use of WINREVAIR

WINREVAIR may increase the levels of haemoglobin in your blood, decrease the number of platelets in your blood, or increase the risk of serious bleeding.

Before starting treatment with WINREVAIR, tell your doctor if:

- **you have high levels of haemoglobin in your blood** (a protein in red blood cells that carries oxygen).
This can increase the chance of a blood clot forming, that can block a blood vessel. Your doctor will check haemoglobin levels with regular blood tests before each of your first 5 doses of WINREVAIR, or longer before each dose if needed, and regularly while you are using this medicine.
- **you have low number of platelets in your blood** (blood cells that help blood to clot).
This can cause easy bruising, continued bleeding from cuts and nosebleeds. Your doctor will check your number of platelets with regular blood tests before each of your first 5 doses of WINREVAIR, or longer before each dose if needed, and regularly while you are using this medicine. In case the number of platelets in your blood is repeatedly very low, your doctor will not start your treatment.
- **You have signs and symptoms of serious bleeding:**
 - persistent headache
 - nausea
 - weakness
 - black or tarry stool
 - blood in your stool
 - discharge of bright red blood in vomit or cough
 - persistent abdominal cramps
 - severe back pain
 - abnormally heavy menstrual bleeding

These are signs and symptoms of serious bleeding that can happen if you take WINREVAIR and are more likely to happen if you take WINREVAIR with certain medicines. Your doctor will inform you on how to recognize them. Talk to your doctor if you notice any of these signs or symptoms. Serious bleeding could lead to hospitalisation, need for blood transfusion or other treatments, and could be life-threatening.

2.3 Children and adolescents

WINREVAIR is intended for use in adults who are 18 years of age and older. Do not give this medicine to children and adolescents below the age of 18 years. There is no data on the safety and efficacy of WINREVAIR under 18 years of age.

2.4 Tests and follow-up

Before each of your first 5 doses, or longer before each dose if needed, and regularly while taking WINREVAIR, your doctor will perform blood tests.

2.5 Interactions with other medicines

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

2.6 Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to become pregnant, consult the doctor or pharmacist before using any medicine. Also, tell your doctor immediately if you become pregnant or think you may be pregnant while using this medicine.

Pregnancy

WINREVAIR may harm your unborn baby.

This medicine is not recommended for use during pregnancy. It is recommended to perform a pregnancy test before you start your treatment, and you should use effective birth control (contraception) during your treatment and for at least 4 months after the last dose of

WINREVAIR. Consult your doctor or pharmacist about birth control methods that would work well for you.

Breast-feeding

It is not known whether WINREVAIR passes into breast milk. A risk to newborns/infants cannot be excluded. Breast-feeding should be discontinued during your treatment and do not breast-feed for at least 4 months after the last dose of WINREVAIR. Consult your doctor or pharmacist about the best way to feed your baby.

Fertility

WINREVAIR may decrease female and male fertility.

2.7 Driving and using machines

WINREVAIR (sotatercept) has no or negligible effect on your ability to drive and use machines.

2.8 Important information about some of WIREVAIR ingredients

WINREVAIR contains sodium

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

WINREVAIR contains polysorbate 80

WINREVAIR contains 0.20 mg of polysorbate 80 in each mL of reconstituted solution. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. HOW SHOULD YOU USE WINREVAIR?

Always use WINREVAIR according to the doctor's instructions.

You should check with the doctor or pharmacist if you are not sure regarding the dosage and treatment regimen. The dosage and treatment regimen will be determined by the doctor only.

The recommended dosing schedule is one injection every 3 weeks.

Do not exceed the recommended dose.

Your dose

- Your dose of WINREVAIR depends on your body weight and blood tests. You will begin your treatment with a dose of 0.3 mg/kg, which will be subsequently increased to 0.7 mg/kg.
- Your doctor will tell you how much WINREVAIR to take and when to take it. It is very important that you follow the instructions of your doctor.
- Do not take WINREVAIR more often than your doctor tells you to. If you are not sure when to take WINREVAIR, talk to your doctor or pharmacist.

Your doctor will monitor your dose

- Before each of your first 5 doses, or longer before each dose if needed, and regularly while taking WINREVAIR, your doctor will perform blood tests. This is to enable your doctor to monitor you and find the best dose for you.
- Your doctor may change your dose, delay treatment, or stop treatment depending on how you respond to WINREVAIR.

Method of administration

Use WINREVAIR as an injection just under your skin (subcutaneous (SC)) only in the following injection sites:

- **stomach** (abdomen), at least 5 cm away from the belly button, **or**
- **upper thigh**

Note: In case your doctor or nurse is giving you the injection, they may also use your upper arm as an injection site, as they have received training in how to do it properly.

Before you use WINREVAIR

- If your doctor decides that you or your caregiver can give the injections of WINREVAIR at home, you or your caregiver should receive training. This training will teach you the right way to prepare and inject WINREVAIR. Do not try to inject WINREVAIR until your doctor has shown you how to do it the right way.
- Your doctor will tell you how much WINREVAIR to take and when to take it.
- **Read the separate “Instructions for Use”** booklet that comes with WINREVAIR.

If you have accidentally used a lower or a higher dose of WINREVAIR than you should

If you use a lower or a higher dose of WINREVAIR than you should, talk to your doctor or pharmacist.

If you have forgotten to take WINREVAIR

If you miss your prescribed dose of WINREVAIR and it is within 3 days of when you should have injected it, inject it immediately and follow your usual schedule for your next dose. If you miss your prescribed dose of WINREVAIR and it is more than 3 days of when you should have injected it, your injection schedule has to be changed. Talk to your doctor or pharmacist for guidance.

If you stop using WINREVAIR

Do not change your dose or stop taking WINREVAIR without talking to your doctor.

Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding the use of this medicine, consult with a doctor, a pharmacist or a nurse.

4. SIDE EFFECTS

As with any medicine, using WINREVAIR may cause side effects in some users. Do not be alarmed by reading the list of side effects; you may not suffer from any of them.

Serious side effects:

Talk to your doctor or pharmacist **immediately** if you notice:

- Easy bruising, prolonged bleeding from cuts and nosebleeds. These could be signs of a low number of platelets (thrombocytopenia). This will be shown in your blood tests.

In addition, your doctor will perform regular blood tests to test whether you have:

- High levels of haemoglobin.

The serious side effects listed above may affect more than 1 in 10 people.

Other side effects:

Talk to your doctor or pharmacist if you notice any of the following side effects:

Very common side effects – appear in more than 1 in 10 people:

- Headache
- Nosebleeds (epistaxis)
- Spider veins or tiny blood vessels that look like pink or red lines on the skin (telangiectasia)
- Diarrhoea
- Dizziness
- Skin rash

Common side effects – appear in up to 1 in 10 people:

- High blood pressure
- Redness of the skin
- Bleeding gums
- Itching at the injection site

If a side effect appears, if any of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by using the link 'Adverse Drug Reactions Report' at the home page of the Ministry of Health's web site (www.health.gov.il) which refers to the online side effects reporting form, or by using this link: <https://sideeffects.health.gov.il/>

5. HOW TO STORE WINREVAIR?

- Avoid poisoning! This medicine and any other medicines must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the pack. The expiry date refers to the last day of the indicated month.
- **Storage conditions:**
Store in a refrigerator (2°C-8°C). Do not freeze. Store in the original package in order to protect from light.

You should inject this medicine right away after mixing the medicine powder with the sterile water for injection, but no later than 4 hours after mixing.

- Medicines should not be disposed of via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, WINREVAIR also contains:

- In the powder:
Sucrose, trisodium citrate dihydrate, citric acid monohydrate, polysorbate 80.
- In the solvent:
Water for injections

What WINREVAIR looks like and contents of the pack

Powder and solvent for solution for injection. White to off-white powder in a 2 mL glass vial containing 45 mg or 60 mg of sotatercept. The solvent is a clear and colourless water for injection in a prefilled syringe of 1 mL or 1.3 mL.

WINREVAIR 45 mg is available in:

- Pack containing 1 vial of 45 mg (powder), 1 prefilled syringe of 1.0 mL (solvent), 1 vial adaptor, 1 dosing syringe, 1 needle and 4 alcohol wipes.
- Pack containing 2 vials of 45 mg (powder), 2 prefilled syringes of 1.0 mL (solvent), 2 vial adaptors, 1 dosing syringe, 1 needle and 8 alcohol wipes.

WINREVAIR 60 mg is available in:

- Pack containing 1 vial of 60 mg (powder), 1 prefilled syringe of 1.3 mL (solvent), 1 vial adaptor, 1 dosing syringe, 1 needle and 4 alcohol wipes.
- Pack containing 2 vials of 60 mg (powder), 2 prefilled syringes of 1.3 mL (solvent), 2 vial adaptors, 1 dosing syringe, 1 needle and 8 alcohol wipes.

Not all pack sizes may be marketed.

Marketing authorization holder and importer:

Merck Sharp & Dohme (Israel - 1996) Ltd., 34 Hacharash St., Hod Hasharon.

Revised in July 2025.

Drug registration no. listed in the official Registry of the Ministry of Health:

Winrevair 45 mg - 179-20-38120

Winrevair 60 mg - 179-21-38121

Instructions for Healthcare Professionals

The following information is intended for healthcare professionals only:

WINREVAIR powder and solvent for solution for injection should be reconstituted before use and administered as a single injection according to patient weight (see section 4.2 of the Summary of Product Characteristics for recommended dose regimen).

See the separate Instructions for Use booklet provided together with this leaflet for detailed step by step instructions on how to prepare and administer WINREVAIR powder and solvent for solution for injection. An overview of the reconstitution and administration instructions is provided below.

Reconstitution instructions

- Remove the kit from the refrigerator and wait 15 minutes to allow the prefilled syringe(s) and medicinal product to come to room temperature prior to preparation.
 - Check the vial to ensure the medicinal product is not expired. The powder should be white to off-white and may look like a whole or broken up cake.
 - Remove the lid from the vial containing the powder and swab the rubber stopper with an alcohol wipe.
 - Attach the vial adaptor to the vial.
 - Visually inspect the prefilled syringe for any damage or leaks and the sterile water inside to ensure there are no visible particles.
 - Break off the cap of the prefilled syringe and attach the syringe to the vial adaptor.
 - Inject all of the sterile water from the attached syringe into the vial containing the powder:
 - The prefilled syringe provided with the vial 45 mg contains 1.0 mL of sterile water.
 - The prefilled syringe provided with the vial 60 mg contains 1.3 mL of sterile water.
- After reconstitution, the 45 mg vial can only provide up to a dose of 0.9 mL of medicinal product and the 60 mg vial can only provide up to a dose of 1.2 mL of

medicinal product.

The final concentration after reconstitution is 50 mg/mL.

- Gently swirl the vial to reconstitute the medicinal product. Do not shake or vigorously agitate.
- Allow the vial to stand for up to 3 minutes to allow bubbles to disappear.
- Visually inspect the reconstituted solution. When properly mixed, the reconstituted solution should be clear to opalescent and colourless to slightly brownish-yellow, and should not have clumps or powder.
- Unscrew the syringe from the vial adaptor and discard the emptied syringe.
- If prescribed a 2-vial kit, repeat the steps within this section to prepare the second vial.
- Use the reconstituted solution as soon as possible, but no later than 4 hours after reconstitution.

Dosing syringe preparation

- Before preparing the dosing syringe, visually inspect the reconstituted solution. The reconstituted solution should be clear to opalescent and colourless to slightly brownish-yellow, and should not have clumps or powder.
- Swab the vial adaptor with an alcohol wipe.
- Remove the dosing syringe from its packaging and attach the syringe to the vial adaptor.
- Turn the syringe and vial upside-down and withdraw the appropriate volume for injection, based on the patient's weight.
 - If the dose amount requires the use of two vials, withdraw the entire contents of the first vial and slowly transfer the entire contents into the second vial, to ensure dose accuracy.
 - Turn the syringe and vial upside-down and withdraw the required amount of medicinal product.
- If necessary, push the plunger in to remove excess medicinal product or air from the syringe.
- Remove the syringe from the vial adaptor and attach the needle.

Administration instructions

WINREVAIR is to be administered as a single SC injection.

- Select the injection site on the abdomen (at least 5 cm away from navel), upper thigh, or upper arm and swab with an alcohol wipe. Select a new site for each injection that is not scarred, tender, or bruised.
 - For administration by the patient or caregiver, train them to inject only in the abdomen or upper thigh (see "**Instructions for Use**" booklet).
- Perform SC injection.
- Discard the emptied syringe. Do not reuse the syringe.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

See section 4.4 of the Summary of Product Characteristics for instructions on the traceability of biological medicinal products.

Instructions for use

Winrevair 45 mg powder and solvent for solution for injection (1 vial - pack)
Winrevair 60 mg powder and solvent for solution for injection (1 vial - pack)
sotatercept

IMPORTANT: read this booklet before use

Instructions for use

Winrevair 45 mg powder and solvent for solution for injection (1 vial - pack)

Winrevair 60 mg powder and solvent for solution for injection (1 vial - pack)

This booklet contains instructions on how to prepare and inject Winrevair powder and solvent for solution for injection. The package leaflet, also provided in the pack, contains all the important information for you.

Dose based on patient weight

For subcutaneous (SC) injection only (inject directly under the skin)

In this booklet: **(Important)**

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Before you start

Read this booklet

Read these instructions from start to finish before you use Winrevair for the first time and before every administration. There may be new information.

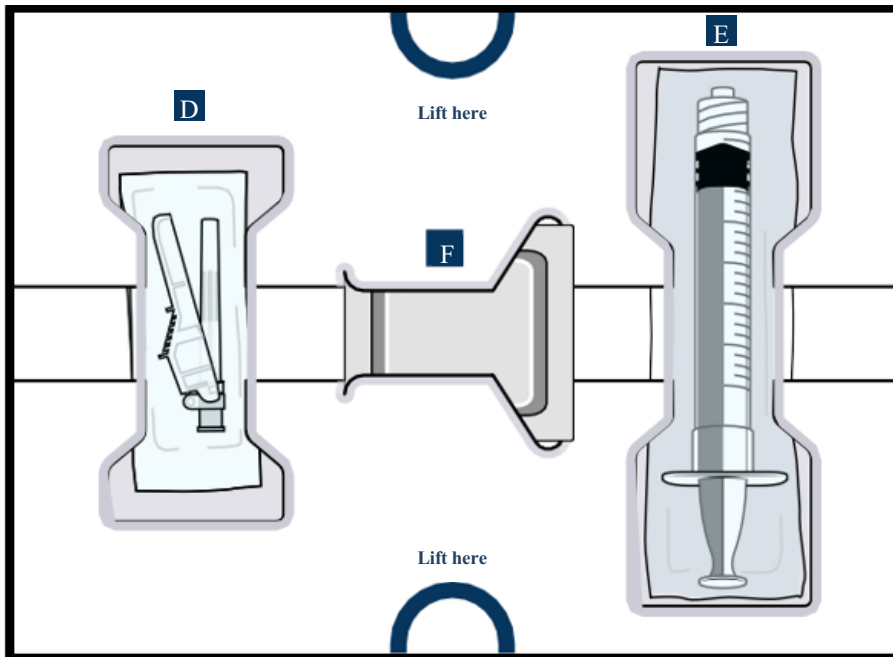
Start with your doctor or nurse

Do not use Winrevair until your doctor or nurse has shown you or your caregiver the right way to prepare and inject it. Your doctor or nurse should show you how to inject Winrevair before you use it for the first time.

Questions?

If you have questions about how to give Winrevair the right way or need more information, talk to your doctor, pharmacist, or nurse.

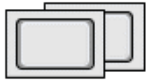
Bottom tray: Use to inject the medicine



D ■ 1 Needle for injection



E ■ 1 Empty dosing syringe to measure, withdraw, and inject your medicine



F ■ 4 Alcohol wipes (2 on each tray)

Important information to know before injecting

- You must mix this product before using it. Make sure the medicine powder in the vial is completely dissolved when you inject it.
- **Check your prescribed dose (amount in ‘mL’) each time you use the product. Your prescribed dose may change.**
- Use only the supplies that are in the pack to prepare your prescribed dose.
- Do not open the pack or mix the medicine until you are ready to use it.
- **Do not reuse any of the supplies.** After your injection, dispose of any unused medicine and used supplies according to local requirements. See section **How to throw away Winrevair** for more information.

Storing your pack

- Store the entire pack in the refrigerator, but do not freeze.
- Keep the medicine and supplies in the pack and away from light.
- Keep pack out of the sight and reach of children and pets.

Get Started

Any patient or caregiver who is to prepare and inject Winrevair must first be trained and deemed capable of independent administration of Winrevair by a healthcare professional.

1 Check Winrevair product and expiry date

Remove the Winrevair pack from the refrigerator.

- ✓ **Check the expiry date and look for any signs of damage** on the pack or in the supplies.
 - ⚠ If expired or damaged, do not use. Talk to your doctor or pharmacist immediately to get a new pack.
- ✓ **Check that you have the medicine** that your doctor prescribed.

2 Let your pack come to room temperature, gather supplies, and wash your hands

Wait 15 minutes to allow your pack to warm to room temperature.

Cold medicine is more painful to inject.



15 minutes

Along with your pack, gather these items and find a clean, flat surface where you will prepare and inject your dose.

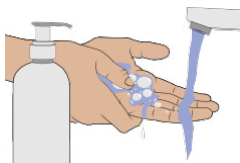


Sharps
disposal
container



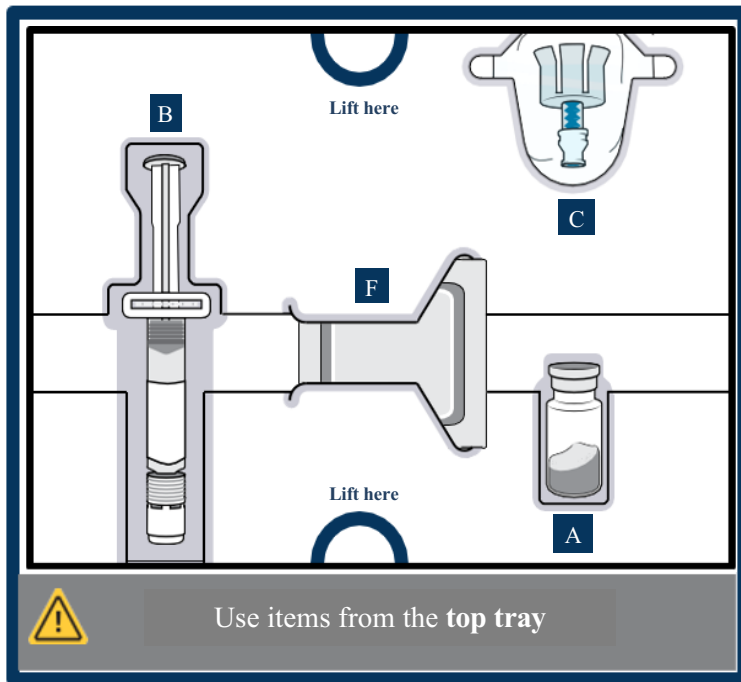
Gauze,
cotton ball
or bandage

Wash your hands with soap and water.

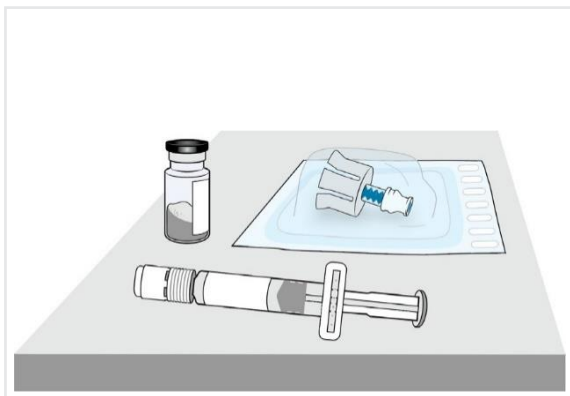


Mix powdered medicine into liquid form (Mix)

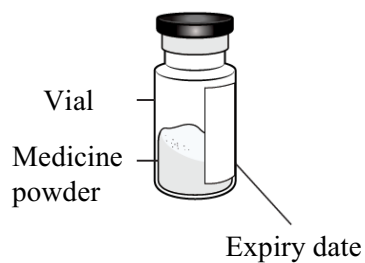
Start with the top tray



3 Remove vial, prefilled syringe, and vial adaptor from the pack



4a Check the medicine and the vial



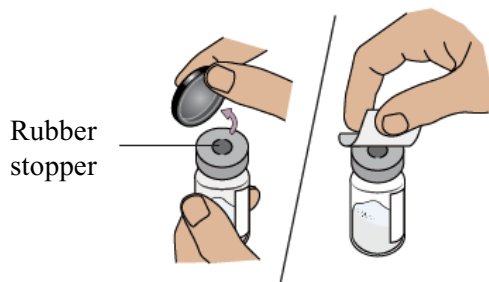
- ✓ Not damaged?
- ✓ No visible particle?
- ✓ Not expired?

Check the vial label to **confirm the medicine is not expired.**

Visually inspect the medicine powder. It should be white to off-white and may look like a whole or broken up cake.

⚠ Do not use if expired, damaged, or you can see particles in it.

4b Remove plastic cap and clean the vial

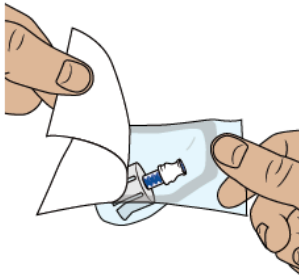


Flip off the plastic cap and **clean the rubber stopper on top of the vial** with an alcohol wipe.

- ⚠ Do not use if vial cap is missing
- ⚠ Do not touch the cleaned rubber stopper

Set vial aside on a clean, flat surface.

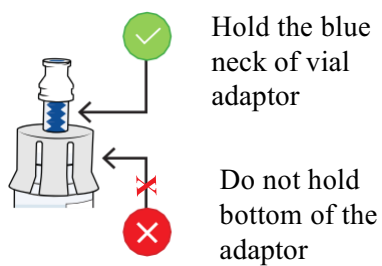
5a Align vial adaptor to vial



Peel open the vial adaptor package and remove it from its package.



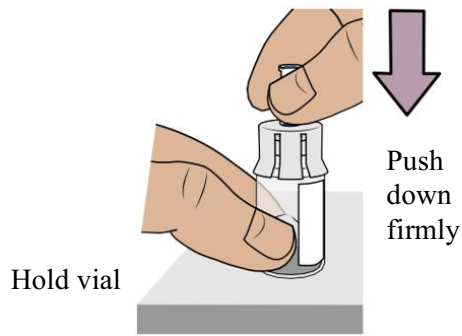
To attach the vial adaptor:



Hold the blue neck of the adaptor and align the vial adaptor on top of the vial.

⚠ Do not touch the inside of the vial adaptor to keep it clean and avoid sharps

5b Attach vial adaptor to vial



Hold the vial with one hand. **Push the vial adaptor down firmly** so it snaps in place (you may feel some resistance).

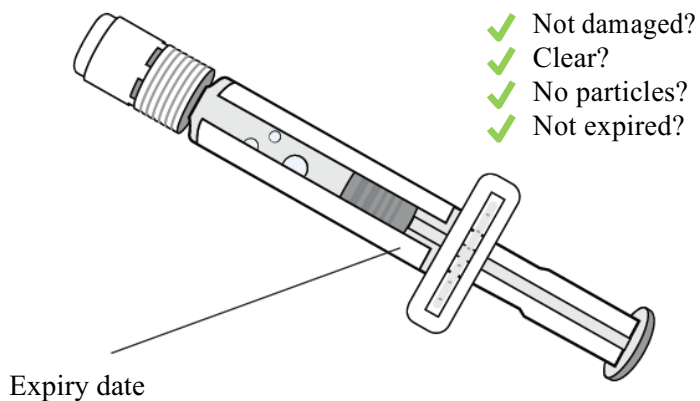
5c Clean vial adaptor



Clean the top of the vial adaptor with an alcohol wipe.

6 Check prefilled syringe

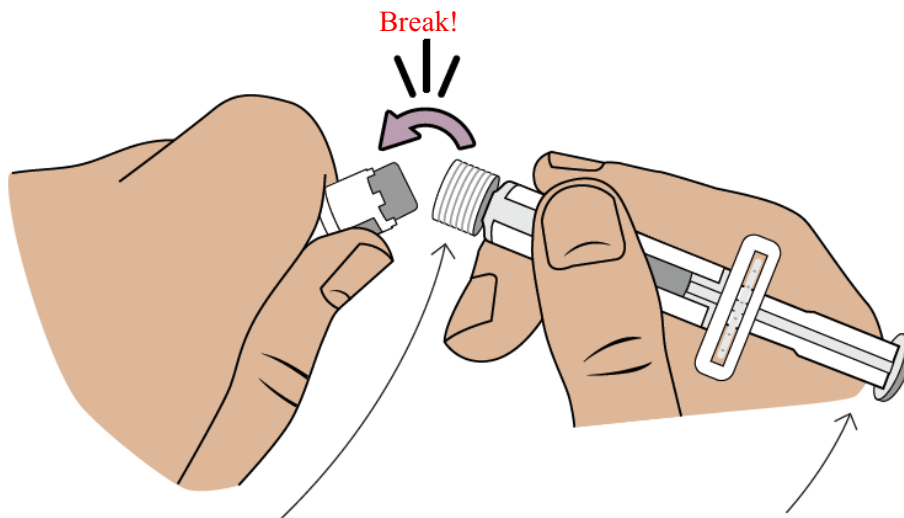
Confirm the product is not expired. Visually inspect that the sterile water inside the prefilled syringe is clear.



⚠ Do not use if you see any clumps, particles, discolouration, or product is expired.

7 Break off prefilled syringe white cap

Break off the prefilled syringe cap along the perforation.



⚠ Do not touch the tip of the prefilled syringe

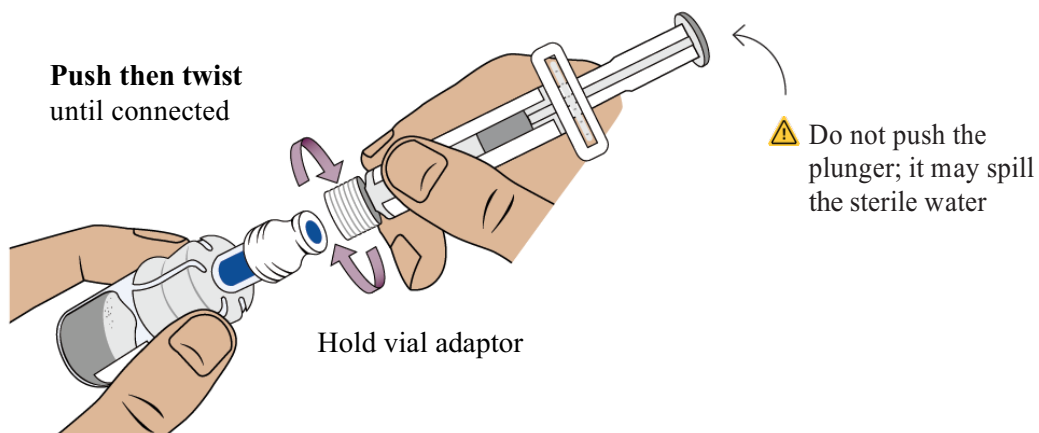
⚠ Do not push the plunger; it may spill the sterile water

8 Connect prefilled syringe to vial adaptor

Now, pick up the medicine vial with the vial adaptor attached.

Align the prefilled syringe tip on the blue circle of the vial adaptor.

Push and twist the prefilled syringe onto the vial adaptor until you cannot turn further. While twisting, be sure to hold onto the vial adaptor.

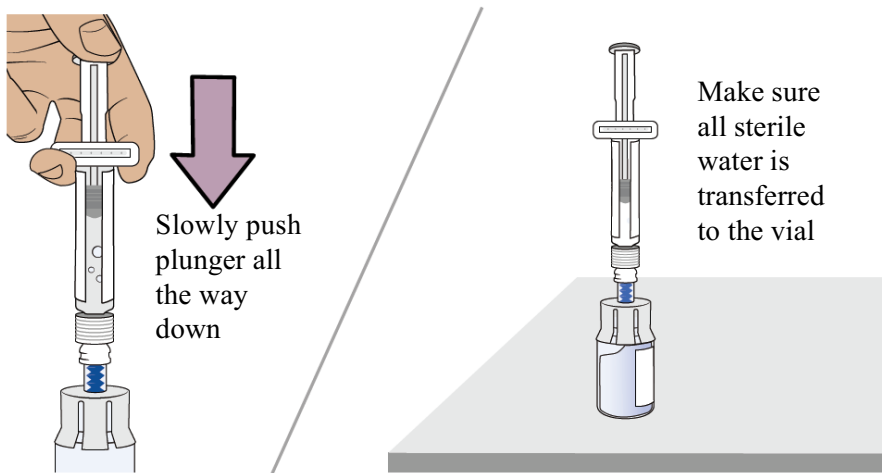


Push then twist
until connected

Hold vial adaptor

⚠ Do not push the plunger; it may spill the sterile water


9 Transfer sterile water from prefilled syringe to vial



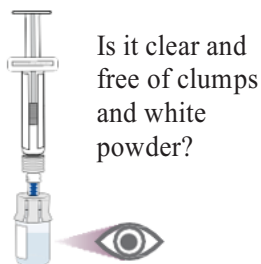
Slowly push the plunger all the way down to transfer all the sterile water into the vial (the plunger will move up; this is normal).

10 Swirl to mix medicine

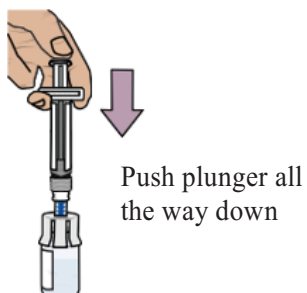


 Do not shake the vial

Hold the prefilled syringe and ***gently swirl the vial in a circular motion*** until the powder is fully dissolved. This may take up to **2 minutes**. **Do not shake or agitate vigorously.**

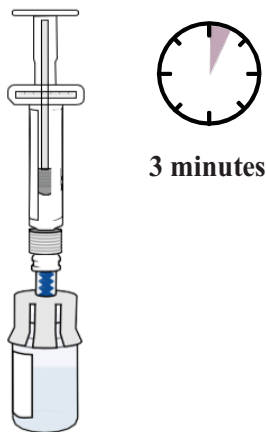


When the medicine is mixed well, it should be clear. If not, repeat this step until it is clear.



Press the plunger down again to make sure all the liquid is in the vial since some liquid could have moved back into the syringe (the plunger will move up; this is normal).

11 Wait for the bubbles to go away



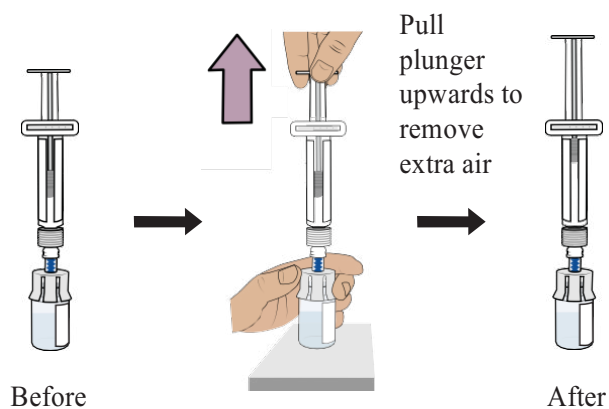
Set the vial aside for bubbles to go away.

This may take up to 3 minutes.

- ⚠ Before you continue, make sure the medicine in the vial:
- ✓ Is clear to opalescent and colourless to slightly brownish-yellow.
 - ✓ Does not have clumps or powder.
 - ✓ Does not have large bubbles.

It is okay to have slight foam (small bubbles) around the edges of the vial.

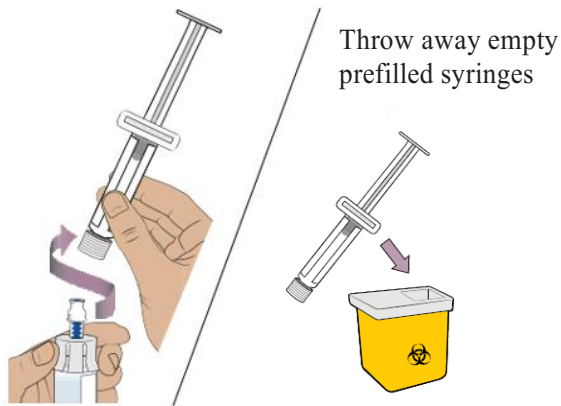
12 Prepare vial by removing extra air



While the vial oriented upright, **gently pull the plunger upwards** to the top of the barrel but be careful not to pull the plunger out of the syringe.

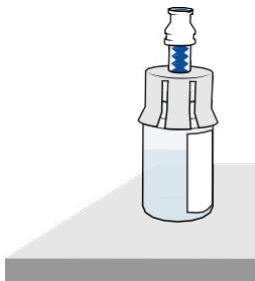
Tip: This step only pulls extra air out of the vial to reduce the pressure in the vial and prevent medicine from spilling during the syringe removal.

13 Remove prefilled syringe from vial



Hold the vial adaptor and unscrew the syringe from the vial.

Throw away the syringe in the sharps container.

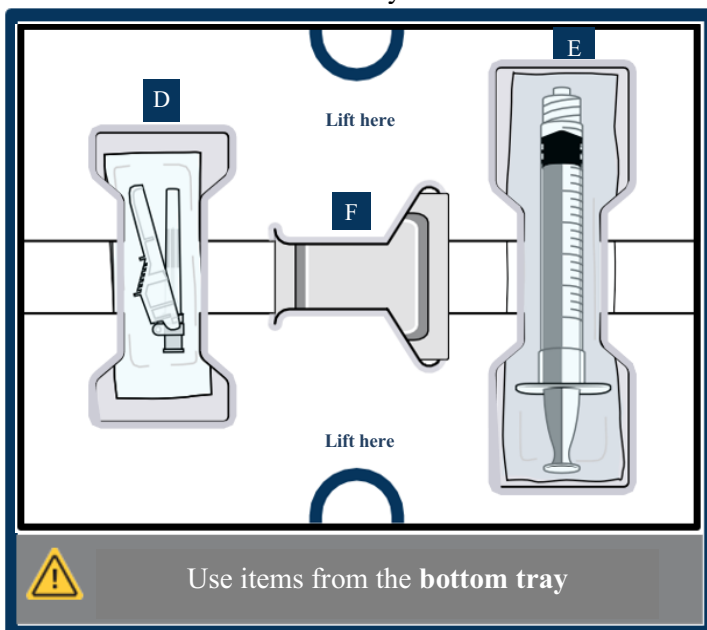


You should have a vial of medicine prepared and ready to be used in the next steps.

Withdraw your prescribed dose (Withdraw)

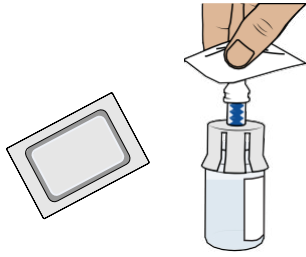
For the next steps, you will need:

- Mixed vial of medicine
- Items from the bottom tray



14 Clean top of vial adaptor

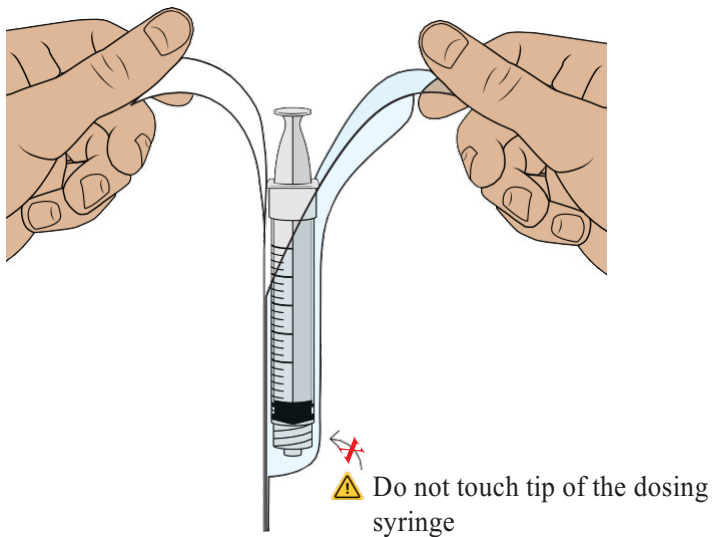
With a new alcohol wipe from the bottom tray, clean the top of the vial adaptor.



15 Remove empty dosing syringe from its package

Find the empty dosing syringe in the bottom tray and remove it from its package.

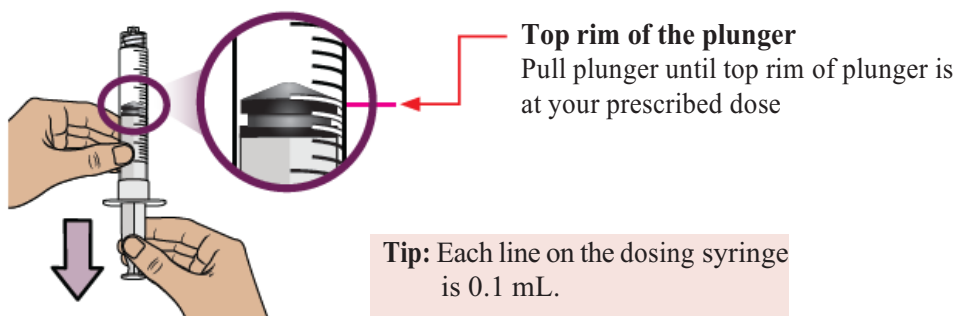
You will use this dosing syringe to measure out the medicine you need (based on your prescribed dose).



16 Pull air into the dosing syringe

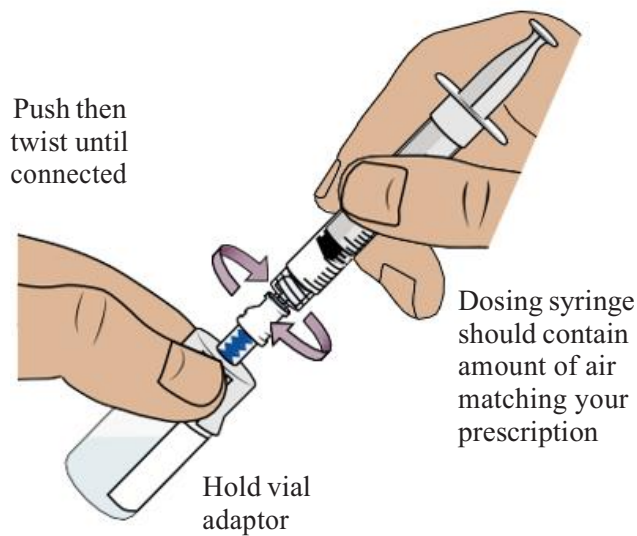
⚠ You must do this to make sure pressure in the vial is even and you get an accurate dose.

Hold the dosing syringe upright and pull down the plunger to **draw air into the dosing syringe. Stop when you get to the amount in 'mL' listed in your prescription.**



17 Connect dosing syringe to the vial

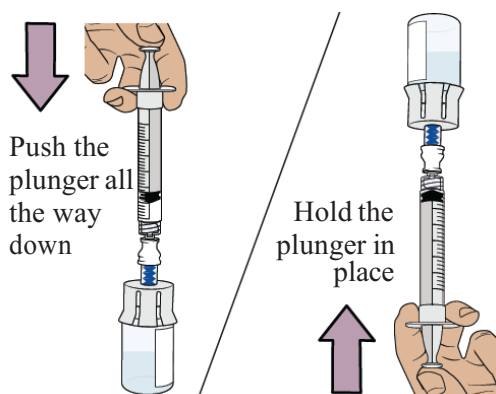
While holding the vial adaptor, screw the dosing syringe on until it stops.



18 Push air into vial, then flip upside down

Push the plunger all the way down to transfer all the air into the vial.

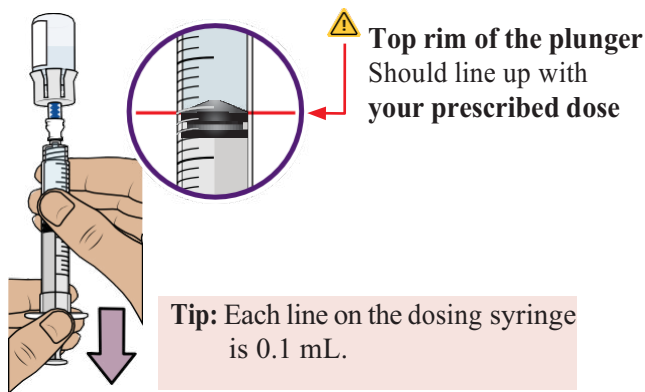
Then **hold the plunger in place** with your thumb and flip the vial upside down.



19 Pull plunger back to withdraw your dose

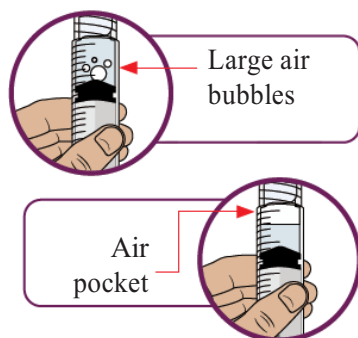
With the vial and dosing syringe upside down, **slowly pull the plunger back.**

Stop when you get to the **amount in 'mL' listed on your prescription.**



20 Check for air bubbles and air pockets

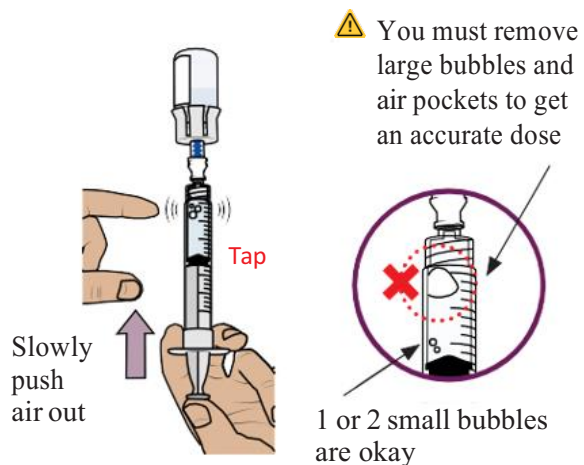
Check to see if there are large air bubbles or an air pocket in the syringe. You will remove extra air in the next steps.



21 Remove air bubbles and air pockets

If you see air bubbles or an air pocket, tap the side of the dosing syringe to move the air to the top.

Slowly push the plunger up to remove extra air.



22 Compare amount to prescribed dose

After removing all extra air, **compare the amount to your prescribed dose.**

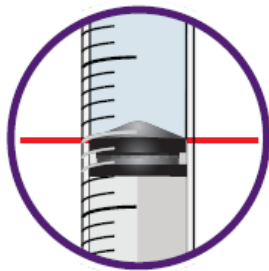
If you do not have your prescribed amount in your syringe, *slowly* pull the plunger back again to withdraw more medicine.



Repeat Steps 19 to 21 until you reach **your prescribed dose** and no large bubbles are visible.

23 Confirm your prescribed dose.

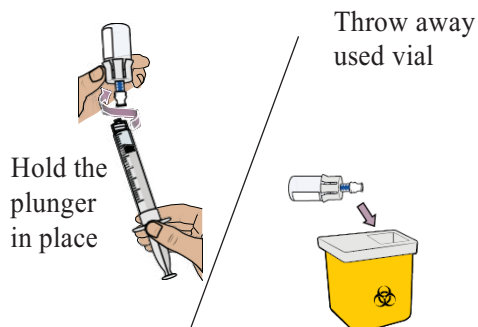
Before you continue, check to make sure you have the prescribed dose in the dosing syringe.



The top rim of the plunger should line up with **your prescribed dose**

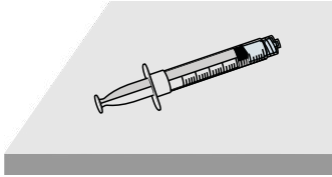
⚠ If the amount does not match your prescribed dose, repeat Steps 19 to 22.

24 Remove the dosing syringe from the vial and set the dosing syringe aside



Hold the plunger in place with one hand. With the other hand, hold the vial adaptor and unscrew the filled dosing syringe from the vial.

Throw away the vial into the sharps container.

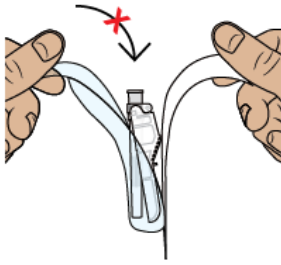


Place the filled dosing syringe on a clean, flat surface.

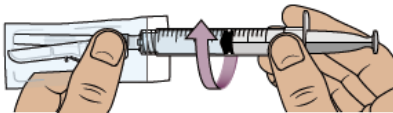
⚠ Do not touch the dosing syringe tip or let it touch any surfaces.

25 Attach the injection needle

⚠ Do not touch the connection hub of the needle



Find the needle in the bottom tray and open its package.



With the needle still in the package, **grip the base of the needle** and **twist on the dosing syringe** until it stops. Remove the needle package.

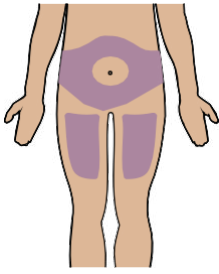


Move the safety shield away from the needle and toward the syringe to the angle shown.

Place the dosing syringe on a clean, flat surface.

⚠ Do not uncap the needle

26 Choose and clean your injection site

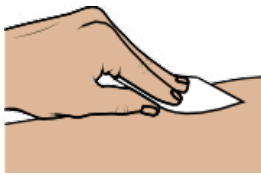


Select an injection site on your stomach (abdomen) or your upper thigh. If injecting on your stomach area, avoid a 5 cm area around your belly button.

Choose a different site every time you inject.

⚠ Do not inject into skin that is damaged, sore, bruised, or has red patches

⚠ Do not inject through clothes



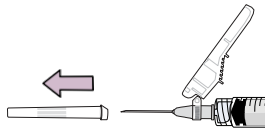
Clean the injection site with a new alcohol wipe.

⚠ Do not touch the cleaned injection site again

Now, you are ready to inject the medicine.

Inject your medicine (Inject)

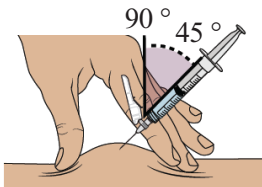
27 Inject your medicine



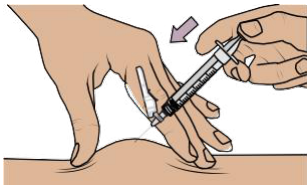
Pull the cap straight off the needle.

Throw away the cap.

⚠ Do not touch the plunger until ready to inject so you don't lose any medicine



Gently **pinch and hold a fold of skin** where you will inject. Insert the needle with a **dartlike motion at a 45° to 90° angle**. This helps you inject directly under the skin (subcutaneous injection).

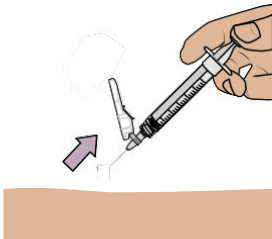


Push the plunger with slow, steady pressure all the way down until the dosing syringe is empty.

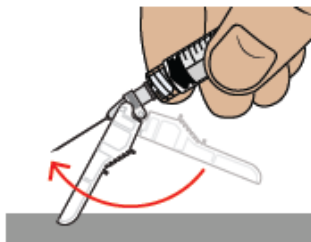
Confirm all the medicine has been injected.

You can let go of the skin fold now.

⚠ Keep your fingers away from the needle at all times.



While keeping the plunger pushed in, **remove the needle from your skin** at the same angle you inserted it.



To reapply the safety shield, push the shield against a flat surface until you hear a “click” and see that the needle is covered.



Throw away the dosing syringe and used items in a sharps disposal container.

⚠ Do not remove the needle from the dosing syringe

How to throw away Winrevair

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment. Make sure to follow local requirements for disposal as they may be different from the general recommendations below.


- Throw away any used vial (including any remaining Winrevair liquid), needle, vial and needle caps, and used syringes in a sharps disposal container.
- Do not throw away the Winrevair vials, syringes, or needle in your household waste.
- **Do not reuse any of the supplies.** This product is disposable and should only be used one time.
- **Important:** Always keep the sharps disposal container out of reach of children and pets.



If you do not have a sharps disposal 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 sharp objects 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 container is almost full, you will need to follow local guidelines for the right way to throw away your container.

 Do not recycle your used container

Frequently asked questions

What should I do if I'm bleeding from the injection site?

Place a cotton ball or bandage on your skin right away and apply a small amount of pressure. If the bleeding does not stop, call your doctor or pharmacist right away.

Where can I find my prescription amount?

Your prescription amount in 'mL' is on your prescription. Contact your doctor or pharmacist if you can't find your prescription amount.

What should I do if I accidentally get some medicine on my skin or my work surface?

Wash the area thoroughly with soap and water right away.

What should I do if I'm not sure I administered my prescribed dose correctly?

Call your doctor or pharmacist.

What should I do if the plunger of my dosing syringe moves automatically when I try to withdraw medicine from the vial?

Don't worry if your plunger moves slightly on its own when you are filling your dosing syringe with medicine.

With one hand, **hold the plunger in place to stop the plunger from moving.**

With the other hand, unscrew the vial from the dosing syringe. Once unscrewed, it is safe to let go of the plunger.

You can avoid this automatic plunger movement by pushing air into the vial before filling your dosing syringe with medicine. Refer to Steps 16 to 23 for detailed instructions.

What should I do if my pack parts are damaged or compromised (for example, discoloured, cloudy, or has particles)?

If your pack parts are damaged or compromised, do not use it. Call your doctor or pharmacist to get a new pack.

What should I do if my medicine does not turn clear after mixing and swirling?

Do not use the medicine if you have swirled the medicine vial for about 2 minutes and let it stand for another 3 minutes, but your medicine vial remains cloudy or has clumps, powder, or foreign particles. Call your doctor or pharmacist to get a new pack.

What should I do if the sterile water won't come out of the prefilled syringe?

Check that the vial adaptor is attached to the vial securely. If not, hold the vial and press the vial adaptor down firmly to make sure the vial adaptor punctures the vial rubber stopper.

What should I do if I dropped my pack components?

Do not use if any items are damaged. If you are unsure, call your doctor or pharmacist to get a new pack.

Can I use my pack that has been left out of the refrigerator?

If the unused pack has been out of the refrigerator for an extended period of time, please contact your doctor or pharmacist before proceeding.

Do I need to use mixed medicine right away?

We recommend you inject the medicine right after mixing but no later than 4 hours after mixing. If it has been more than 4 hours, throw away unused mixed medicine. If you have questions or are unsure about the process, please contact your doctor or pharmacist.

How can I get help preparing and giving my injection?

If you have questions about how to give Winrevair the correct way or need more information, you can call your doctor or pharmacist.

For any other information about this medicine, please contact your doctor or pharmacist, or the local representative of the Marketing Authorisation Holder. You will find the details of the local representative in the Package leaflet: Information for the patient.

Instructions for use
Winrevair 45 mg powder and solvent for solution for injection (2 vial – pack)
Winrevair 60 mg powder and solvent for solution for injection (2 vial - pack)
sotatercept

IMPORTANT: read this booklet before use

Instructions for use

Winrevair 45 mg powder and solvent for solution for injection (2 vial - pack)

Winrevair 60 mg powder and solvent for solution for injection (2 vial - pack)

This booklet contains instructions on how to prepare and inject Winrevair powder and solvent for solution for injection. The package leaflet, also provided in the pack, contains all the important information for you.

Dose based on patient weight

For subcutaneous (SC) injection only (inject directly under the skin)

In this booklet: (Important)

| | |
|--|----|
| Important information for healthcare professionals | 3 |
| Before you start | 4 |
| Get to know the parts of your pack | 6 |
| Important information to know before injecting | 8 |
| Storing your pack | 9 |
| Get started | 10 |
| - Mix powdered medicine into liquid form | 12 |
| - Combine medicine from both vials | 24 |
| - Withdraw your prescribed dose | 30 |
| - Inject your medicine..... | 36 |
| How to throw away Winrevair | 38 |
| Frequently asked questions | 40 |



Important information for healthcare professionals

A healthcare professional will provide training regarding proper preparation and administration of Winrevair following this “Instructions for Use” (IFU) booklet step-by-step, and decide whether a patient or caregiver is capable of preparing and administering Winrevair independently.

Make sure the patient or caregiver can do the following correctly:

1. Reconstitute the medicine
2. Combine medicine from both vials
3. Measure the correct amount of medicine according to patient’s prescription
4. Select and prepare a proper injection site
5. Inject the medicine subcutaneously

Before you start

Read this booklet

Read these instructions from start to finish before you use Winrevair for the first time and before every administration. There may be new information.

Start with your doctor or nurse

Do not use Winrevair until your doctor or nurse has shown you or your caregiver the right way to prepare and inject it. Your doctor or nurse should show you how to inject Winrevair before you use it for the first time.

Questions?

If you have questions about how to give Winrevair the right way or need more information, talk to your doctor, pharmacist, or nurse.



How to use this product

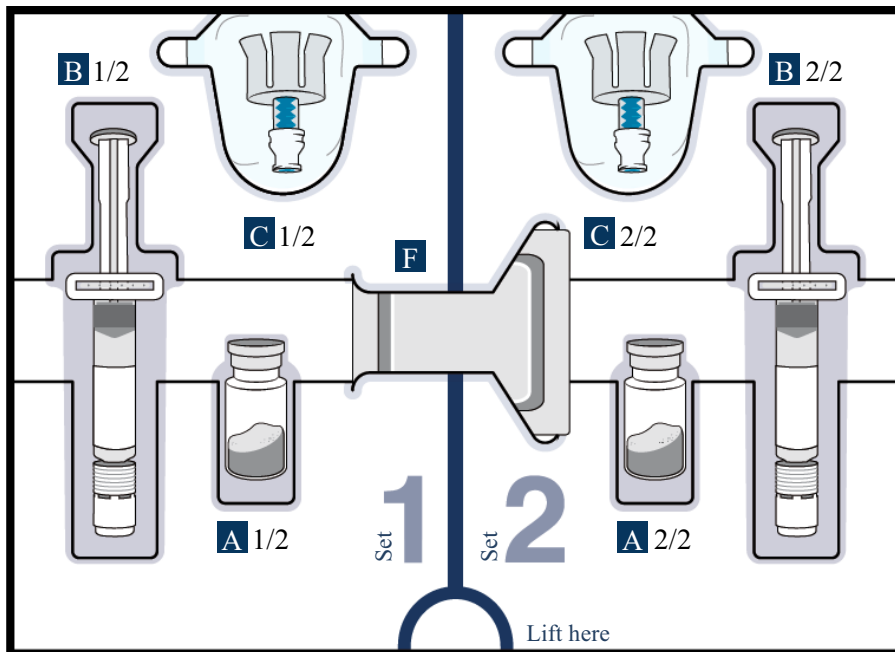
Before injecting, make sure you read the full instructions in this booklet to get the right dose of medicine.

- **Mix** medicine in vial 1
- **Mix** medicine in vial 2
- **Combine** medicine from both vials
- **Withdraw** your prescribed dose from vial 2
- Then, you’ll be ready to **inject** your medicine

Proceed to the next pages for step-by-step directions.

Get to know the parts of your pack

Top tray: Use to **mix** the medicine

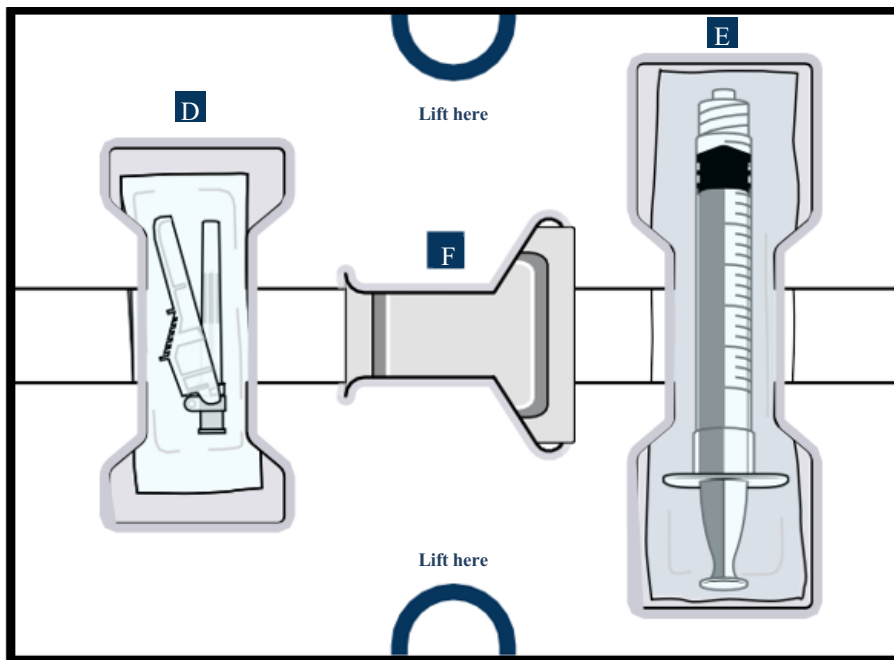


A 2 Vials of Winrevair
medicine powder

Medicine powder



Bottom tray: Use to inject the medicine



D ■ 1 Needle for injection



E ■ 1 Empty dosing syringe to measure, withdraw, and inject your medicine



F ■ 8 Alcohol wipes (4 on each tray)

Important information to know before injecting

- You must mix this product before using it. Make sure the medicine powder in the vial is completely dissolved when you inject
- **Check your prescribed dose (amount in ‘mL’) each time you use the product. Your prescribed dose may change.**
- Use only the supplies that are in the pack to prepare your prescribed dose.
- Do not open the pack or mix the medicine until you are ready to use it.
- **Do not reuse any of the supplies.** After your injection, dispose of any unused medicine and used supplies according to the local requirements. See section **How to throw away Winrevair** for more information.

Storing your pack

- Store the entire pack in the refrigerator, but do not freeze.
- Keep the medicine and supplies in the pack and away from light.
- Keep pack out of the sight and reach of children and pets.

Get Started

Any patient or caregiver who is to prepare and inject Winrevair must first be trained and deemed capable of independent administration of Winrevair by a healthcare professional.

1 Check Winrevair product and expiry date

Remove the Winrevair pack from the refrigerator.

- ✓ **Check the expiry date and look for any signs of damage** on the pack or in the supplies.

⚠ If expired or damaged, do not use. Talk to your doctor or pharmacist immediately to get a new pack.

- ✓ **Check that you have the medicine** that your doctor prescribed.

2 Let your pack come to room temperature, gather supplies, and wash your hands

Wait 15 minutes to allow your pack to warm to room temperature.

Cold medicine is more painful to inject.



15 minutes

Along with your pack, gather these items and find a clean, flat surface where you will prepare and inject your dose.

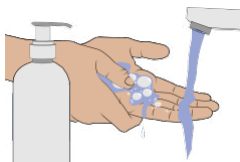


Sharps
disposal
container



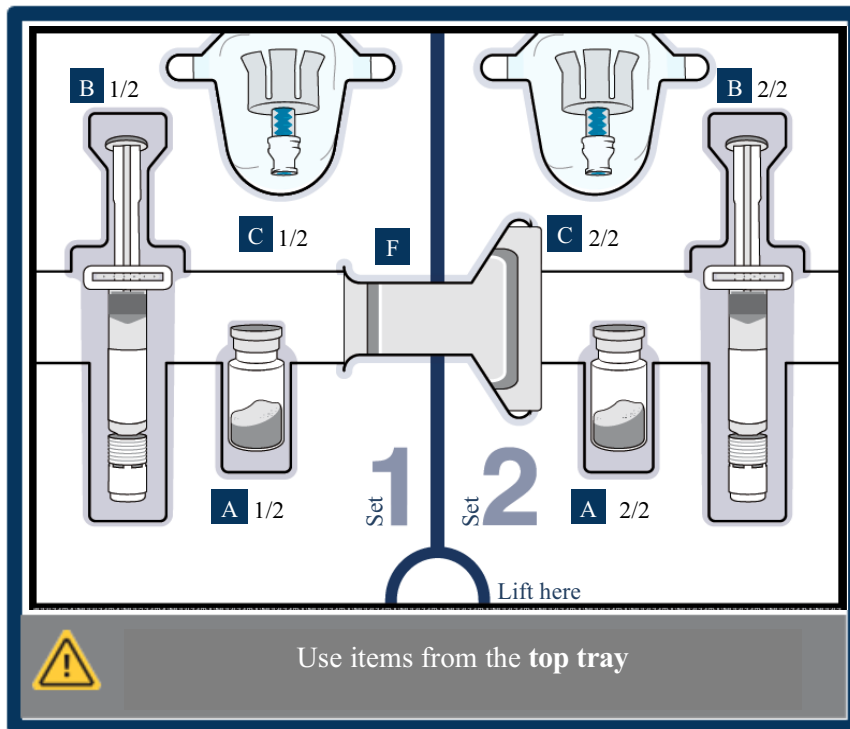
Gauze,
cotton ball
or bandage

Wash your hands with soap and water.

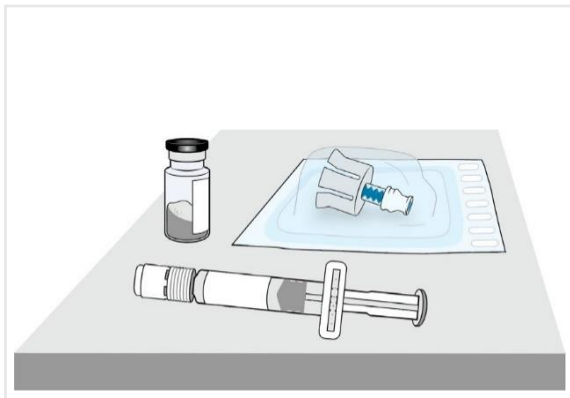


Mix powdered medicine into liquid form (Mix)

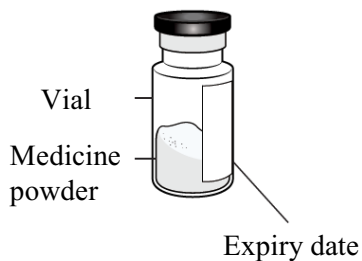
Start with the top tray



3 Remove vial 1, prefilled syringe 1, and vial adaptor 1 from the pack



4a Check the medicine and the vial



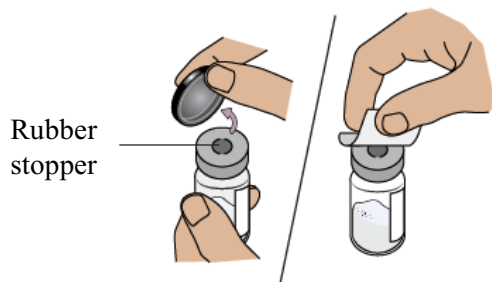
- ✓ Not damaged?
- ✓ No visible particle?
- ✓ Not expired?

Check the vial label to **confirm the medicine is not expired.**

Visually inspect the medicine powder. It should be white to off-white and may look like a whole or broken up cake.

⚠ Do not use if expired, damaged, or you can see particles in it

4b Remove plastic cap and clean the vial

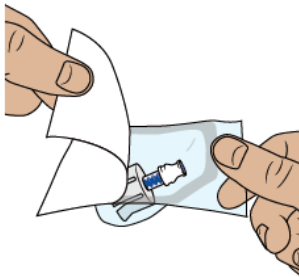


Flip off the plastic cap and **clean the rubber stopper on top of the vial** with an alcohol wipe.

- ⚠ Do not use if vial cap is missing
- ⚠ Do not touch the cleaned rubber stopper

Set vial aside on a clean, flat surface.

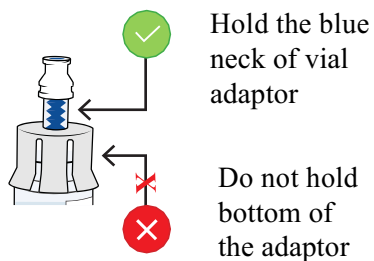
5a Align vial adaptor to vial



Peel open the vial adaptor package and remove it from its package.



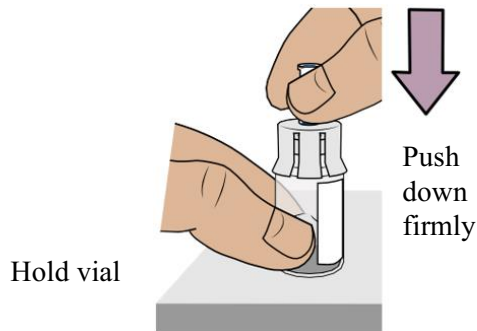
To attach the vial adaptor:



Hold the blue neck of the adaptor and align the vial adaptor on top of the vial.

⚠ Do not touch the inside of the vial adaptor to keep it clean and avoid sharps

5b Attach vial adaptor to vial



Hold the vial with one hand. **Push the vial adaptor down firmly** so it snaps in place (you may feel some resistance).

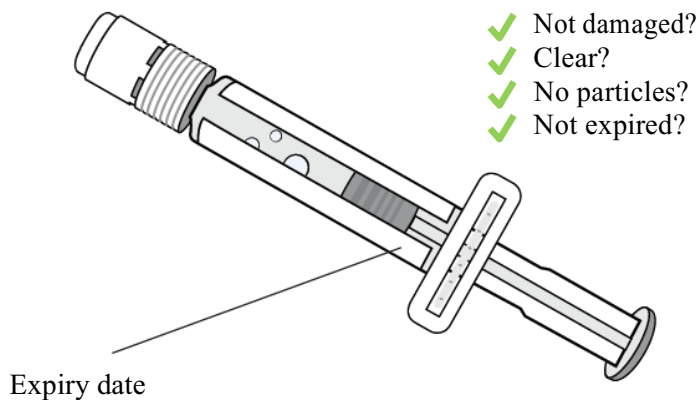
5c Clean vial adaptor



Clean the top of the vial adaptor with an alcohol wipe.

6 Check prefilled syringe

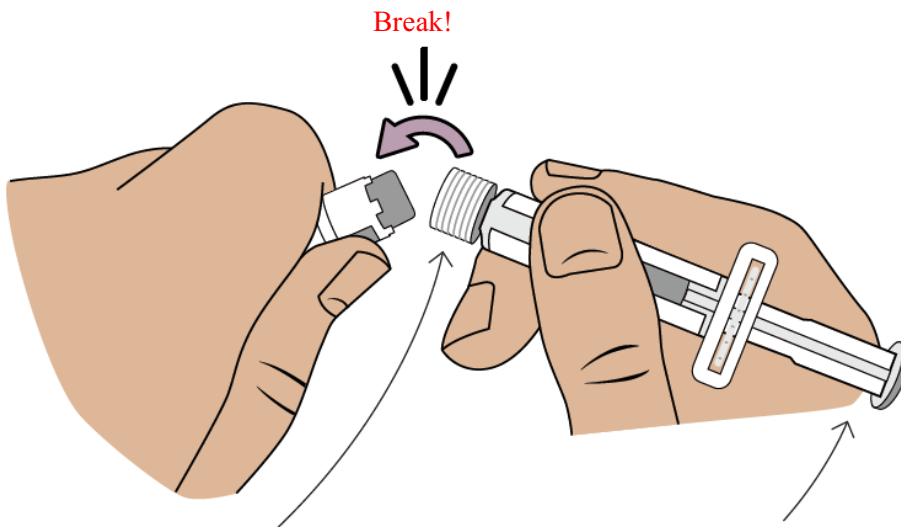
Confirm the product is not expired. Visually inspect that the sterile water inside the prefilled syringe is clear.



⚠ Do not use if you see any clumps, particles, discolouration, or product is expired

7 Break off prefilled syringe white cap

Break off the prefilled syringe cap along the perforation.



⚠ Do not touch the tip of the prefilled syringe

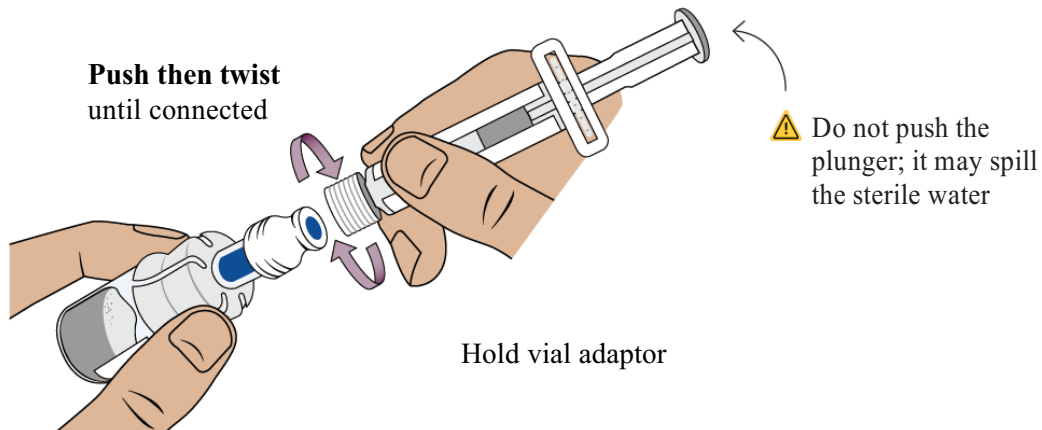
⚠ Do not push the plunger; it may spill the sterile water

8 Connect prefilled syringe to vial adaptor

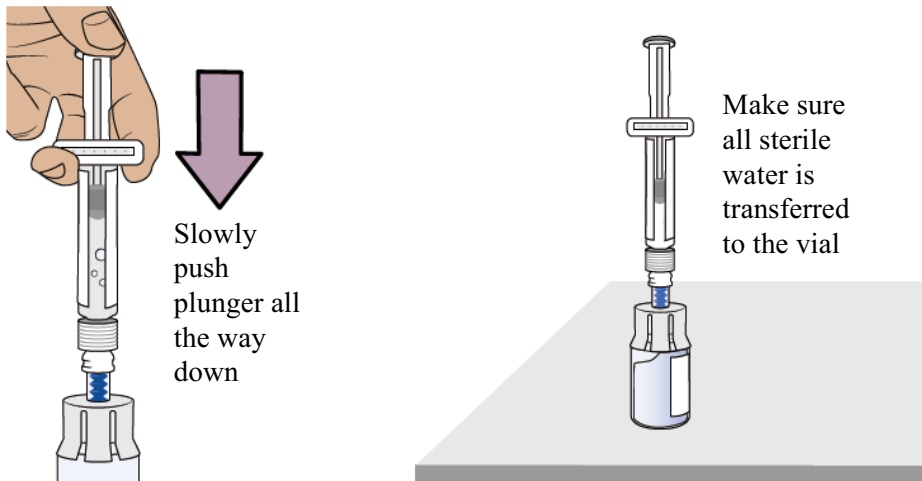
Now, pick up the medicine vial with the vial adaptor attached.

Align the prefilled syringe tip on the blue circle of the vial adaptor.

Push and twist the prefilled syringe onto the vial adaptor until you cannot turn further. While twisting, be sure to hold onto the vial adaptor.



9 Transfer sterile water from prefilled syringe to vial



Slowly push the plunger all the way down to transfer all the sterile water into the vial (the plunger will move up; this is normal).

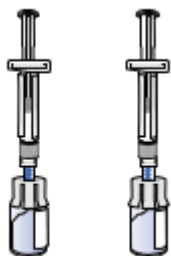
Leave the prefilled syringe attached to the vial and set aside on a flat surface.

10 Prepare vial 2, prefilled syringe 2, and vial adaptor 2

Remove **vial 2, prefilled syringe 2, and vial adaptor 2** from the pack.

⚠ Important:

Repeat Steps 4 to 9 to prepare vial 2.

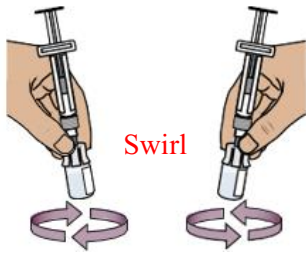


Vial 1 Vial 2

Stop and check if you have both vial 1 and vial 2 prepared.

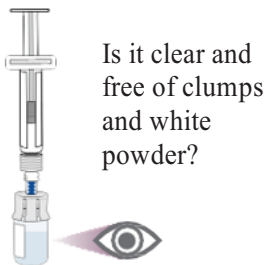
You need both vials prepared before you can continue to Step 11.

11 Swirl to mix medicine

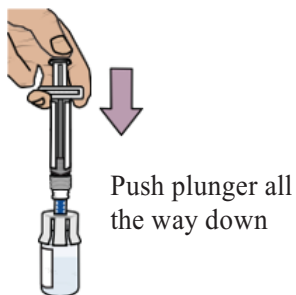


⚠ Do not shake the vials

Hold one prefilled syringe in each hand and ***gently swirl both vials in a circular motion*** until the powder is fully dissolved. This may take up to **2 minutes**. **Do not shake or agitate vigorously.**

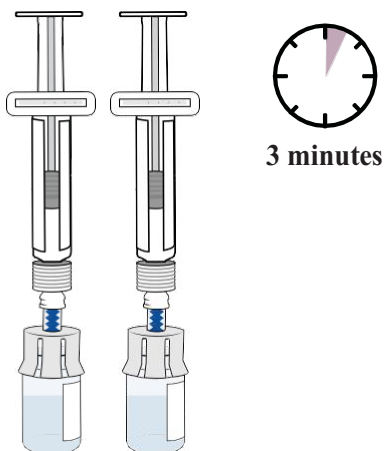


When the medicine is mixed well, it should be clear. If not, repeat this step until it is clear.



For each vial, **press the plunger down** again to make sure all the liquid is in the vial since some liquid could have moved back into the syringe (the plunger will move up; this is normal).

12 Wait for the bubbles to go away

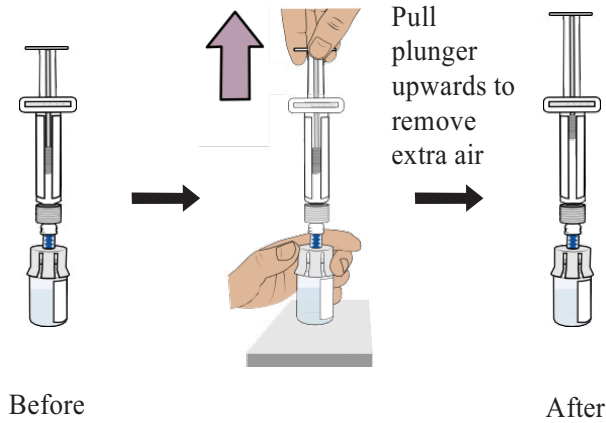


Set both vials aside for bubbles to go away.
This may take up to 3 minutes.

- ⚠ Before you continue, make sure the medicine in the vial:
- ✓ Is clear to opalescent and colourless to slightly brownish-yellow
 - ✓ Does not have clumps or powder
 - ✓ Does not have large bubbles

It is okay to have slight foam (small bubbles) around the edges of the vial

13 Prepare vial by removing extra air

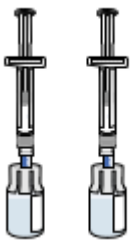


Start with either vial. While having the vial oriented upright, **gently pull the plunger upwards** to the top of the barrel but be careful not to pull the plunger out of the syringe.

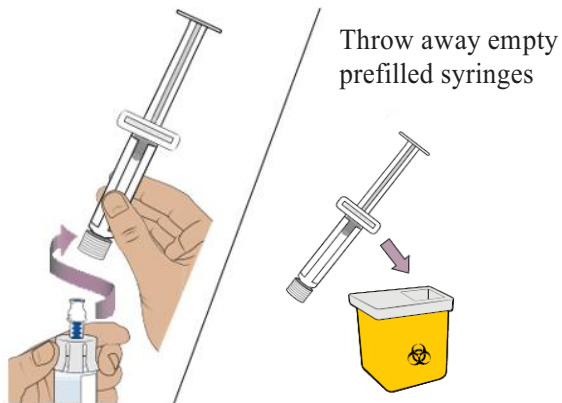
Tip: This step only pulls extra air out of the vial to reduce the pressure in the vial and prevent medicine from spilling during the syringe removal.

Important:

⚠ Perform this step for **both** vials. Stop and check you have **both** vials prepared before continuing.

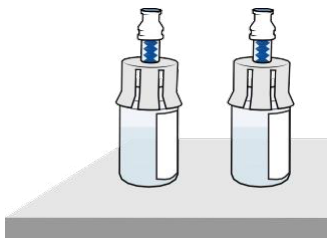


14 Remove prefilled syringe from vial



Hold the vial adaptors and unscrew **both** syringes from the vials.

Throw away **both** syringes in the sharps container.

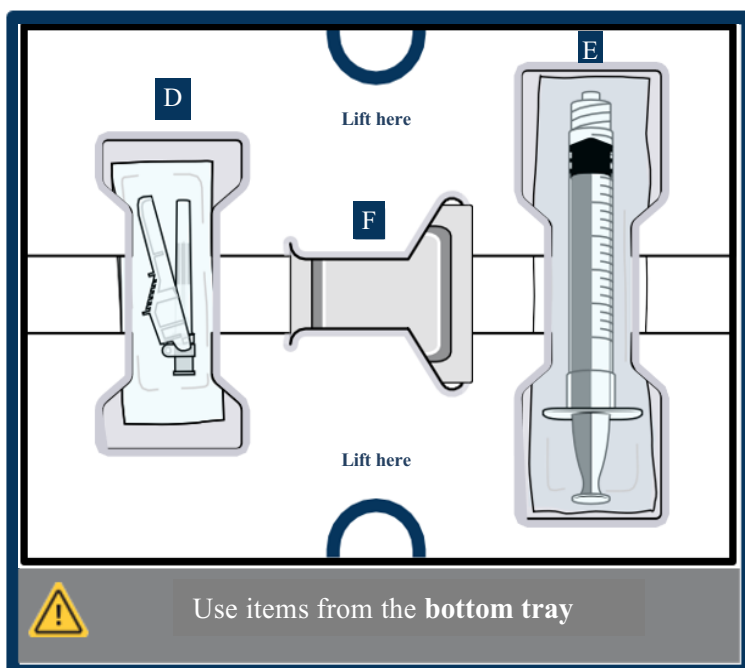


You should have 2 vials of medicine prepared and ready to be combined in the next steps.

Combine medicine from both vials (Combine)

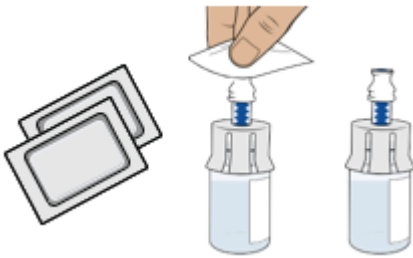
For the next steps, you will need:

- Mixed vial 1 and vial 2
- Items from the bottom tray



15 Clean top of both vial adaptors

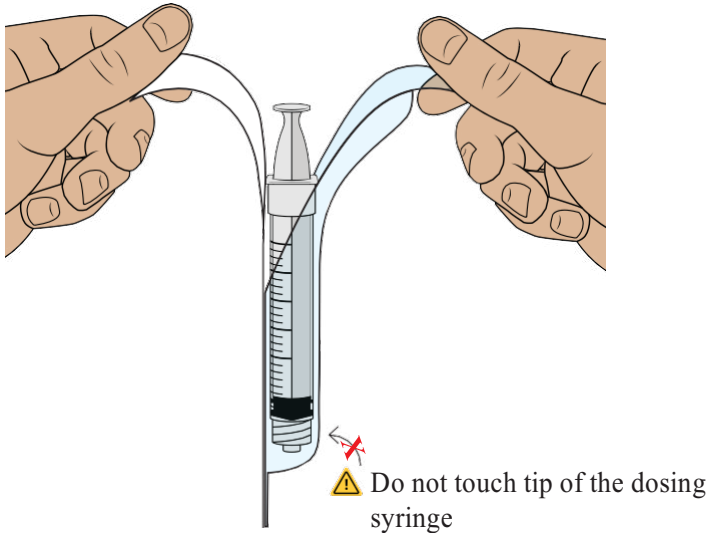
With 2 new alcohol wipes from the bottom tray, clean the top of the vial adaptors.



16 Remove empty dosing syringe from its package

Find the empty dosing syringe in the bottom tray and remove it from its package.

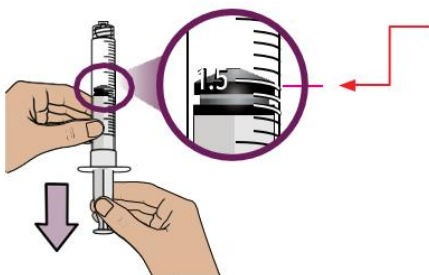
You will use this dosing syringe to measure out the medicine you need (based on your prescribed dose).



17 Pull air into the dosing syringe

⚠ You must do this to make sure pressure in the vial is even and you get an accurate dose.

Hold the dosing syringe upright and pull down the plunger to **draw in 1.5 mL of air**.

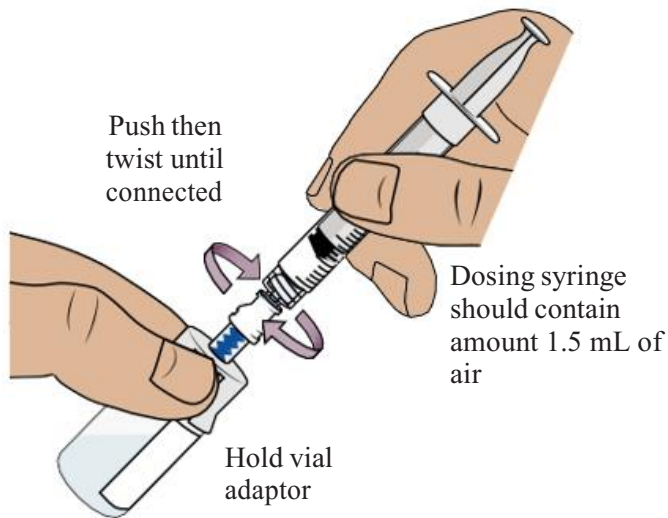


Top rim of the plunger
Pull plunger until top rim of plunger is at 1.5 mL

Tip: Each line on the dosing syringe is 0.1 mL.

18 Connect dosing syringe to one of the vials

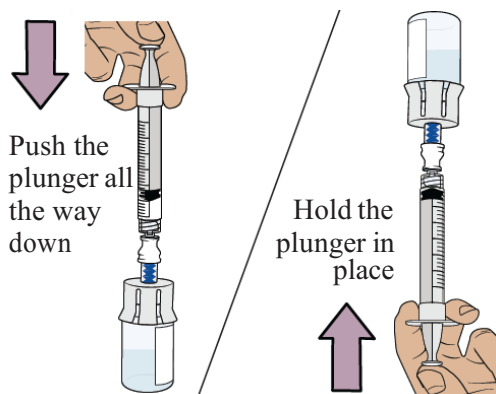
While holding the vial adaptor, screw the dosing syringe on until it stops.



19 Push air into vial, then flip upside down

Push the plunger all the way down to transfer all the air into the vial.

Then **hold the plunger in place** with your thumb and flip the vial upside down.



20 Drain all the medicine from 1st vial

Slowly pull the plunger back. **Stop at 1.5 mL.**

This will make sure all the medicine in the vial is in the dosing syringe.

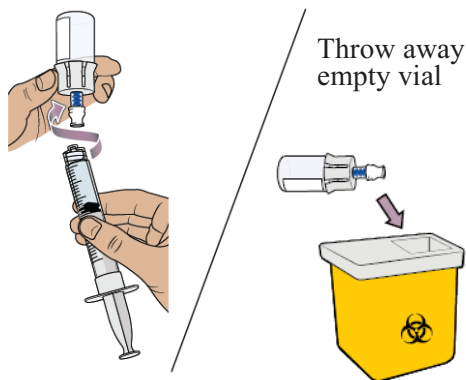
- ⚠ Do not pull the plunger beyond 1.5 mL. **Stop at 1.5 mL**
- ⚠ Be careful not to pull the plunger out of the dosing syringe



21 Remove 1st vial from the dosing syringe

Hold the vial adaptor and unscrew the filled dosing syringe from the vial.

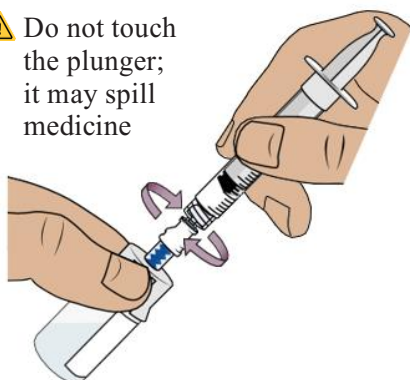
Throw away the **empty** vial into the sharps container.



22 Connect the dosing syringe to the 2nd vial

While holding the vial adaptor of the 2nd vial, screw the partially filled dosing syringe onto the vial adaptor until it stops.

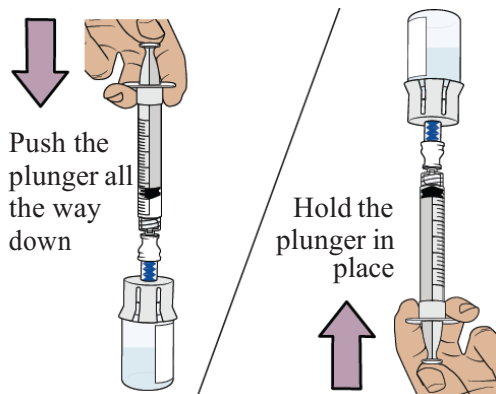
⚠ Do not touch the plunger; it may spill medicine



23 Push all the medicine into the 2nd vial, then flip upside down

Slowly push the plunger all the way down to transfer **all of the medicine into the vial** to ensure dose accuracy. This combines the medicine from both vials.

Then **hold the plunger in place** with your thumb and flip the vial upside down.

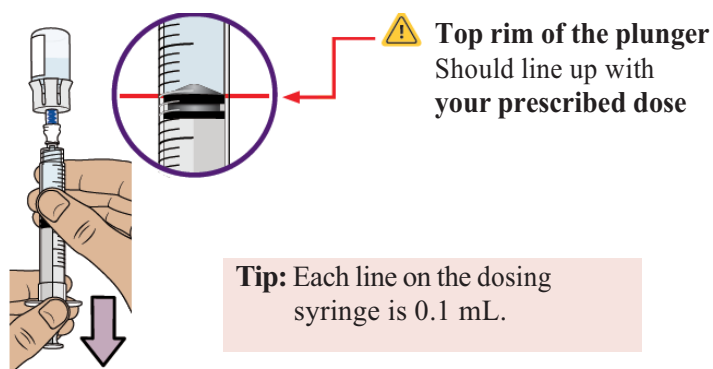


Withdraw your prescribed dose (Withdraw)

24 Pull plunger back to withdraw your dose

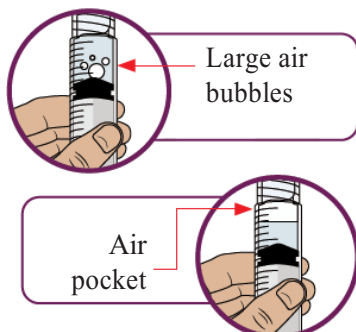
With the vial and dosing syringe upside down, **slowly pull the plunger back**.

Stop when you get to the **amount in 'mL' listed on your prescription**.



25 Check for air bubbles and air pockets

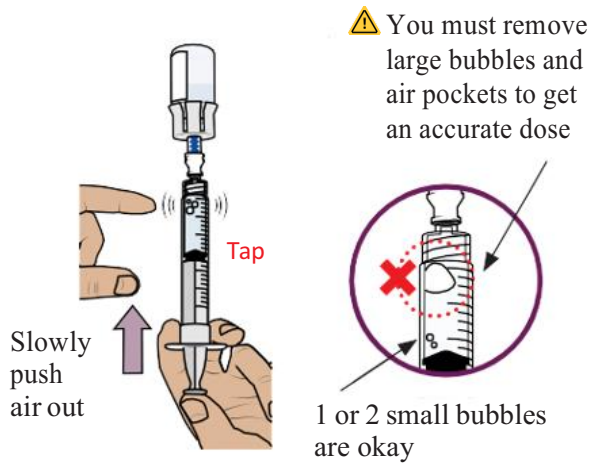
Check to see if there are large air bubbles or an air pocket in the syringe. You will remove extra air in the next steps.



26 Remove air bubbles and air pockets

If you see air bubbles or an air pocket, tap the side of the dosing syringe to move the air to the top.

Slowly push the plunger up to remove extra air.



27 Compare amount to prescribed dose

After removing all extra air, **compare the amount to your prescribed dose.**

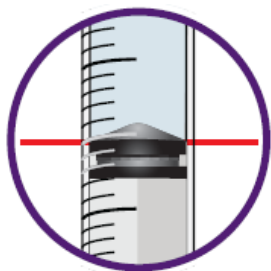
If you do not have your prescribed amount in your syringe, *slowly* pull the plunger back again to withdraw more medicine.



Repeat Steps 24 to 26 until you reach **your prescribed dose** and no large bubbles are visible.

28 Confirm your prescribed dose

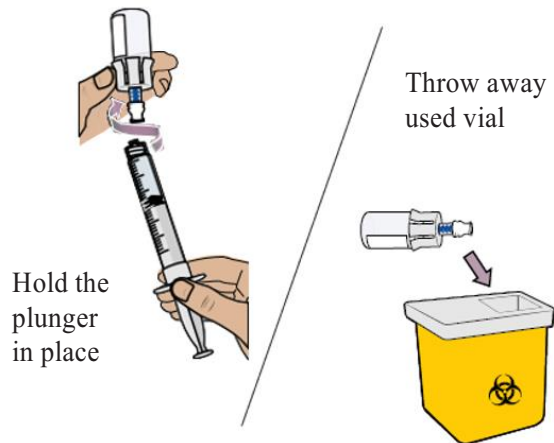
Before you continue, check to make sure you have the prescribed dose in the dosing syringe.



The top rim of the plunger should line up with **your prescribed dose**

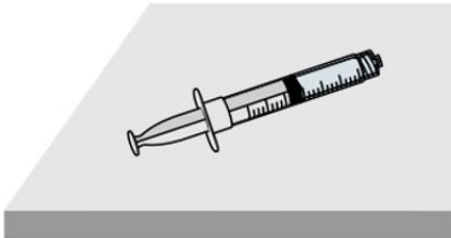
⚠ **If the amount does not match your prescribed dose, repeat Steps 24 to 27.**

29 Remove the dosing syringe from the vial and set the dosing syringe aside



Hold the plunger in place with one hand. With the other hand, hold the vial adaptor and unscrew the filled dosing syringe from the vial.

Throw away the vial into the sharps container.

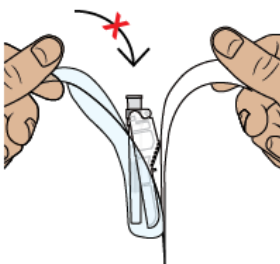


Place the filled dosing syringe on a clean, flat surface.

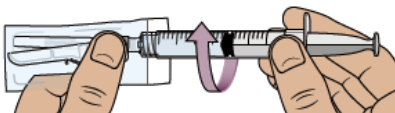
⚠ Do not touch the dosing syringe tip or let it touch any surfaces.

30 Attach the injection needle

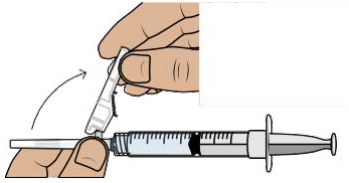
⚠ Do not touch the connection hub of the needle



Find the needle in the bottom tray and open its package.



With the needle still in the package, **grip the base of the needle** and **twist on the dosing syringe** until it stops. Remove the needle package.

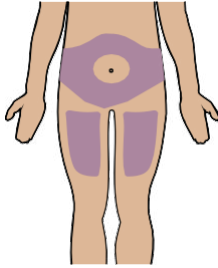


Move the safety shield away from the needle and toward the syringe to the angle shown.

Place the dosing syringe on a clean, flat surface.

⚠ Do not uncap the needle

31 Choose and clean your injection site



Select an injection site on your stomach (abdomen) or your upper thigh. If injecting on your stomach area, avoid a 5 cm area around your belly button.

Choose a different site every time you inject.

⚠ Do not inject into skin that is damaged, sore, bruised, or has red patches

⚠ Do not inject through clothes



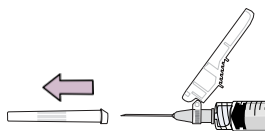
Clean the injection site with a new alcohol wipe.

⚠ Do not touch the cleaned injection site again

Now, you are ready to inject the medicine.

Inject your medicine

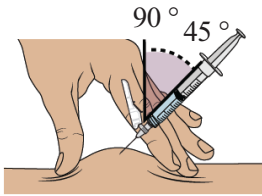
32 Inject your medicine (Inject)



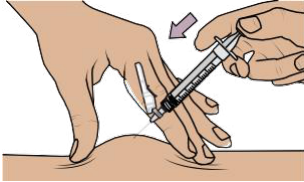
Pull the cap straight off the needle.

Throw away the cap.

⚠ Do not touch the plunger until ready to inject so you don't lose any medicine

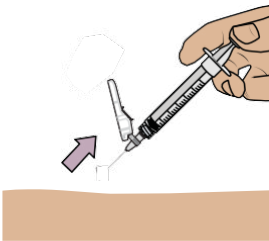


Gently **pinch and hold a fold of skin** where you will inject. Insert the needle with a **dartlike motion at a 45° to 90° angle**. This helps you inject directly under the skin (subcutaneous injection).

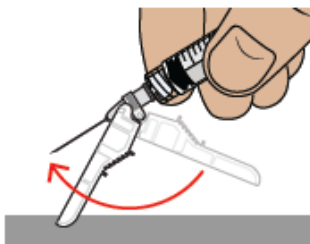


Push the plunger with slow, steady pressure all the way down until the dosing syringe is empty. **Confirm all the medicine has been injected.** You can let go of the skin fold now.

⚠ Keep your fingers away from the needle at all times.



While keeping the plunger pushed in, **remove the needle from your skin** at the same angle you inserted it.



To reapply the safety shield, push the shield against a flat surface until you hear a “click” and see that the needle is covered.



Throw away the dosing syringe and used items in a sharps disposal container.

⚠ Do not remove the needle from the dosing syringe

How to throw away Winrevair

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment. Make sure to follow local requirements for disposal as they may be different from the general recommendations below:


- Throw away any used vial (including any remaining Winrevair liquid), needle, vial and needle caps, and used syringes in a sharps disposal container.
- Do not throw away the Winrevair vials, syringes, or needle in your household waste.
- **Do not reuse any of the supplies.** This product is disposable and should only be used one time.
- **Important:** Always keep the sharps disposal container out of reach of children and pets.



If you do not have a sharps disposal 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 sharp objects 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 container is almost full, you will need to follow local guidelines for the right way to throw away your container.

 Do not recycle your used container

Frequently asked questions

What should I do if I'm bleeding from the injection site?

Place a cotton ball or bandage on your skin right away and apply a small amount of pressure. If the bleeding does not stop, call your doctor or pharmacist right away.

Where can I find my prescription amount?

Your prescription amount in 'mL' is on your prescription. Contact your doctor or pharmacist if you can't find your prescription amount.

What should I do if I accidentally get some medicine on my skin or my work surface?

Wash the area thoroughly with soap and water right away.

What should I do if I'm not sure I administered my prescribed dose correctly?

Call your doctor or pharmacist.

What should I do if the plunger of my dosing syringe moves automatically when I try to withdraw medicine from the vial?

Don't worry if your plunger moves slightly on its own when you are filling your dosing syringe with medicine.

With one hand, **hold the plunger in place to stop the plunger from moving.**

With the other hand, unscrew the vial from the dosing syringe. Once unscrewed, it is safe to let go of the plunger.

You can avoid this automatic plunger movement by pushing air into the vial before filling your dosing syringe with medicine. Refer to Steps 17 to 28 for detailed instructions.

What should I do if my pack parts are damaged or compromised (for example, discoloured, cloudy, or has particles)?

If your pack parts are damaged or compromised, do not use it. Call your doctor or pharmacist to get a new pack.

What should I do if my medicine does not turn clear after mixing and swirling?

Do not use the medicine if you have swirled the medicine vial for about 2 minutes and let it stand for another 3 minutes, but your medicine vial remains cloudy or has clumps, powder, or foreign particles. Call your doctor or pharmacist to get a new pack.

What should I do if the sterile water won't come out of the prefilled syringe?

Check that the vial adaptor is attached to the vial securely. If not, hold the vial and press the vial adaptor down firmly to make sure the vial adaptor punctures the vial rubber stopper.

What should I do if I dropped my pack components?

Do not use if any items are damaged. If you are unsure, call your doctor or pharmacist to get a new pack.

Can I use my pack that has been left out of the refrigerator?

If the unused pack has been out of the refrigerator for an extended period of time, please contact your doctor or pharmacist before proceeding.

Do I need to use mixed medicine right away?

We recommend you inject the medicine right after mixing but no later than 4 hours after mixing. If it has been more than 4 hours, throw away unused mixed medicine. If you have questions or are unsure about the process, please contact your doctor or pharmacist.

How can I get help preparing and giving my injection?

If you have questions about how to give Winrevair the correct way or need more information, you can call your doctor or pharmacist.

For any other information about this medicine, please contact your doctor or pharmacist, or the local representative of the Marketing Authorisation Holder. You will find the details of the local representative in the Package leaflet: Information for the patient.