

PATIENT INFORMATION
INBRIJA[®] (in-BRIH-jah)
(levodopa inhalation powder)
for oral inhalation use

What is INBRIJA?

INBRIJA is an inhaled prescription levodopa medicine used to treat the return of Parkinson's symptoms (known as OFF episodes) in people with Parkinson's disease who are treated with carbidopa-levodopa medicines. It does not replace the regular carbidopa-levodopa medicines.

It is not known if INBRIJA is safe or effective in children.

Do not use INBRIJA if you:

- take another medicine called a nonselective monoamine oxidase inhibitor (MAOI), such as phenelzine and tranylcypromine, or have taken a nonselective MAOI within the last 2 weeks. Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI.

Before you use INBRIJA, tell your healthcare provider about all of your medical conditions, including if you:

- have asthma, chronic obstructive pulmonary disease (COPD), or any chronic lung disease.
- have daytime sleepiness from a sleep disorder or get drowsy or sleepy without warning or take a medicine to help you sleep.
- feel dizzy, nauseated, sweaty, or faint when you stand up from sitting or lying down.
- have a history of abnormal movement (dyskinesia).
- have or have had a mental health problem such as hallucinations or psychosis.
- have urges that you are unable to control (for example, gambling, increased sexual urges, intense urges to spend money, or binge eating).
- have glaucoma.
- are pregnant or plan to become pregnant. It is not known if INBRIJA will harm your unborn baby.
- are breastfeeding or plan to breastfeed. Levodopa the medicine in INBRIJA can pass into your breastmilk. It is not known if it can harm your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Using INBRIJA and certain other medicines may affect each other and cause serious side effects.

Especially tell your healthcare provider if you take:

- MAO-B inhibitors
- dopamine D2 receptor antagonists, including phenothiazines, butyrophenones, risperidone, and metoclopramide, or isoniazid
- iron salts or multivitamins with iron salts

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist each time you get a new medicine.

How should I use INBRIJA?

- **See the step-by-step Instructions for Use** that come with your INBRIJA prescription.
- Your healthcare provider should show you the right way to use INBRIJA before you start using it.
- INBRIJA is **for oral inhalation use only**.
- **Do not** swallow INBRIJA capsules.
- **Do not** open INBRIJA capsules.
- Only use INBRIJA capsules with the INBRIJA inhaler. **Do not** use the INBRIJA inhaler to take any other medicine.
- You must be taking a daily Parkinson's disease medicine that contains carbidopa and levodopa before you start taking INBRIJA. You must not stop taking your daily Parkinson's medicine. INBRIJA does not replace your daily medicine.
- Use INBRIJA exactly as prescribed.
- The dose of INBRIJA is 2 capsules. **Do not** take more than 1 dose (2 capsules) for any OFF period.
- Take an INBRIJA dose as soon as you feel Parkinson's symptoms start to return.
- **Do not** take more than 5 doses of INBRIJA in 1 day.

What should I avoid while using INBRIJA?

- **Do not** drive, operate machinery, or do other activities until you know how INBRIJA affects you. INBRIJA can cause sleepiness and falling asleep suddenly as late as 1 year after you start treatment.

What are the possible side effects of INBRIJA?

INBRIJA can cause serious side effects including:

- **falling asleep during normal daily activities.** INBRIJA may cause you to fall asleep while you are doing normal daily activities such as driving a car, doing physical tasks, using hazardous machinery, talking with other people, or eating.
 - You could fall asleep without being drowsy or without warning. If you become drowsy while using INBRIJA, you should not drive or do activities where you need to be alert for your safety or the safety of others.
 - Your chances of falling asleep while doing normal activities while using INBRIJA are greater if you take other medicines that cause drowsiness. Tell your healthcare provider if you take medicines that can make you sleepy such as sleep medicines, antidepressants, or antipsychotics.
- **withdrawal-emergent hyperpyrexia and confusion.** INBRIJA may cause a problem that can happen in people who suddenly lower their dose, stop using, or change their dose of INBRIJA. Symptoms may include:
 - fever
 - confusion
 - stiff muscles
 - changes in breathing and heartbeat
- **low blood pressure.** People on INBRIJA may also develop low blood pressure (hypotension) that can happen without or with the following symptoms:
 - dizziness
 - fainting
 - nausea
 - sweatingGet up slowly after sitting or lying down, especially if you have been sitting or lying down for a long time. Tell your healthcare provider if you have any of these symptoms.
- **hallucinations and other psychosis.** INBRIJA can cause or worsen psychotic symptoms including:
 - hallucinations (seeing or hearing things that are not real)
 - confusion, disorientation, or disorganized thinking
 - trouble sleeping (insomnia)
 - dreaming a lot
 - being overly suspicious or feeling people want to harm you (paranoid ideation)
 - believing things that are not real (delusional beliefs)
 - acting aggressive
 - feeling agitated or restlessIf you have hallucinations or any of these changes, talk with your healthcare provider.
- **unusual urges.** Some people using medicines like INBRIJA for Parkinson's have had unusual urges such as gambling, binge eating or eating that you cannot control (compulsive), compulsive shopping and sexual urges. If you or your family members notice that you are having unusual urges, talk to your healthcare provider.
- **uncontrolled, sudden body movements (dyskinesia).** INBRIJA may cause or worsen movements you cannot control in your face, tongue, or other body parts. Tell your healthcare provider if this happens. Your treatment with INBRIJA may need to be stopped or your other medicines for Parkinson's may need to be changed.
- **bronchospasm.** People with lung disease such as asthma, COPD, or other lung diseases have a risk of wheezing or difficulty breathing (bronchospasm) after inhaling INBRIJA. If you have these symptoms, stop taking INBRIJA and call your healthcare provider or go to the nearest hospital emergency room right away.
- **increased eye pressure.** INBRIJA may cause increased intraocular pressure in people with glaucoma. Your healthcare provider should check your eyes while you are using INBRIJA.
- **changes in certain lab values.** INBRIJA may cause changes in certain lab tests, including liver tests.

The most common side effects of INBRIJA include:

- cough
- upper respiratory tract infection
- nausea
- change in the color of your saliva or spit

These are not all the possible side effects with INBRIJA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store INBRIJA?

- Store the inhaler and capsules in a dry place at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep capsules in their foil (blister) packages until just before you are ready to use them.

- **Do not store capsules inside 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 the reach of children.

General information about the safe and effective use of INBRIJA

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet. Do not use INBRIJA for a condition for which it was not prescribed. Do not give INBRIJA to other people even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about INBRIJA that is written for health professionals.

What are the ingredients in INBRIJA?

Active ingredient: levodopa

Inactive ingredients: 1,2-dipalmitoyl-sn-glycero-3-phosphocholine (DPPC), sodium chloride.

For more information, go to www.INBRIJA.com, or call 1-800-367-5109.

This Patient Information has been approved by the U.S. Food and Drug Administration

Issued: 09/2019

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](#))

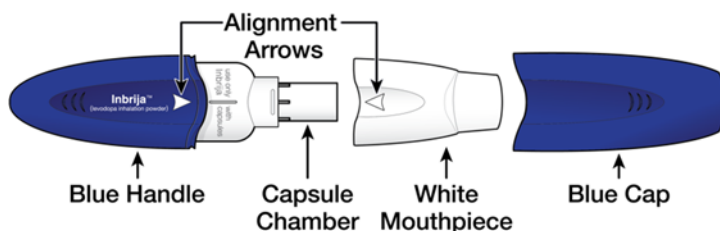


Fig. A

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

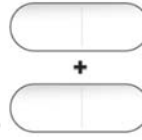


Fig. D

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.

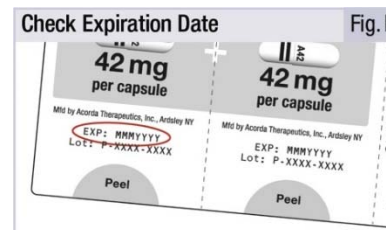
Tear off package of 2 capsules (see [Figure E](#)).



Tear Off Package of 2 Capsules Fig. E

Step 2. Check Expiration

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

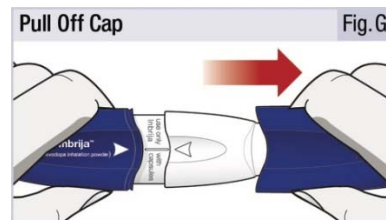


Check Expiration Date Fig. F

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.

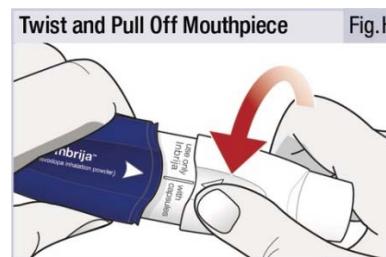


Pull Off Cap Fig. G

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.



Twist and Pull Off Mouthpiece Fig. H

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.**

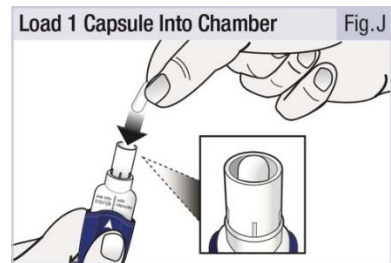


Step 6. Load Capsule

Hold the inhaler upright using the handle.

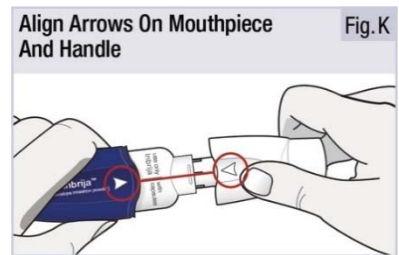
Drop 1 capsule into the opening of the capsule chamber (see [Figure J](#)).

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

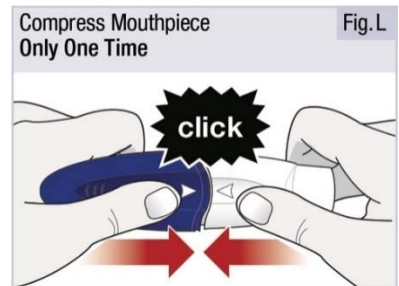


Step 7. Attach White Mouthpiece

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](#)).

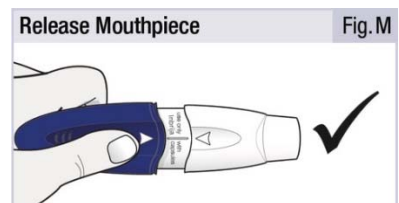


Release the mouthpiece. The mouthpiece will spring back and stay attached (see [Figure M](#)).

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

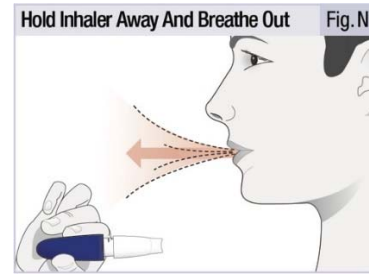
Step 8. Breathe Out (Exhale)

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.

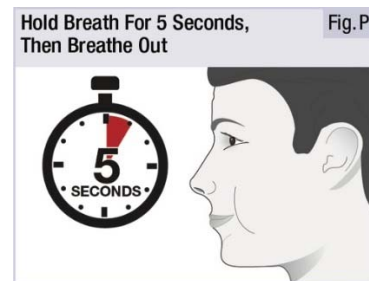


Important: If you did not hear or feel the capsule “whirl” while inhaling you may need to take a deeper, longer breath. Start again from the beginning of Step 8 using the same capsule.

Step 10. Hold Breath, Then Breathe Out

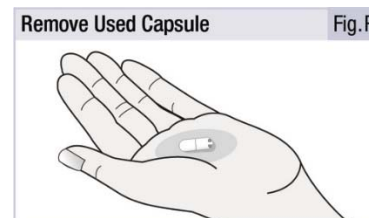
Take the inhaler out of your mouth and hold your breath for 5 seconds (see [Figure P](#)).

Then breathe out.



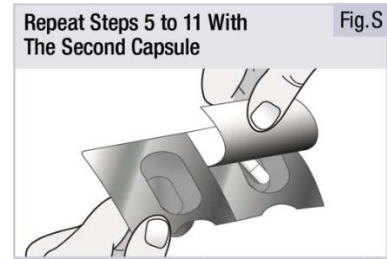
Step 11. Remove Capsule From Inhaler

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



Step 12. Dose With 2nd 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

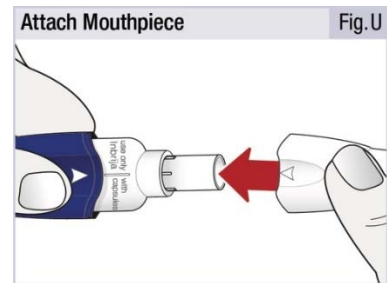
Throw out used capsules in the household trash (see [Figure T](#)).



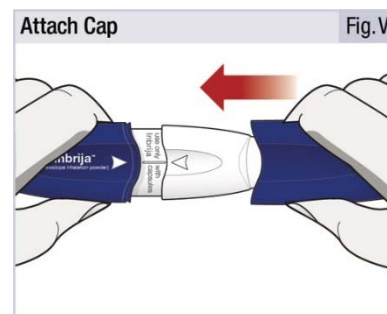
Step 14. Store Inhaler

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

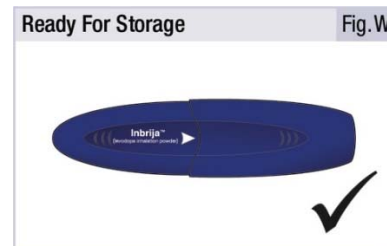
Attach the mouthpiece to the handle by pushing until you hear a click (see [Figure U](#)).



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



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



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 on the inhaler.
- While cleaning the inhaler is not necessary, 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 Rev: 09/2019

Manufactured by:

Acorda Therapeutics, Inc.
420 Saw Mill River Road
Ardsley, NY 10502 USA

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