INSTRUCTIONS FOR USE
AFREZZA® (uh-FREZZ-uh)
(insulin human)
inhalation powder, for oral inhalation use

This Instructions for Use contains information on how to use AFREZZA® (insulin human) inhalation powder dry powder inhaler.

Read this Instructions for Use all the way through 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 or your child (10 years of age or older) how to use the AFREZZA Inhaler the right way before it is used for the first time. Contact your healthcare provider if you have any questions.

Important Information You Need to Know Before Inhaling AFREZZA:

- **AFREZZA starts acting fast,** so take your medicine right before you eat a meal.
- **For oral inhalation only.**
- **AFREZZA is a mealtime (short acting) insulin.**
- **Contact your healthcare provider before switching insulins.**
- **Do not** put cartridges in your mouth.
- **Do not** swallow cartridges.
- **Do not** use AFREZZA cartridges if they are expired.
- **Only use AFREZZA cartridges with the AFREZZA Inhaler. Do not** breathe in the AFREZZA powder any other way.
- **Do not** open the cartridges**.** The inhaler opens the cartridge automatically during use.
- **Do not** reuse cartridges. **Cartridges are single use and should only be used 1 time.**
- **You can tell a cartridge has been used** when the cartridge cup has moved from the front to the middle position in the cartridge base.
- **If your prescribed AFREZZA dose is higher than 12 units**, you will need to use more than 1 cartridge.
- **If using more than 1 cartridge for a dose**, the cartridges can be used in any order, regardless of cartridge strength.
- **Do not** insert more than 1 cartridge into the inhaler at a time. Always remove the used cartridge from the inhaler before inserting a new one.
- **Only use 1 inhaler at a time**. The same inhaler should be used for the 4 unit, 8 unit or 12 unit cartridges. The same inhaler should be used even when needing to use more than 1 cartridge for your dose.
- **Do not** share the AFREZZA Inhaler with anyone else.
- **The inhaler lasts for 15 days. After 15 days of use, throw away your used inhaler and get a new one.**

Warning:

- **After a cartridge is loaded into the inhaler, keep the inhaler level** until the inhaler mouthpiece is in your mouth to avoid spilling the AFREZZA powder. **Do not** flip or rotate inhaler.
- **If any AFREZZA powder spills**, throw away the cartridge into regular household trash, and wash your hands. Then restart the procedure with a new cartridge.

AFREZZA Inhaler Parts (Figure A)**:**

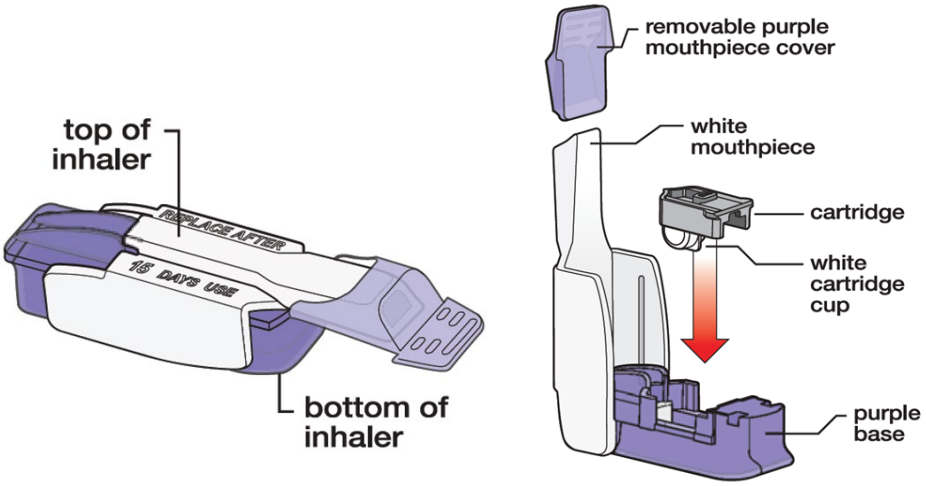


Figure A

AFREZZA Cartridge Parts and Strengths (Figure B):

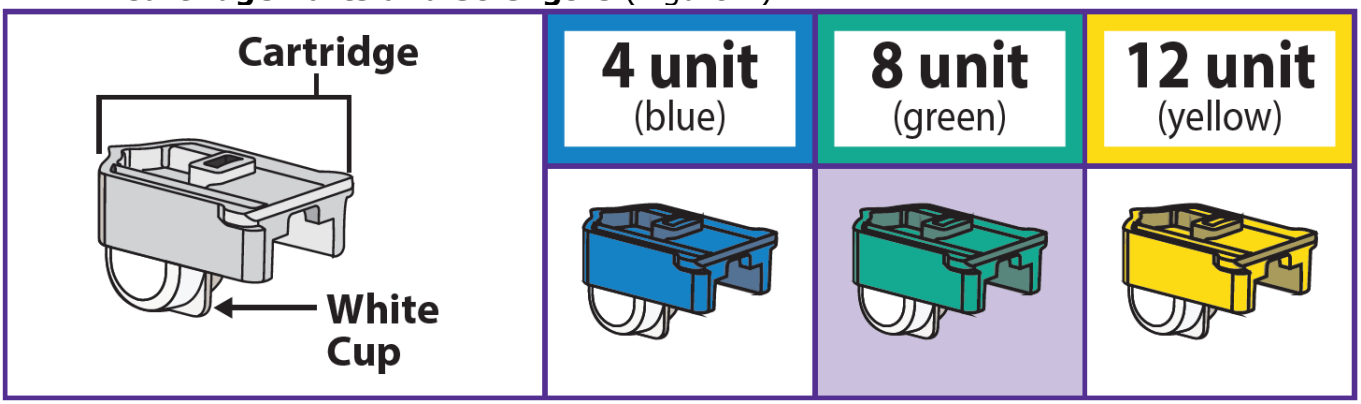


Figure B

Storage Information (Figure C)

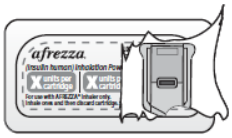
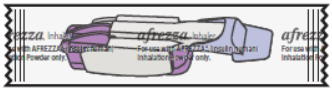
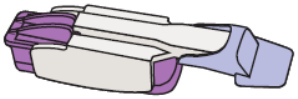
	If Stored in the Refrigerator between 36°F and 46°F (2°C and 8°C)	If Stored at Room Temperature between 68°F and 77°F (20°C and 25°C) in a clean dry place
Unopened (Sealed) foil packages 	May be used **until the expiration date**	Must be used **within 10 days**
Unopened (sealed) blister cards and blister strips 	Must be used **within 1 month**	Must be used **within 10 days**
Opened blister strips 	**Do not** store opened blister strips in the refrigerator.	Must be used **within 3 days**
Unused (sealed) inhaler 	**Until ready to use**	**Until ready to use**
Opened in-use inhaler 	For up to **15 days after first use**	For up to **15 days after first use**

Figure C

Additional Storage Information

- **Important: Before use, cartridges and inhaler should be left out at room temperature for at least 10 minutes.**
- **Do not** put blister cards or blister strips back into the refrigerator after being opened or stored at room temperature.
- **Keep AFREZZA and all medicines out of reach of children.**
- **Do not** let cartridge or inhaler get wet.
- **Do not** leave or store cartridges in the inhaler.
- **Use 1 inhaler at a time.** The same inhaler should be used to take 4 unit, 8 unit or 12 unit cartridges.
- **Always store the inhaler with the mouthpiece cover on.**

Preparing to Inhale AFREZZA

Step 1: Choose cartridges for dose

1.1 Figure out what AFREZZA cartridges are needed for your dose.

Use the dosage chart below (Figure D) to determine the number of AFREZZA cartridges you can use for your dose.

Note: If your prescribed AFREZZA dose is higher than 12 units, you will need to use more than 1 cartridge. **If using more than 1 cartridge for a dose,** the cartridges can be used in any order, regardless of cartridge strength.

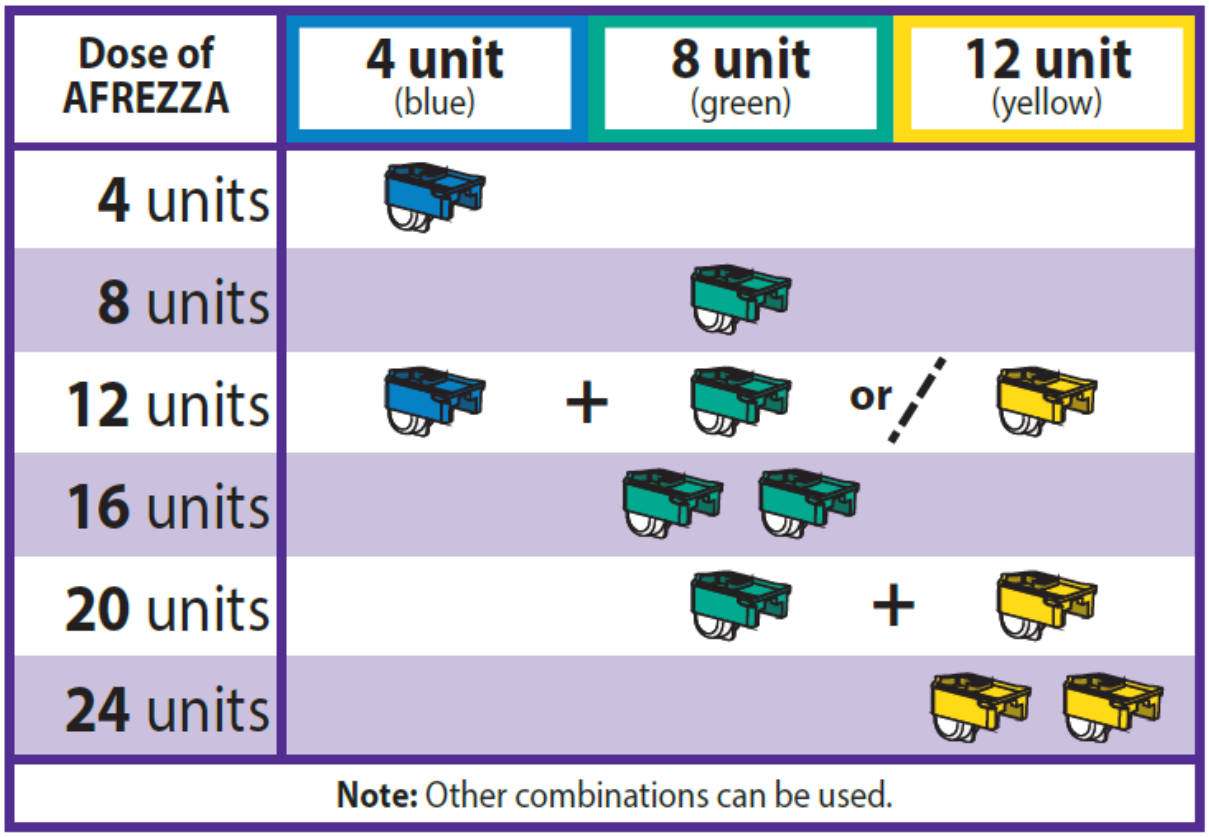


Figure D

Step 2: Get and check blister strip(s)

2.1 Open Foil package and remove blister card(s) needed for your dose (Figure E).

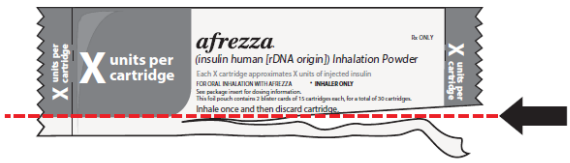


Figure E

2.2 Get the blister strip(s) with the cartridges you need for your dose

If needed, tear blister strip from the blister card (Figure F).

Important: Any blister cards or blister strips that are unopened and will not be needed for your dose should be returned to the refrigerator for storage.

Refer to the Storage Information section for more information.

Do not use cartridges if stored longer than allowed in the **Storage Information** (Figure C).



Figure F

2.3 Check the expiration date printed on the blister strip(s) (Figure G).

Do not use cartridges if the expiration date has passed.

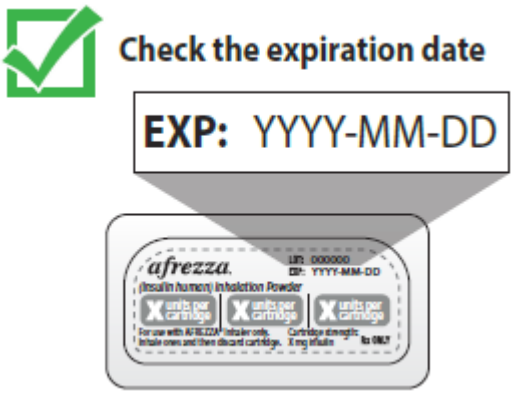


Figure G

Step 3: Remove cartridge(s) from blister strip(s)

3.1 Remove cartridge(s) from the strip by pressing on the clear plastic to push the cartridge out (Figure H).

Note: Pushing on the clear plastic will not damage the cartridge.

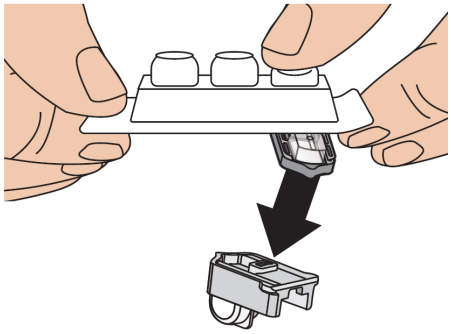


Figure H

3.2 If stored in the refrigerator, cartridge(s) and inhaler should be left out at room temperature for **10 minutes** before use (Figure I).

Do not use cold cartridge(s) or inhaler until after they have been allowed to come to room temperature

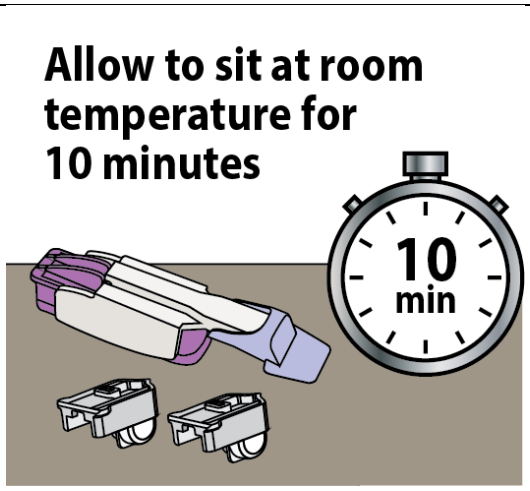


Figure I

3.3 Check that you have the correct cartridge(s) for your dose (Figure J).

Do not use cartridges if they are incorrect for your dose

Important: Opened blister strips with cartridges not needed for your dose should be stored at room temperature.

Do not put a blister strip into the refrigerator after it has been opened.

Refer to the Storage Information section for more information.

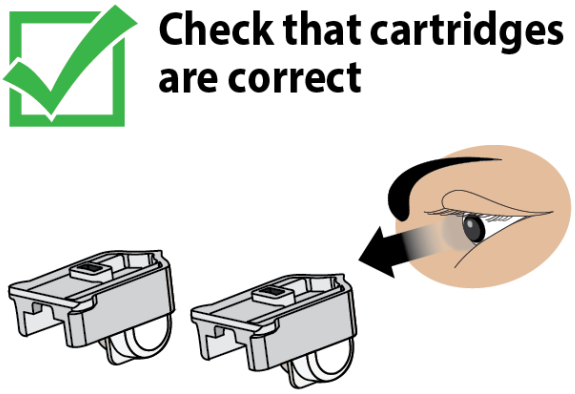


Figure J

Step 4: Load a cartridge

4.1 Open the inhaler by lifting the mouthpiece to an upright (vertical) position (Figure K).

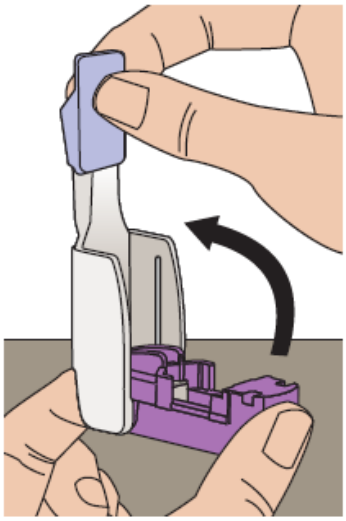


Figure K

4.2 Place Inhaler on a flat surface (Figure L)

4.3 Place Cartridge in the inhaler (Figure L)

- Hold the cartridge with the white 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 so that it sits flat.

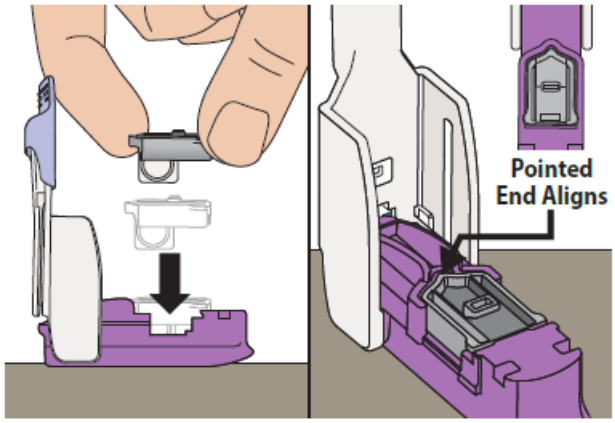


Figure L

Warning:

Keep the inhaler level until you are ready to breathe in your dose (Figure M). After you have loaded the cartridge, tilting the inhaler may spill AFREZZA powder.

If any AFREZZA powder spills from the cartridge:

- Remove and throw away the cartridge into household trash (see Step 8).
- Wash your hands right away if the powder medicine comes into contact with your hands.
- Get a new cartridge and repeat Step 4 to load it into the inhaler.

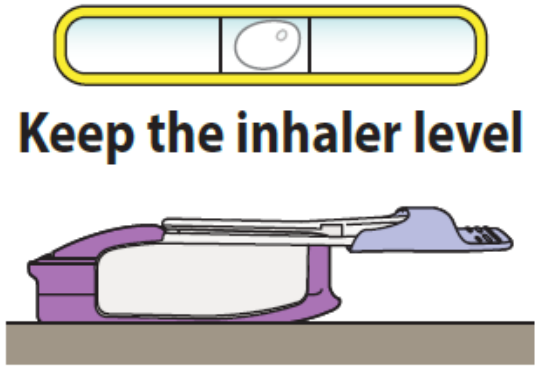


Figure M

4.4 Close the inhaler. You should feel a snap when the inhaler is closed (Figure N).

Note: Closing the inhaler automatically opens the cartridge inside. Tilting or flipping your inhaler before dosing may spill AFREZZA powder. **Keep the inhaler level** until the inhaler mouthpiece is in your mouth.

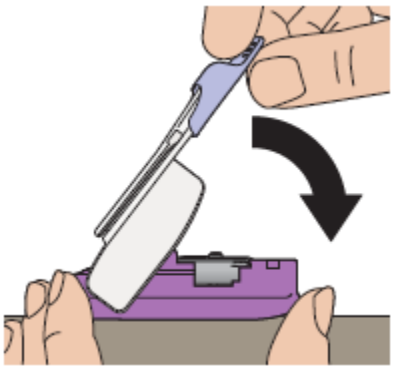


Figure N

Inhaling AFREZZA

Step 5: Remove cover and get ready

Important: Read steps 5 and 6 all the way through before attempting to inhale AFREZZA.

5.1 Pull off the mouthpiece cover (Figure O).

Important: Keep the inhaler level until the inhaler is in your mouth to avoid spilling the AFREZZA powder.

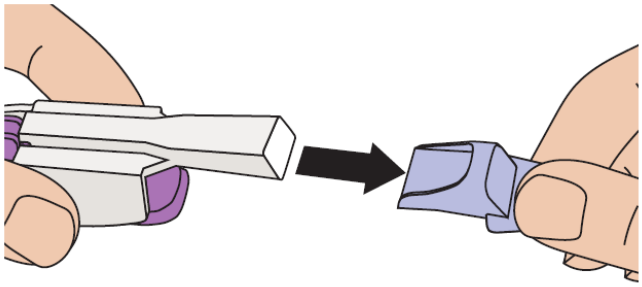


Figure O

5.2 Sit upright, looking straight with your head level (Figure P)

5.3 While keeping the inhaler level, **carefully pick up the inhaler and hold it away from your mouth** (Figure P).

Keep the inhaler level until the inhaler mouthpiece is in your mouth to avoid spilling the AFREZZA powder.

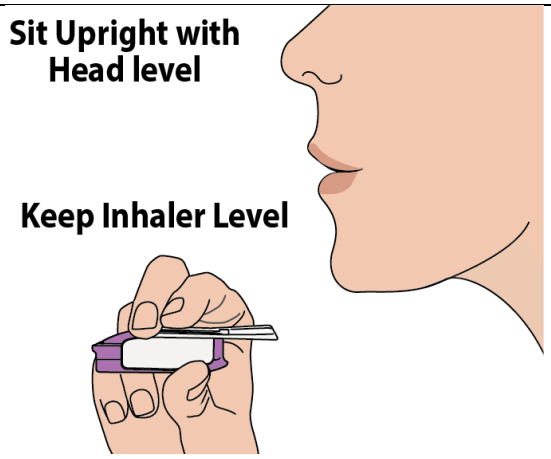


Figure P

Step 6: Inhale AFREZZA

6.1 Hold the inhaler away from your mouth or next to the side of your head and fully **breathe out (exhale)** (Figure Q).

Do not blow into the inhaler.

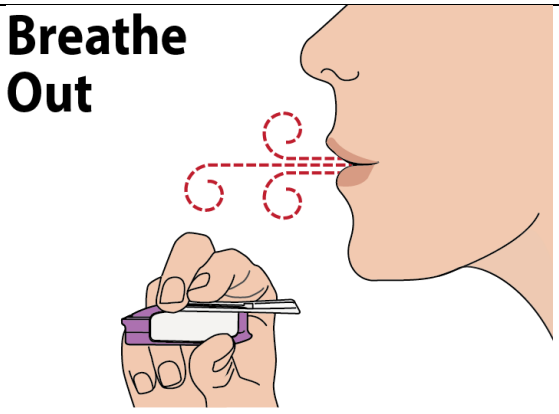
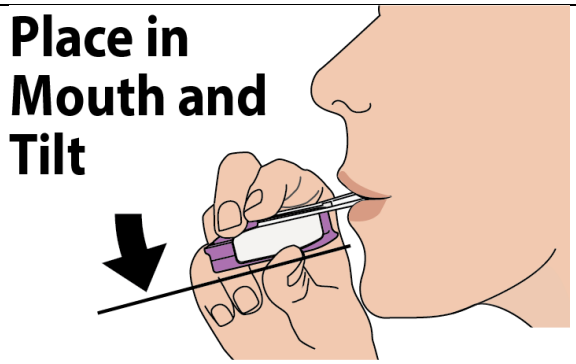
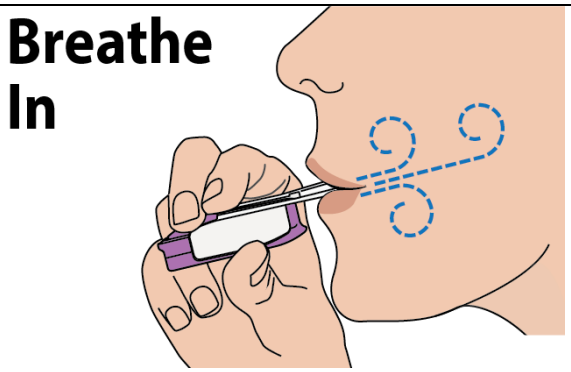
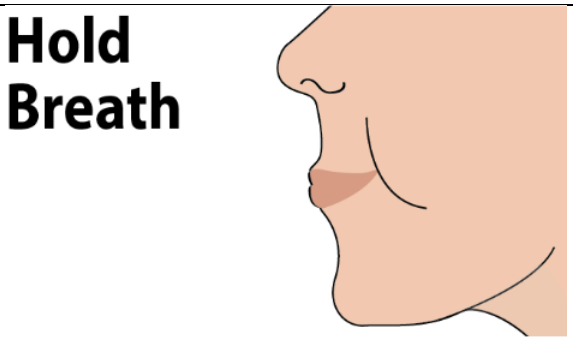
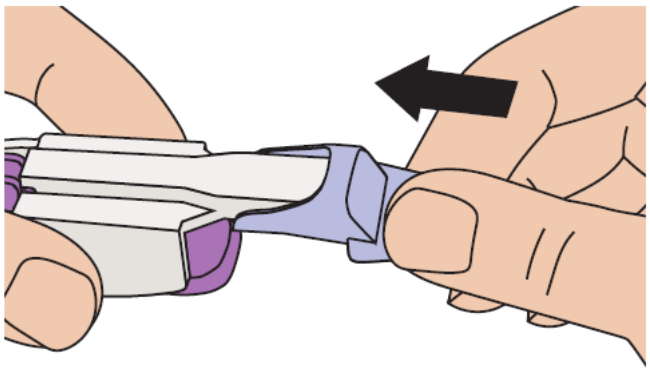
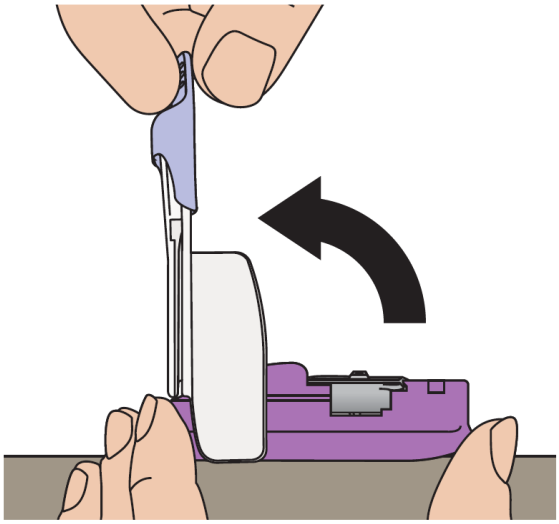


Figure Q

6.2 Place the inhaler into your mouth and close your lips around the mouthpiece (Figure R). **6.3 Tilt the inhaler slightly downward.** This helps prevent the powder from being blocked by your tongue (Figure S).	 **Figure R**
6.4 Breathe in (inhale) quickly and deeply through the mouthpiece (Figure S).	 **Figure S**
6.5 Remove the inhaler from your mouth. **Hold your breath for as long as comfortable** (Figure T). **Then breathe out normally.**	 **Figure T**

After Inhaling AFREZZA	
Step 7: Remove and throw away cartridge	
7.1 Put the mouthpiece cover back onto the inhaler (Figure U). This keeps your fingers off the exposed mouthpiece.	 **Figure U**
7.2 Open the inhaler by lifting up the mouthpiece to an upright (vertical) position (Figure V).	 **Figure V**

7.3 Remove cartridge.

- Remove the used cartridge from the purple base (Figure W).
- The white cup should now be in the middle of the used cartridge (Figure W).

If any medicine from the cartridge spills on your hands, wash your hands right away.

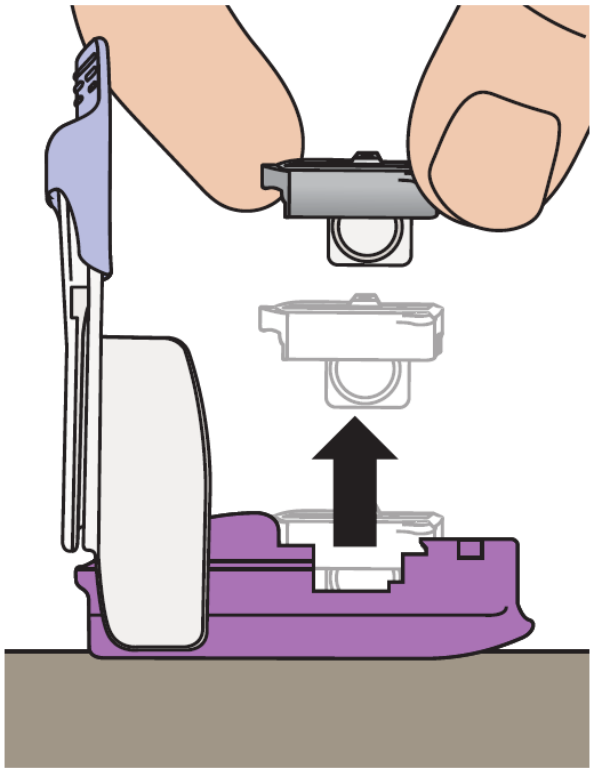


Figure W

7.4 Throw away the used cartridge in your regular household trash (Figure X).

Also, the used cartridge (composed of HDPE, assigned recycling number 2) can be recycled.

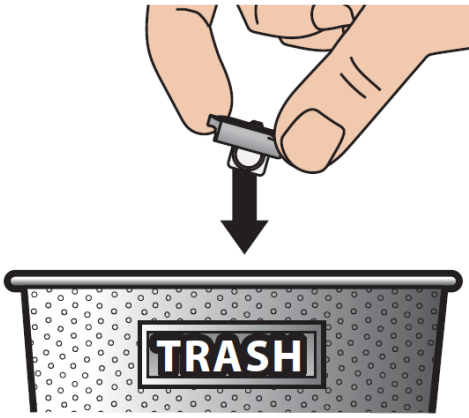


Figure X

Step 8: Dosing with more cartridges

8.1 If your dose requires you to inhale more cartridges repeat Steps 4 to 7 for each AFREZZA cartridge needed to finish your required dose (Figure Y).

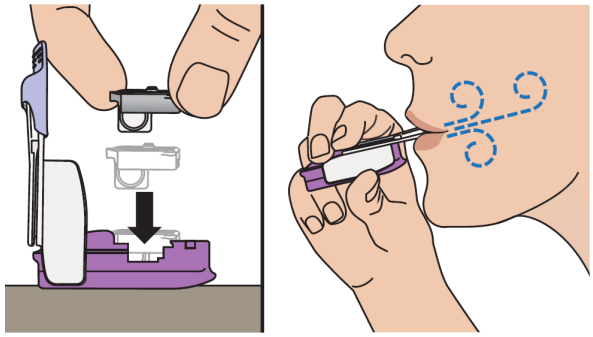


Figure Y

Warning:

Do not reuse cartridges. **Cartridges are single use and should only be used 1 time.**

Be careful not to mix new cartridges with used cartridges. The white cup moves to the middle of the cartridge when it has been used (Figure Z).

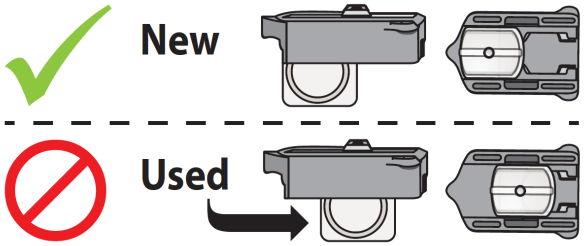


Figure Z

Caring for Your AFREZZA Inhaler

Cleaning AFREZZA Inhalers

- After taking your dose, powder residue inside the mouthpiece is normal; this will not affect your dose.
- The outside of the inhaler can be wiped with a clean, dry cloth only, if needed**.**

Do not wash the inhaler or let the inhaler get wet. **Always keep the inhaler dry.**

Storing AFREZZA Inhalers

- **Store AFREZZA Inhalers with the mouthpiece cover on, in a clean dry place at room temperature.**
- **Do not** leave or store cartridges in the inhaler.

Refer to the Storage Information section for more information.

Disposing of your AFREZZA Inhaler after 15 days.

- **Only use 1 inhaler at a time.** The same inhaler should be used to take 4 unit, 8 unit or 12 unit cartridges.
- **Replace the inhaler 15 days after first use.** Keep track of 15 days from when you start using the inhaler with a calendar (Figure AA) or use the chart on the box.
- **Throw away (dispose of) used inhaler into household trash 15 days after first use.**

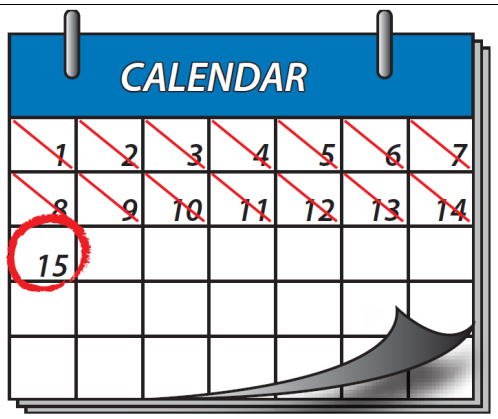


Figure AA

If you are having problems with your AFREZZA Inhaler, have an adverse event, or if your AFREZZA Inhaler breaks and you need a new one, please call 1-877-323-8505.

Manufactured by: MannKind Corporation
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This Instructions for Use has been approved by the U.S. Food and Drug Administration.
Revised: 05/2026

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