

## INSTRUCTIONS FOR USE

### INBRIJA® (in-BRIH-jah) (levodopa inhalation powder) For Oral Inhalation Only

Read and follow these instructions before you start using INBRIJA and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your healthcare provider about your medical condition or treatment.

#### Important Information about using INBRIJA

- Do not swallow INBRIJA capsules
- INBRIJA capsules should only be used with the INBRIJA inhaler and inhaled through your mouth (oral inhalation)

#### Overview:

A complete dose is 2 capsules.

You will load 1 capsule into the inhaler and breathe in (inhale). Then, you will remove the used capsule and load a second capsule into the inhaler and breathe in. Do not swallow INBRIJA capsules.

- Each carton contains 1 INBRIJA inhaler and capsules in sealed foil packages. When you open a new carton, always use the new inhaler supplied.
- Do not use capsules after the expiration date printed on the package.
- Do not load 2 capsules at the same time.
- Throw out all used capsules immediately after use.
- Throw out the inhaler after all capsules in the carton have been used.
- Make sure your hands are clean and dry when using the inhaler and capsules.

If you have any questions, ask your healthcare provider or pharmacist. If you have problems using INBRIJA, or if your INBRIJA inhaler becomes lost or damaged and you need a replacement, contact INBRIJA support at 1-800-367-5109. Then, call your healthcare provider for treatment instructions until you receive your replacement inhaler.

#### Parts of your INBRIJA Inhaler

(see [Figure A](#))

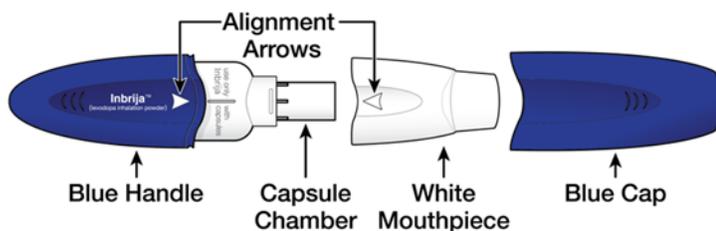


Fig. A

## Capsules

(see [Figure B](#))

Each carton includes strips of 4 capsules.



Fig. B

(see [Figure C](#))

Prepare and take a total of 2 capsules.

Take each capsule 1 at a time for a full dose.



Fig. C

(see [Figure D](#))

Full Dose = 2 Capsules

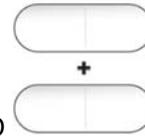


Fig. D

## Prepare Your Dose

### Step 1. Gather Supplies

Find a clean and dry surface.

Make sure your hands are clean and dry.

Get inhaler and strip of capsules.

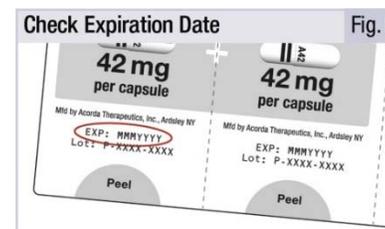
Tear off package of 2 capsules (see [Figure E](#)).



Tear Off Package Of 2 Capsules Fig. E

### Step 2. Check Expiration

Check the expiration date on the package (see [Figure F](#)).

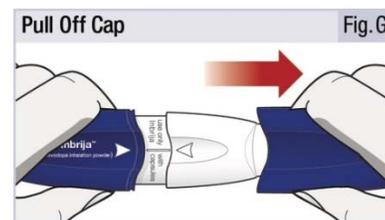


Check Expiration Date Fig. F

### Step 3. Remove Blue Cap

Pull the cap straight off (see [Figure G](#)).

Place the cap to the side. You will need it later to store the inhaler.

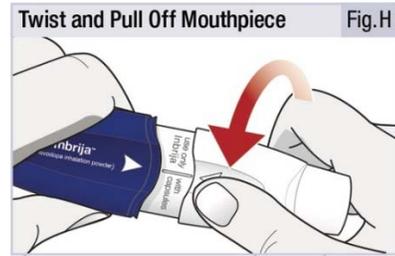


Pull Off Cap Fig. G

#### Step 4. Twist Off White Mouthpiece

Twist and pull off the mouthpiece to separate it from the handle (see [Figure H](#)).

Place the mouthpiece and inhaler on a clean and dry surface.



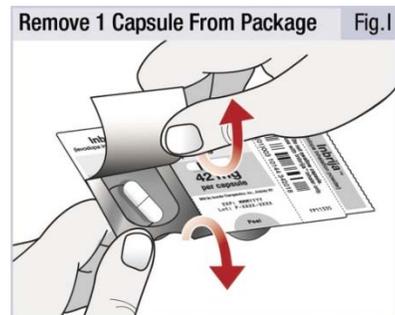
#### Step 5. Remove 1 Capsule From Package

Carefully peel back the foil and take out 1 capsule (see [Figure I](#)).

**Do not try to push the capsule through the back of the foil package.**

**Only remove 1 capsule at a time, and just before use.**

**Do not use any capsule that looks crushed, damaged or wet. Throw it away and get a new capsule.**

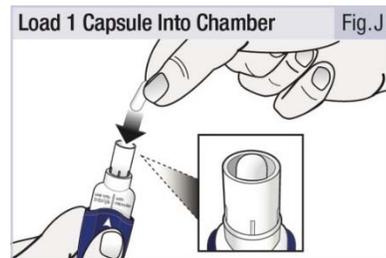


#### Step 6. Load Capsule

Hold the inhaler upright using the handle.

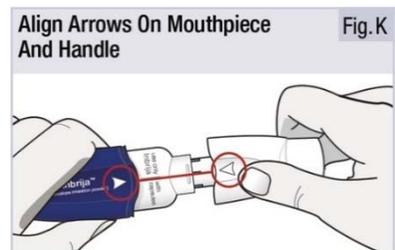
Drop 1 capsule into the opening of the capsule chamber (see [Figure J](#)).

**Do not try to load 2 capsules at the same time.**

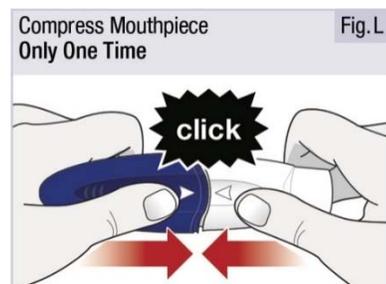


#### Step 7. Attach White Mouthpiece

Line up the white arrows on the handle and mouthpiece (see [Figure K](#)).



Firmly push the mouthpiece and handle together until you hear a click. This punctures the capsule (see [Figure L](#)).

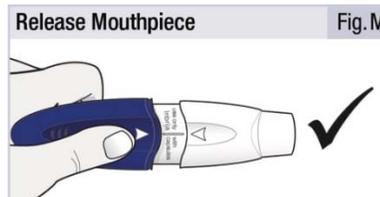


Release the mouthpiece. The mouthpiece will spring back and stay attached (see [Figure M](#)).

Your inhaler is now ready to use.

**Do not push the handle and mouthpiece together more than 1 time. This may damage the capsule, and you may not get your full dose. If this happens throw the capsule away in your household trash and start over at Step 5.**

**Make sure the mouthpiece is securely attached and will not fall off before moving to step 8.**



## Take Your Dose

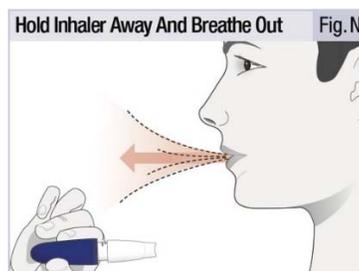
### **Step 8. Breathe Out (Exhale)**

Stand or sit with your head and chest upright.

Hold the inhaler level and away from your mouth (see [Figure N](#)).

Breathe out completely (see [Figure N](#)).

**Do not breathe into mouthpiece.**



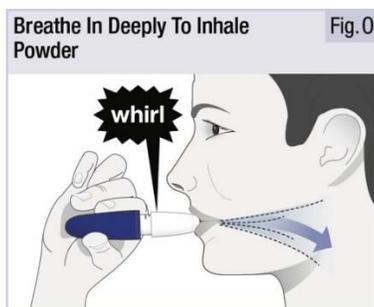
### **Step 9. Breathe In Deeply (Inhale)**

While keeping the inhaler level, close your lips firmly around the mouthpiece (see [Figure O](#)).

**Take in a deep, comfortable breath until your lungs feel full. This normally takes several seconds.**

As you breathe in, you will hear and feel the capsule “whirl” (spin). The whirl means the inhaler is working and you are getting your medicine.

If you cough or stop your dose, start again from the beginning of Step 8 using the same capsule.

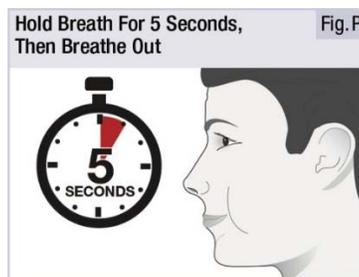


**Important: If you did not hear or feel the capsule “whirl” while inhaling you may need to take a deeper, longer breath or may need to clean the mouthpiece. Refer to Step 14 – Clean Mouthpiece. Start again from the beginning of Step 8 using the same capsule.**

### **Step 10. Hold Breath, Then Breathe Out**

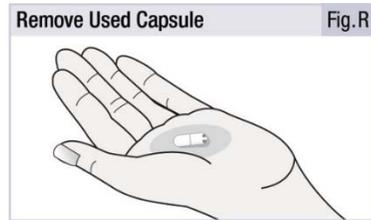
Take the inhaler out of your mouth and hold your breath for 5 seconds (see [Figure P](#)).

Then breathe out.



### Step 11. Remove Capsule From Inhaler

Twist and pull off the mouthpiece (see [Figure Q](#)) and take out the used capsule (see [Figure R](#)).



### Step 12. Dose With 2<sup>nd</sup> Capsule

Repeat Steps 5 to 11 with the second capsule to finish the full dose (see [Figure S](#)).



## Dispose and Store

### Step 13. Throw Out Used Capsules

Throw out used capsules in the household trash (see [Figure T](#)).



## Step 14. Clean Mouthpiece

It is normal for some powder to remain in or on the inhaler. To avoid powder buildup, clean the powder off of the mouthpiece holes using a circular motion with a new dry cotton swab as needed.

First, clean the holes from the top end of the mouthpiece (see [Figure U](#)).

Next, clean the holes from the bottom end of the mouthpiece (see [Figure V](#)).

You can also use a dry tissue to wipe the outside of the mouthpiece, as needed.

**Do not clean any other parts of the inhaler.**

**Do not rinse the mouthpiece or get the inhaler wet.**

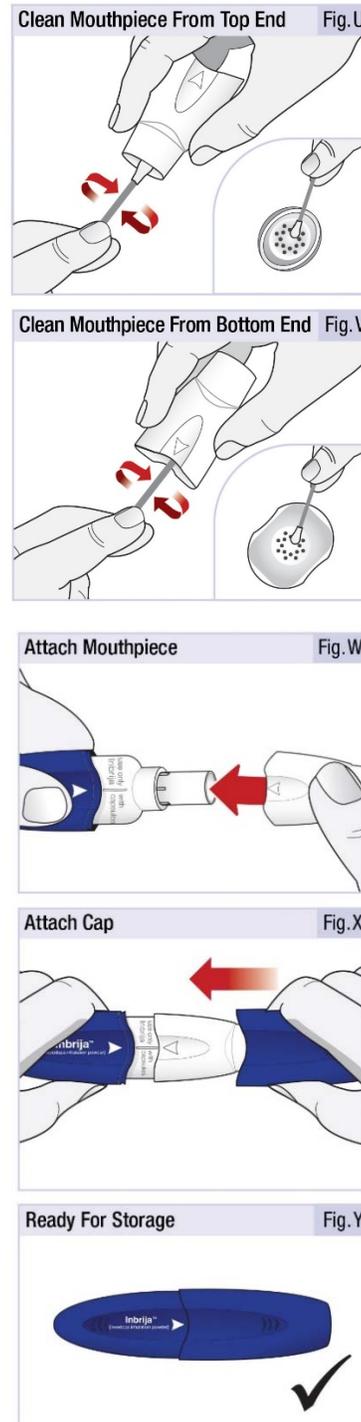
## Step 15. Store Inhaler

Make sure there are no capsules in the inhaler before you store it.

Attach the mouthpiece to the handle by pushing until you hear a click (see [Figure W](#)).

Attach the cap over the mouthpiece (see [Figure X](#)).

Your inhaler is now ready to store (see [Figure Y](#))



## **INBRIJA Storage, Cleaning and Disposal**

### Storing the Inhaler and Capsules

- Store the inhaler and capsules in a dry place at room temperature from 68°F to 77°F (20 to 25°C).
- Keep capsules inside their foil (blister) packages until just before you are ready to use them.
- **Do not store capsules in the inhaler for a future dose.**
- Keep the inhaler and capsules dry.

- Throw out the inhaler after all capsules in the carton have been used. Use the new inhaler that comes with your prescription refill.
- Keep INBRIJA and all medicines out of reach of children.

#### Cleaning the Inhaler

- It is normal for some powder to remain in or on the inhaler.
- If needed, to avoid powder buildup, you may use a dry cotton swab or a dry tissue to wipe the inside or outside of the mouthpiece.

#### Disposing of the Inhaler and Capsules

- Throw out all used capsules in your household trash.
- After all capsules in the carton have been used, throw out the inhaler and use a new carton containing a new inhaler and capsules.

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

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**Marketed by:**

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