

Instructions for Use

AFREZZA® (uh-FREZZ-uh) (insulin human) inhalation powder

Read this Instructions for Use before you start using AFREZZA and each time you get a new AFREZZA inhaler. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Your healthcare provider should show you how to use your AFREZZA inhaler the right way before you use it for the first time.

Important information about AFREZZA:

- **AFREZZA comes in 3 strengths** (See Figure A):
 - 4 units (blue cartridge)
 - 8 units (green cartridge)
 - 12 units (yellow cartridge)

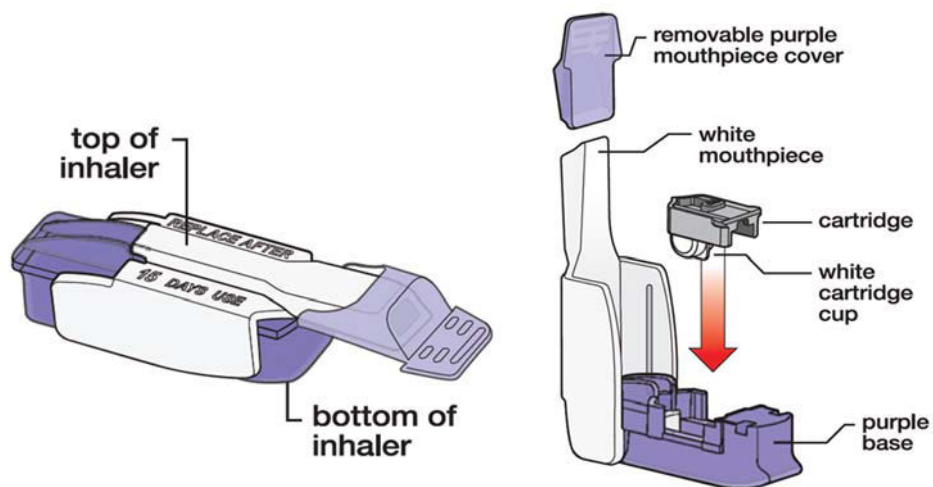
(Figure A)



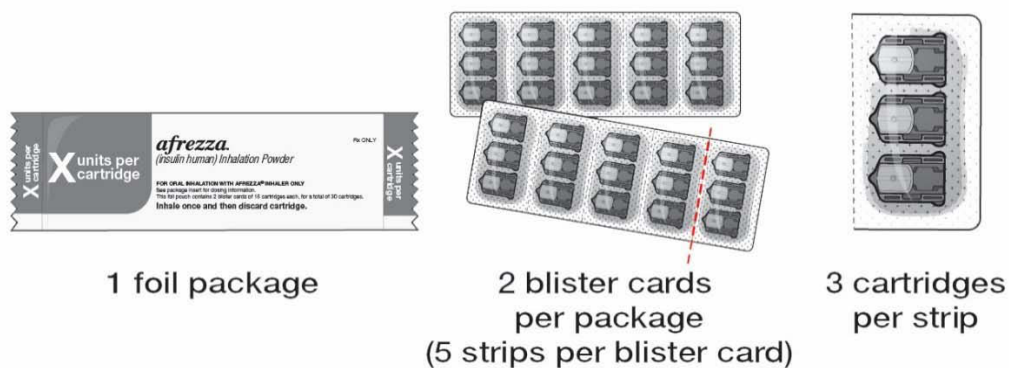
- If your prescribed AFREZZA dose is higher than 12 units, you will need to use more than 1 cartridge.
- If you need to use more than 1 cartridge for your dose, throw away the used cartridge before getting a new one. You can tell when a cartridge has been used, because the cup has moved to the center.
- **Do not try to open the AFREZZA cartridges.** The AFREZZA Inhaler opens the cartridge automatically during use.
- **AFREZZA cartridges should only be used with the AFREZZA Inhaler. Do not** try to breathe in the AFREZZA insulin powder in any other way. **Do not** put cartridges in your mouth and **do not** swallow cartridges.
- Use only 1 AFREZZA Inhaler at a time. The same inhaler should be used for the 4 unit, 8 unit or 12 unit cartridges.
- Store the inhaler in a clean, dry place with the mouthpiece cover on until your next dose.
- Throw away your AFREZZA Inhaler after 15 days and get a new one.

If you are having problems with your AFREZZA inhaler or if it breaks and you need a new one, call 1-877-323-8505.

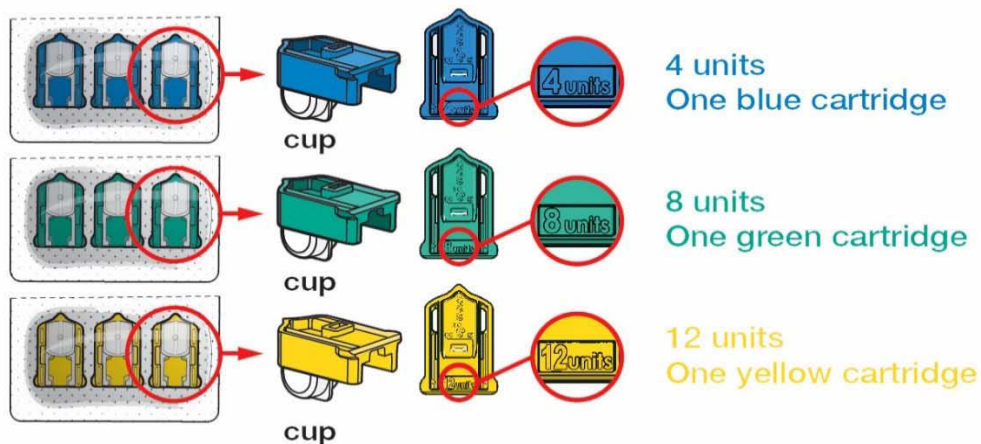
Know your AFREZZA® inhaler:



Know your AFREZZA® cartridges:



There are three strengths of AFREZZA® cartridges:



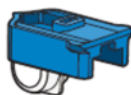
How to take your dose of AFREZZA:

Always be sure you have the right number of AFREZZA cartridges for your dose available before you start. AFREZZA cartridges must only be used with the AFREZZA Inhaler.

Step 1: Select the AFREZZA cartridges for your dose

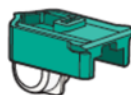
If your prescribed AFREZZA® dose is 4 units, use...

1 blue cartridge.



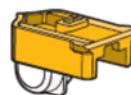
If your prescribed AFREZZA® dose is 8 units, use...

1 green cartridge.














If your prescribed AFREZZA® dose is 12 units, use...

1 yellow cartridge.



If your prescribed AFREZZA® dose is more than 12 units you will need to use **more than 1 cartridge** to get your right dose.

Use the dosage chart below to determine the least number of AFREZZA® cartridges you can use for your dose. Other cartridge combinations can be used.

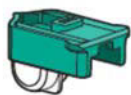
AFREZZA® Dose	# of cartridges needed			
	4 unit (blue)	8 unit (green)	12 unit (yellow)	
4 units				
8 units				
12 units		+	 or/ 	
16 units		 		
20 units			+	
24 units			 	

(Figure B)

Example:

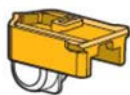
If you need to take **20 units** of AFREZZA® you can use...

1 green
(8 unit)
cartridge



+

1 yellow
(12 unit)
cartridge



Select Cartridges

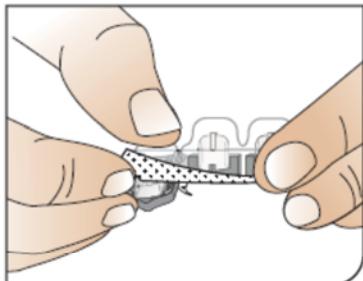
Important: Use the AFREZZA dose chart above (See Figure B) to help you choose the right number of AFREZZA cartridges needed for your dose.



Open Packages

Remove a blister card from the foil package.

Tear along perforation to remove one strip.



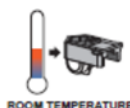
Push Cartridges to Remove

Remove a cartridge from the strip by pressing on the clear side to push the cartridge out. Remove the right number of cartridges for your dose. Pushing on the cup will not damage the cartridge.

AFREZZA cartridges left over in an opened strip must be used within 3 days.



Before use, cartridges and inhaler should be at room temperature for 10 minutes.



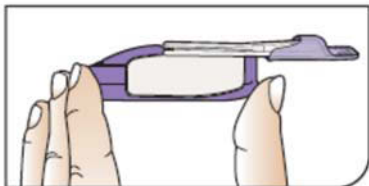
Before Proceeding:

Check that you have the right AFREZZA cartridge(s) for your dose.

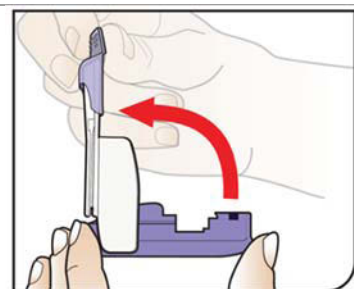
Use only 1 inhaler for multiple cartridges. Throw away your AFREZZA inhaler after 15 days and get a new one.

Step 2: Loading a cartridge

Hold Inhaler



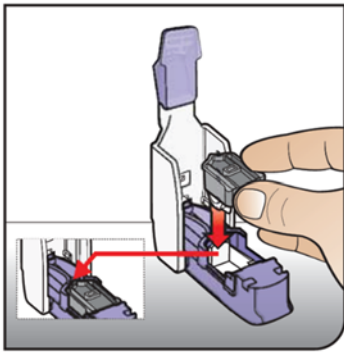
Hold the inhaler level in one (1) hand with the white mouthpiece on the top and purple base on the bottom.



Open Inhaler

Open the inhaler by lifting the white mouthpiece to a vertical position.

Before you put the AFREZZA cartridge in your inhaler, make sure it has been at **room temperature for 10 minutes**.

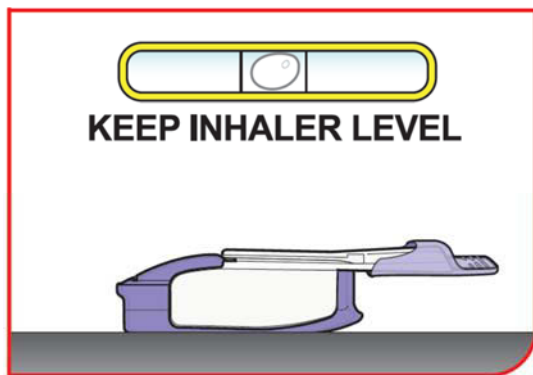


Place Cartridge

Hold the cartridge with the cup facing down.

Line up the cartridge with the opening in the inhaler. The pointed end of the cartridge should line up with the pointed end in the inhaler.

Place the cartridge into the inhaler. Be sure that the cartridge lies flat in the inhaler.



Keep Level Once Loaded!

Now that the cartridge is loaded, keep the inhaler level from this point forward to avoid loss of drug powder.



DO NOT turn inhaler upside down.



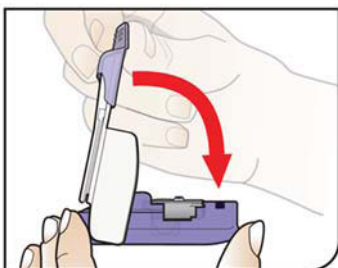
DO NOT point the mouthpiece down.



DO NOT shake or drop the inhaler.

This can result in loss of drug powder.

If any of these occur, throw away the cartridge and load a new cartridge.



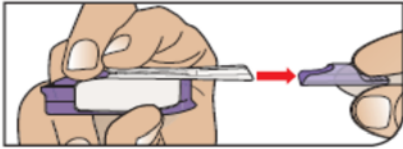
Close Inhaler

Lower the mouthpiece to close the inhaler (this will open the drug cartridge).

You should feel a snap when the inhaler is closed.

Step 3: Inhaling AFREZZA

Remove the Mouthpiece Cover

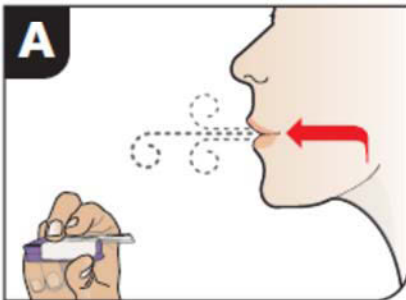


Important: Keep the inhaler level during and after removal of the purple mouthpiece cover.

Check that you are ready to inhale:

- ✓ Purple mouthpiece cover is removed.
- ✓ Inhaler is held level.
- ✓ Fully review the following A-B-C steps prior to beginning the inhale process.

Exhale



Hold the inhaler away from your mouth and fully blow out (exhale).

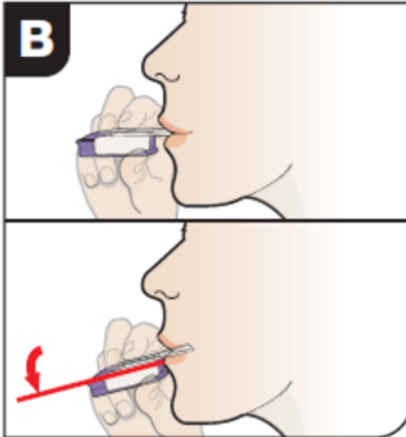
A

Position Inhaler in Mouth

Keeping your head level, place the mouthpiece in your mouth and **tilt the inhaler down towards your chin, as shown.**

Close your lips around the mouthpiece to form a seal.

Tilt the inhaler downward while keeping your head level.

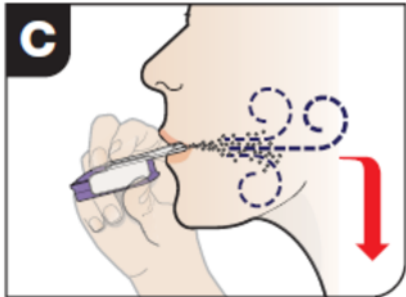


B

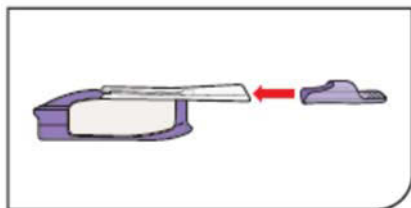
Inhale Deeply and Hold Breath

With your mouth closed around the mouthpiece, **inhale deeply through the inhaler.**

Hold your breath for as long as comfortable and at the same time remove the inhaler from your mouth. After holding your breath, exhale and continue to breathe normally.

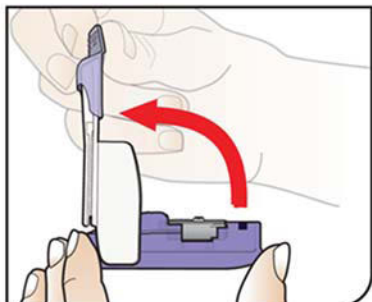


Step 4: Removing a used cartridge



Replace Mouthpiece Cover

Place the purple mouthpiece cover back onto the inhaler.



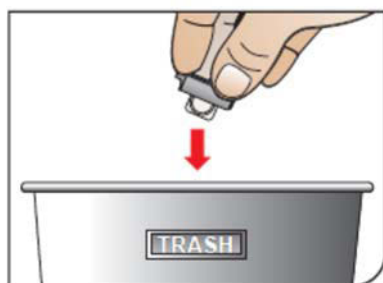
Open Inhaler

Open the inhaler by lifting up the white mouthpiece.



Remove Cartridge

Remove the cartridge from the purple base.

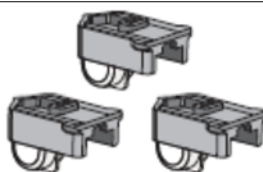


Throw away the Cartridge

Throw away the used cartridge in your regular household trash.

Multiple cartridge dosing

If you need more than one (1) AFREZZA cartridge for your dose, See the AFREZZA dosage chart above (Figure B).



Repeat steps 2 through 4 for each AFREZZA cartridge you need for your prescribed AFREZZA dose.



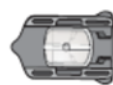
Be careful not to mix NEW cartridges with USED cartridges.



NEW



USED

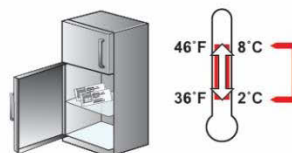



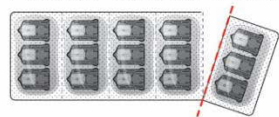
The white cup moves to the middle of the cartridge when it has been used.

How should I store AFREZZA?

Not In Use: Refrigerated Storage

Store unopened drug in a refrigerator 36 – 46°F (2 – 8°C).



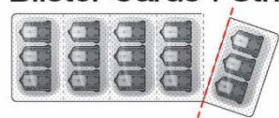
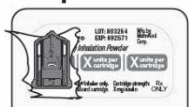
Refrigerated		
Foil Packages 	Sealed (Unopened)	May be used until the Expiration Date*
Blister Cards + Strips 	Sealed (Unopened)	Must be used within 1 month*

*If a foil package, blister card or strip is not refrigerated, the contents must be used within 10 days

In Use: Room Temperature Storage

Opened Foil Packages

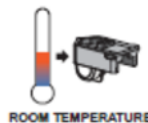
Once a foil package has been opened, see chart below...

Room Temperature		
Blister Cards + Strips 	Sealed (Unopened)	Must be used within 10 Days
Strips 	Opened	Must be used within 3 Days

Do not put a blister card or strip back into the refrigerator after being stored at room temperature



Before use, cartridges and inhaler should be at room temperature for 10 minutes.



10 mins.

Caring for your AFREZZA inhaler:

Storage Instructions

Once you have taken your full dose, make sure the purple mouthpiece cover has been replaced and the inhaler is closed.



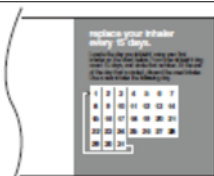
- **Keep the inhaler in a clean, dry place** with the mouthpiece cover on until your next dose.
- May be stored refrigerated, but must be at room temperature before use.
- Never leave or store cartridges in the inhaler.
- Keep out of reach of children.

Care Instructions



- **Use one inhaler at a time. The same inhaler should be used to take 4 unit, 8 unit or 12 unit cartridges. Replace the inhaler every 15 days to maintain drug delivery.**

Keep track of 15 days from when you start using the inhaler with a calendar, or use the chart on the back of the inhaler box.



- After taking your dose, powder residue in the mouthpiece is normal, this does not affect your dose.

The outside of the inhaler can be wiped with a clean, dry cloth if needed. Never wash the inhaler. Keep it dry.

Switching between AFREZZA and injected insulin:



Contact your healthcare provider before switching insulins.

AFREZZA® is a mealtime insulin.

Do not switch from AFREZZA to a long acting insulin.

Do not switch from a long acting insulin to AFREZZA®.

To switch from AFREZZA® to injected mealtime insulin...



Find your AFREZZA® dose in the chart.

AFREZZA® Dose	# of cartridges needed			Injected Mealtime Insulin Dose
	4 unit (blue)	8 unit (green)	12 unit (yellow)	
4 units				4 units
8 units				8 units
12 units		+	or	12 units
16 units				16 units
20 units		+		20 units
24 units				24 units

Find the correct dose of injected insulin.

If you cannot find your injected dose in the chart below, you must talk to a healthcare provider before using AFREZZA®.

To switch from injected mealtime insulin to AFREZZA®...



Find your injected insulin dose in the chart.

Injected Mealtime Insulin Dose	AFREZZA® Dose	# of cartridges needed		
		4 unit (blue)	8 unit (green)	12 unit (yellow)
up to 4 units	4 units			
5-8 units	8 units			
9-12 units	12 units		+	or
13-16 units	16 units			
17-20 units	20 units		+	
21-24 units	24 units			

Find the correct dose of AFREZZA®.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

AFREZZA® is a registered trademark of MannKind Corporation

Patented. See <http://www.mannkindcorp.com/patent-notice>

MannKind Corporation
Danbury, CT 06810

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