

**Important: Read this booklet first**

# Instructions for Use

## **WINREVAIR® (WIN-reh-vair)**

How to use your WINREVAIR injection kit for Pulmonary Arterial Hypertension



**Vial 1**



**Vial 2**

Dose based  
on patient  
weight

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

Important

Mix

Combine

Withdraw

Inject

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## Important information for doctors

A doctor 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 using WINREVAIR and each time you get a refill. There may be new information.



### **Start with your doctor**

Do not use WINREVAIR until your doctor has shown you or your caregiver the right way to prepare and inject it. Your doctor 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, call your doctor.



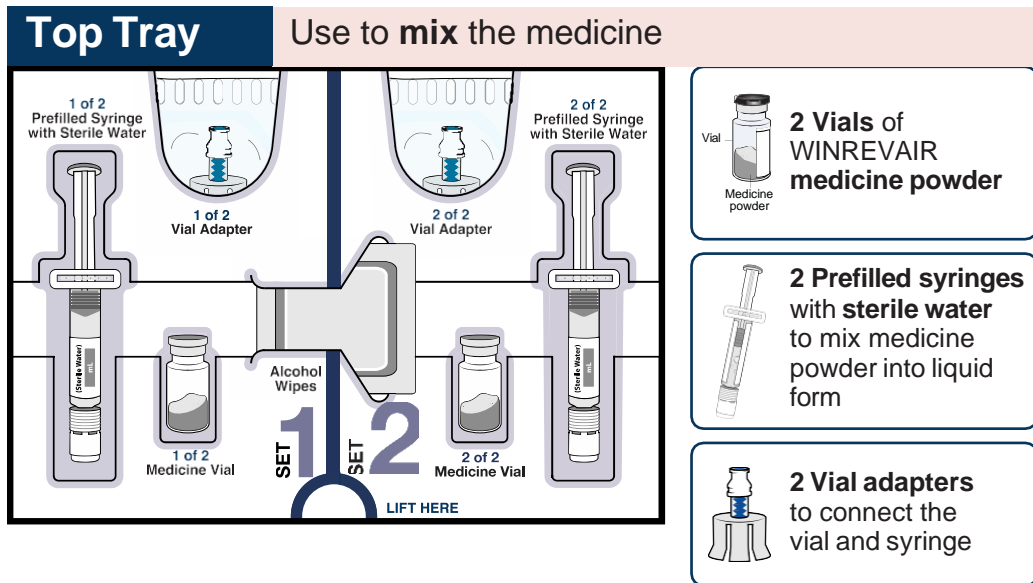
## How to use this product

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 mixture from vial 1 to vial 2
- **Withdraw** your prescribed dose from vial 2
- Then, you'll be ready to **inject** your medicine

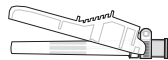
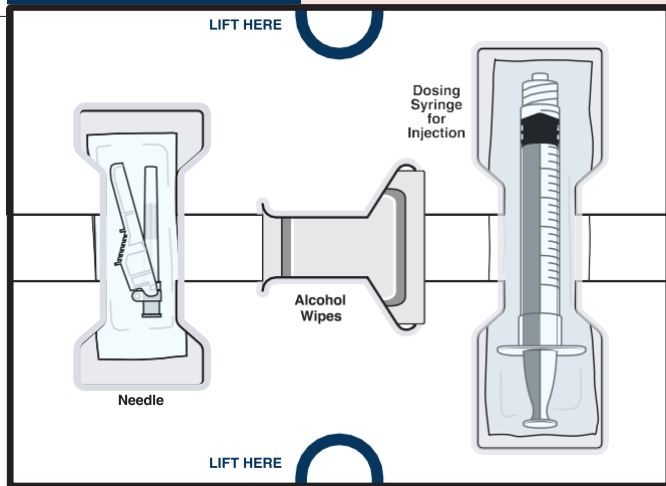
Proceed to the next pages for step-by-step directions.

# Get to know the parts of your kit

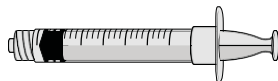


## Bottom Tray

Use to **inject** the medicine



**Needle** for injection



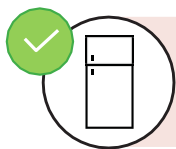
**Empty dosing syringe**  
to measure, withdraw,  
and inject your medicine

# Important information to know before injecting

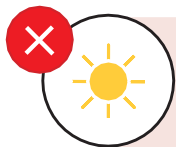
- You must mix this product before using it. Make sure the medicine powder in the vial is completely dissolved when you inject.
- **Check your prescribed dose (amount in ‘mL’) each time you use the product. Your prescribed dose may change.**
- Use only the supplies that are in the kit to prepare your prescribed dose.
- Do not open the package or mix the medicine until you are ready to use it.
- **Do not reuse any of the supplies.** After your injection, throw away the used vials with any remaining WINREVAIR medicine, needle, and syringes in a sharps container. See pages 38-39 for more information.



# Storing your injection kit



Store the entire injection kit in the refrigerator, but do not freeze.



Keep the medicine and supplies in the injection kit and away from light.



Keep injection kit out of the 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 doctor.

## 1 Check WINREVAIR product and expiration date

Remove the WINREVAIR injection kit from the refrigerator.

✓ **Check the expiration date and look for any signs of damage** on the kit or in the supplies.

⚠ If expired or damaged, do not use. Get a new kit.

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

**2**

## Let your kit come to room temperature, gather supplies, and wash your hands

**Wait 15 minutes** to allow your kit to warm to room temperature.

Cold medicine is more painful to inject.



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

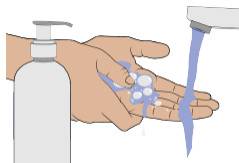


Sharps disposal container



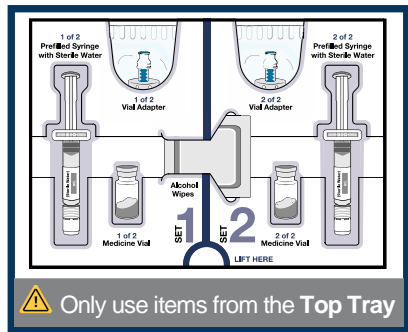
Gauze, cotton ball, or bandage

Wash your hands with soap and water.



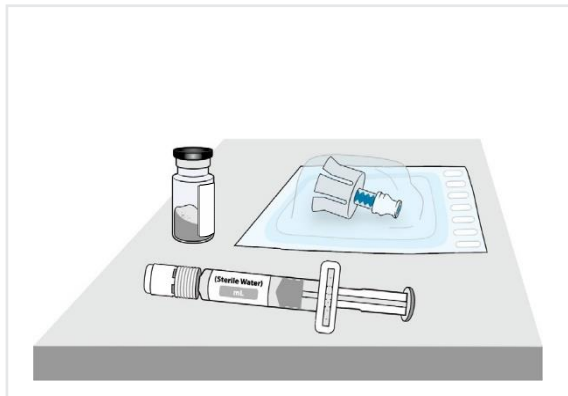
# Mix powdered medicine into liquid form

Start with the Top Tray

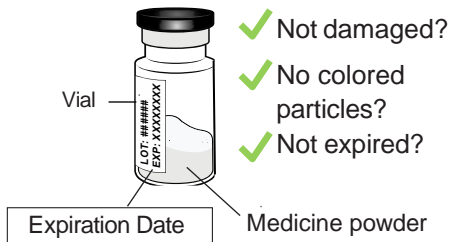


3

Remove vial 1, prefilled syringe 1, and vial adapter 1 from the kit



## 4a Check medicine vial

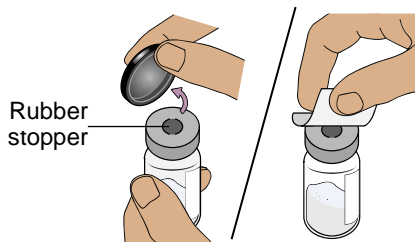


Check the vial label to **confirm the medicine is not expired.**

Inspect the medicine powder. It should be white to off-white and may look like a whole or fragmented cake.

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

## 4b Remove plastic cap and clean vial

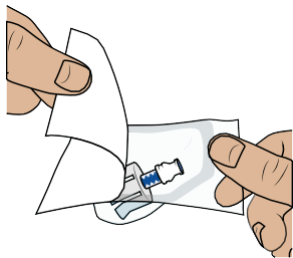


Flip off the plastic cap and **clean the rubber stopper on top of the vial** with an alcohol wipe.

- ⚠ 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 adapter to vial



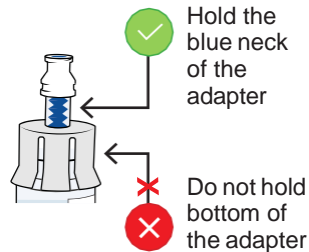
Peel open the vial adapter package and remove it from its package.



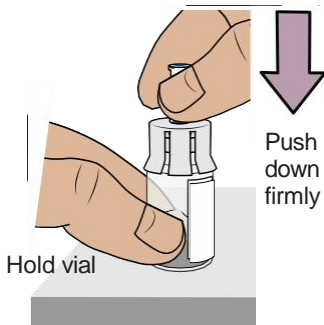
**Hold the blue neck of the adapter** and align the vial adapter on top of the vial.

 Do not touch the inside of the vial adapter

To attach the vial adapter:

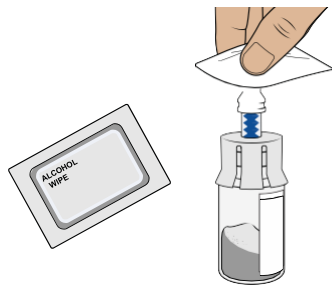


## 5b Attach vial adapter to vial



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

## 5c Clean vial adapter

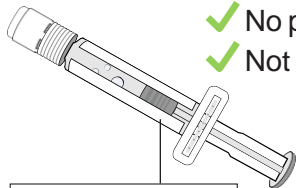


Clean the top of the vial adapter with an alcohol wipe.

## 6 Check prefilled syringe

Confirm the sterile water inside the prefilled syringe is clear and the product is not expired.

- ✓ Not damaged?
- ✓ Clear?
- ✓ No particles?
- ✓ Not expired?

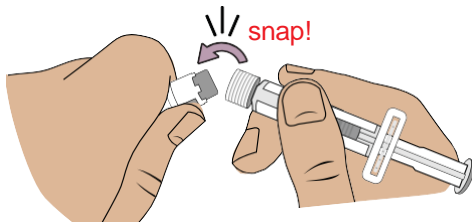


Expiration Date

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

## 7 Snap off prefilled syringe white cap

Snap 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 water



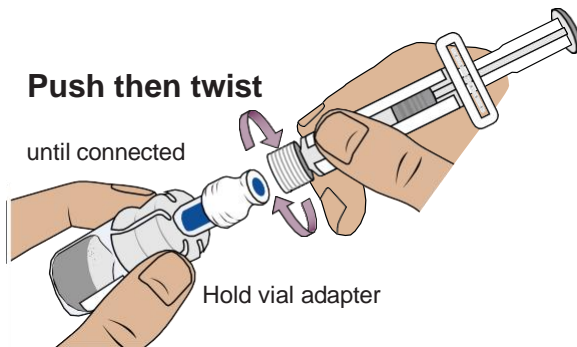
## 8


## Connect prefilled syringe to vial adapter

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

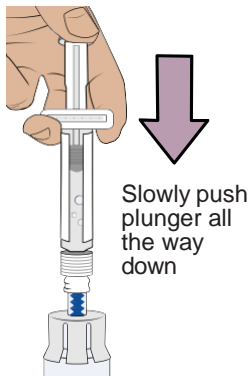
**Align the prefilled syringe tip on the blue circle of the vial adapter.**

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

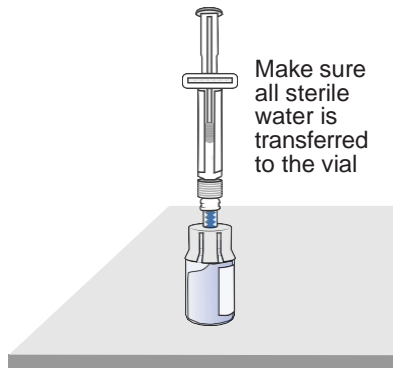


 Do not push the plunger; it may spill the water

## 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.

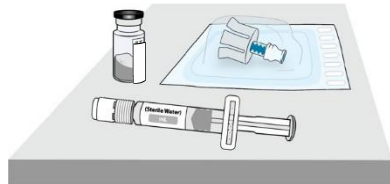
## 10 Prepare vial 2, prefilled syringe 2, and vial adapter 2

Remove **vial 2, prefilled syringe 2, and vial adapter 2** from the kit.



### Important:

Turn back to Page 13 and repeat Steps **4** to **9** to **prepare vial 2**.



Vial 1

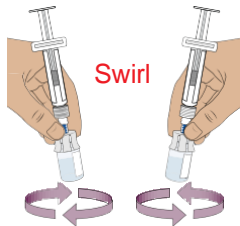


Vial 2

**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.

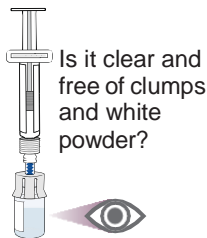
## 11

## Swirl to mix medicine

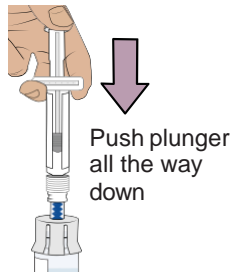


 Do not shake the vials

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**.



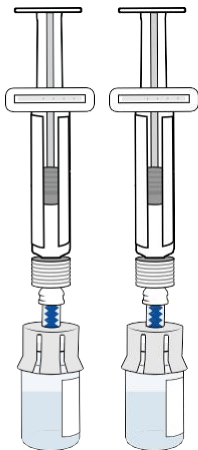
When the medicine is mixed well, it should be clear. If not, repeat this step until it is clear.



For each vial, **press the plunger down** to make sure all the liquid is in the vial (the plunger will move up; this is normal).

**12**

## Wait for bubbles to go away



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

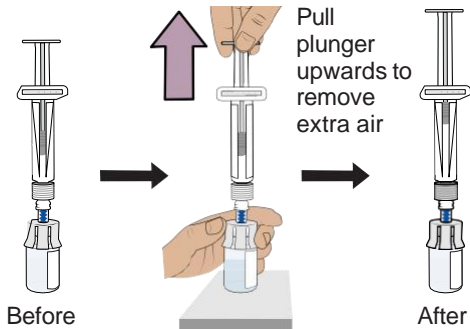


Before you continue, make sure the medicine in the vial:

- ✓ Is clear to slightly pearly and colorless to slightly brownish-yellow
- ✓ Does not have clumps or powder
- ✓ Does not have large bubbles

It is okay to have slight foam around edges of the vial

## 13 Prepare vials by removing extra air



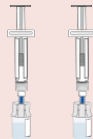
Start with either vial. While having the vial oriented upright, ***gently* pull the plunger upwards** to the top of the barrel but be careful not to pull the plunger out of the syringe.

**Tip:** This step only pulls extra air out of the vials to make sure you have the right dose.

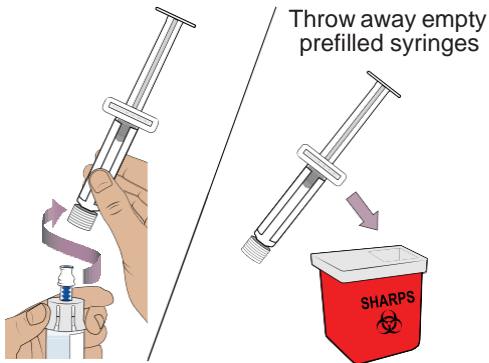


### Important:

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

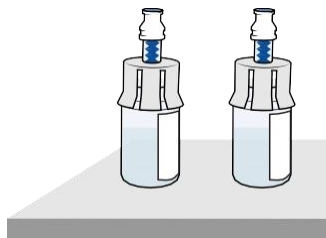


## 14 Remove prefilled syringes from vials



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

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

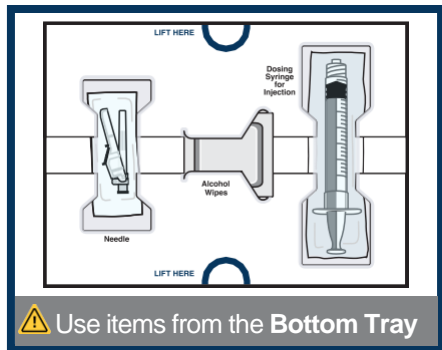


You should have 2 vials prepared and ready to be combined in the next steps.

# Combine medicine from both vials

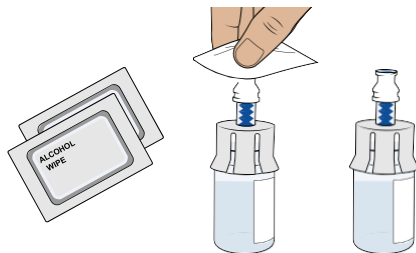
For the next steps, you will need:

- Mixed vial 1 and vial 2
- Items from the Bottom Tray



## 15 Clean top of both vial adapters

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

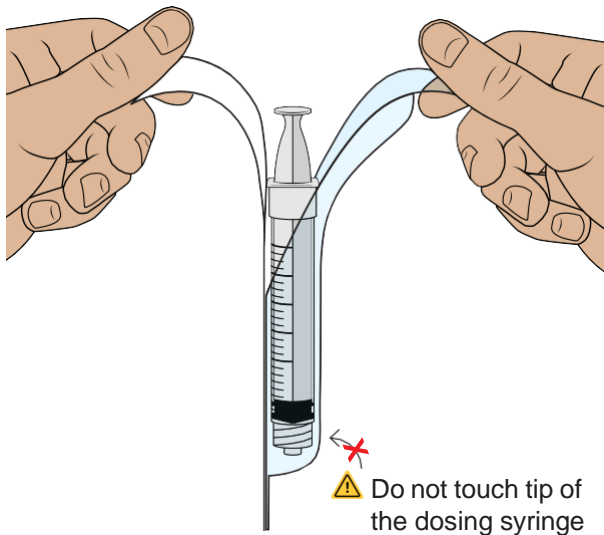





## 16 Remove empty dosing syringe from its package

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

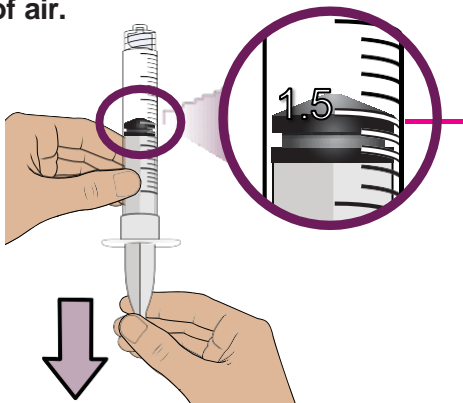
You will use this dosing syringe to combine medicine from both vials and measure out the medicine you need (based on your prescribed dose).



## 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.**



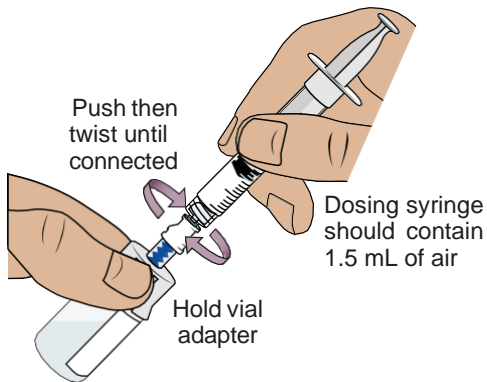
**Top rim  
of plunger**

Pull plunger until top rim  
of plunger is at 1.5 mL

**18**

## Connect dosing syringe to one of the vials

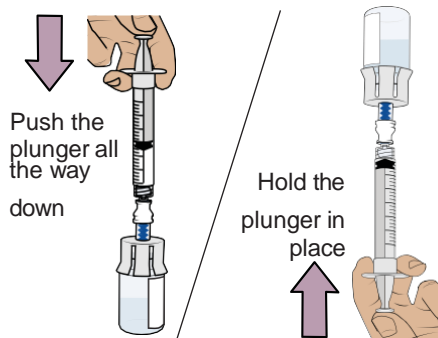
While holding the vial adapter, screw the dosing syringe on until it stops.

**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 1<sup>st</sup> 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.



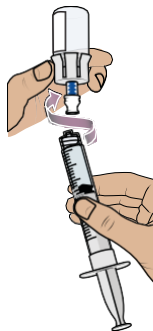
⚠ Do not pull extra air into the syringe  
**Stop at 1.5 mL**

⚠ Be careful not to pull the plunger out of the dosing syringe

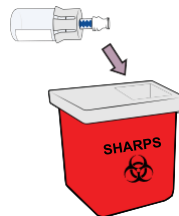
## 21 Remove 1<sup>st</sup> vial from the dosing syringe

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

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




Throw away empty vial

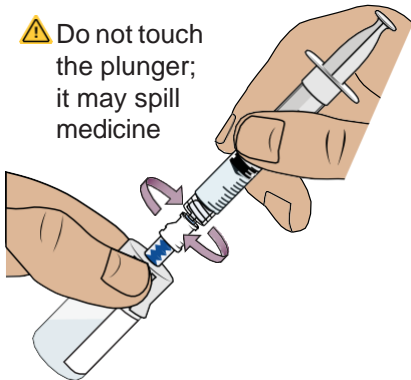


**22**

## Connect the dosing syringe to the 2<sup>nd</sup> vial

While holding the vial adapter of the 2<sup>nd</sup> vial, screw the partially filled dosing syringe onto the vial adapter until it stops.

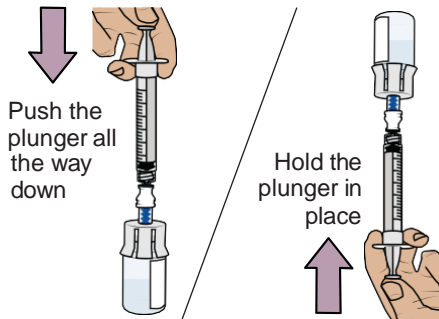
 Do not touch the plunger; it may spill medicine

**23**

## Push all the medicine into the 2<sup>nd</sup> vial, then flip upside down

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

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

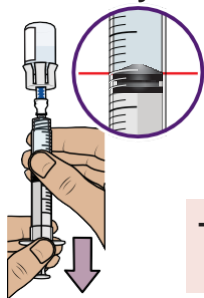



# Withdraw your prescribed dose

## 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**.

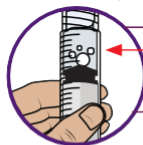


 **Top rim of plunger should line up with your prescribed dose**

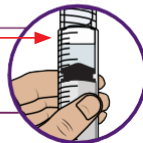
**Tip:** Each line on the dosing syringe is 0.1 mL.

## 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.



Large air bubbles



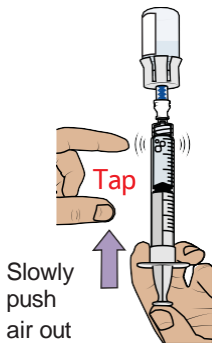
Air pocket

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.



⚠ You must remove large bubbles and air pockets to get an accurate dose



1 or 2 small bubbles are okay

27

## Compare amount to prescribed dose

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

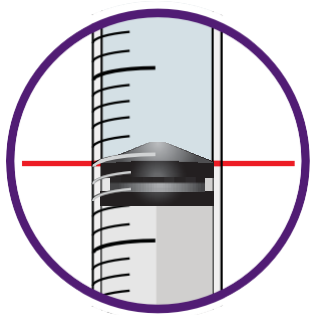
**If you do not have your prescribed amount in your syringe, slowly pull the plunger back again to withdraw more medicine.**




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 dosing syringe aside



Hold the plunger in place

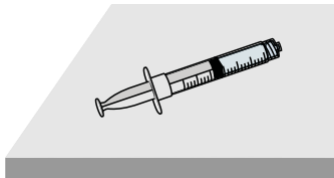
Throw away used vial



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


Throw away the vial into the sharps container.

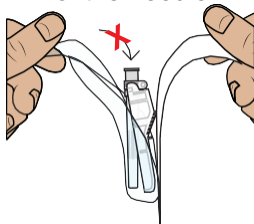
Place the filled dosing syringe on a clean, flat surface.



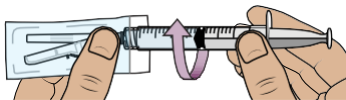
Do not touch the dosing syringe tip or let it to touch any surfaces

## 30 Attach injection needle

 Do not touch the connection hub of the needle



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



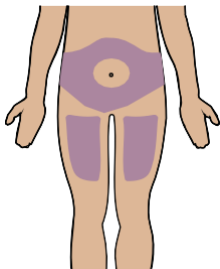
With the needle still in the package, **grip the base of the needle** and **twist on the dosing syringe** until it stops. Remove the needle package.



**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

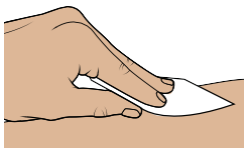


**Select an injection site** on your stomach (abdomen) or your upper thigh. If injecting on your stomach area, avoid a 2-inch area around your belly button.

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



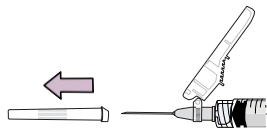
**Clean the injection site** with a new alcohol wipe.

⚠ Do not touch the cleaned injection site again


**Now, you are ready to inject the medicine.**

# Inject your medicine

## 32 Inject your medicine

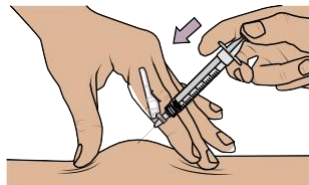


Pull the cap straight off the needle.  
Throw away the cap.


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

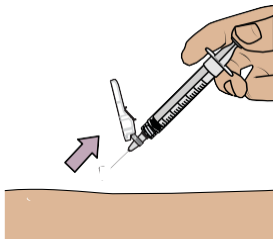


Gently **pinch and hold** a **fold of skin** where you will inject. Insert the needle with a **dartlike motion** at a **45° to 90° angle**. This helps you inject directly under the skin (subcutaneous injection).

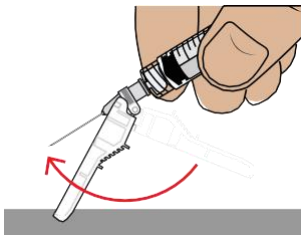


**Push** the plunger with slow, steady pressure all the way down until the dosing syringe is empty. **Confirm all the medicine has been injected.** You can let go of the skin fold now.

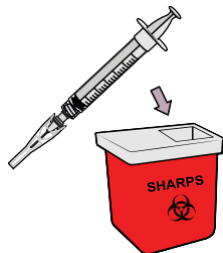
 Keep your fingers away from the needle at all times.




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.

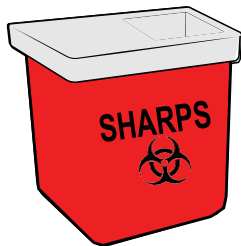


Throw away the dosing syringe and used items in a sharps container.

 Do not remove the needle from the dosing syringe

# How to throw away WINREVAIR

- 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 trash.
- **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 labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to throw away your sharps container. There may be local laws about how you should throw away used needles, dosing syringes, and prefilled syringes.



Do not recycle your used sharps 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 right away.

## **Where can I find my prescription amount?**

Your prescription amount in 'mL' is on your prescription label on your kit. Contact your doctor 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.



### **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 kit parts are damaged or compromised (for example, discolored, cloudy, or has particles)?**

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

# Frequently asked questions

## **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 to get a new kit.

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

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

## **What should I do if I dropped my kit components?**

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

### **Can I use my kit that has been left out of the refrigerator?**

If the unused injection kit has been out of the refrigerator for an extended period of time, please contact your doctor.

### **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 the medicine. If you have questions, please contact your doctor.

### **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.

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