



Package leaflet:
Information for the patient

33 mg
inhalation powder, hard capsules

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Inbrija is and what it is used for.....	2
2. What you need to know before you use Inbrija.....	2
3. How to use Inbrija.....	8
4. Possible side effects.....	10
5. How to store Inbrija.....	14
6. Contents of the pack and other information.....	14

1. What Inbrija is and what it is used for

The active substance in Inbrija is levodopa. Inbrija is a medicine used by inhalation for treating the worsening of your symptoms during the “off periods” of Parkinson’s disease.

Parkinson’s disease affects your movement and it is treated with a medicine that you take regularly. During off periods your usual medicine does not control the condition well enough and movement is likely to be more difficult.

You should continue taking your main medicine for Parkinson’s disease and use Inbrija to control worsening of symptoms (such as inability to move) during off periods.

2. What you need to know before you use Inbrija

Do not use Inbrija:

- if you are **allergic to levodopa** or any of the other ingredients of this medicine (listed in section 6).
- if you get blurred vision, red eyes, severe eye and head pain, halos around lights, pupils of your eyes that are larger than normal size and feel sick. If you have any of these symptoms, you may have a eye condition called **narrow angle glaucoma**, which occurs suddenly: **do not** take Inbrija and **get urgent medical attention**.
- if you have a **rare tumour of the adrenal gland** called phaeochromocytoma.

2. What you need to know before you use Inbrija

- if you are taking certain **antidepressant medicines called non-selective MAO inhibitors** (e.g. isocarboxazid and phenelzine). You must stop taking these medicines at least 14 days before starting treatment with Inbrija. See also under "Other medicines and Inbrija".
- if you have previously suffered from **neuroleptic malignant syndrome**, a life-threatening reaction to certain medicines used to treat severe mental disorders or if you have suffered from **non-traumatic rhabdomyolysis**, a rare muscle disorder in which damaged muscle breaks down rapidly.

2. What you need to know before you use Inbrija

Warnings and precautions

Get urgent medical help if you have tremors, agitation, confusion, fever, rapid pulse, or dizziness and fainting upon standing up, or you notice that your muscles get very rigid or jerk violently. These may be symptoms of "withdrawal-emergent hyperpyrexia". For more information see section 4.

Talk to your doctor or pharmacist before using Inbrija if you have, or have ever had, or you develop:

- asthma, breathing difficulties like chronic obstructive pulmonary disease (COPD) or other long-term lung diseases or breathing problems;

2. What you need to know before you use Inbrija

- any form of severe mental disorder like psychosis;
- a heart attack, or heart beat problems. Your doctor will monitor you closely during start of treatment;
- an ulcer in your stomach or intestines;
- an eye condition called glaucoma, because the pressure in your eyes may need to be monitored;
- severe problems with your kidneys;
- severe problems with your liver.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Inbrija.

2. What you need to know before you use Inbrija

Talk to your doctor or pharmacist if you develop any of the symptoms below whilst using Inbrija:

- **sudden sleep attacks** or sometimes feeling very sleepy;
- **changes in or worsening of your mental state**, which may be severe such as psychotic and suicidal behaviour;
- **hallucinations**, along with being confused, unable to sleep and excessive dreaming. Abnormal thinking including anxiety, depression, being agitated, being paranoid, delusional, or disorientated, aggressive behaviour and delirious;

2. What you need to know before you use Inbrija

- worsening of any **breathing symptoms** or having a **respiratory infection**;
- **urges or cravings** to behave in ways that are unusual for you or you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These behaviours are called impulse control disorders and can include addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings. **Your doctor may need to review your treatments.**;
- new or increased **abnormal body movements** (dyskinesia);

2. What you need to know before you use Inbrija

- **feeling dizzy when getting up** (low blood pressure);
- **melanoma** (a type of skin cancer) or suspicious skin growths or marks.

If you need to have surgery, tell your doctor that you are using Inbrija.

Tests

You may need to have tests on your heart, liver, kidney, and blood cell tests during long-term treatment with your medicines. If you need to have tests on your blood or urine, tell your doctor or nurse that you are taking Inbrija. This is because the medicine may affect the results of some tests.

2. What you need to know before you use Inbrija

Children and adolescents

The use of Inbrija is not recommended in patients under 18 years of age.

Other medicines and Inbrija

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because other medicines can affect the way Inbrija works.

Do not use Inbrija if you have taken medicines called non-selective MAO inhibitors for treating depression in the last 14 days. These medicines include isocarboxazid and phenelzine. If this applies to you, do not take Inbrija and ask your doctor or pharmacist for advice.

2. What you need to know before you use Inbrija

Tell your doctor or pharmacist if you are taking:

- medicines for your Parkinson's disease called selective MAO inhibitors such as rasagiline, selegiline and safinamide, COMT inhibitors such as entacapone, tolcapone and opicapone, or anticholinergics such as orphenadrine and trihexyphenidyl;
- medicines for mental conditions including schizophrenia, such as benperidol, haloperidol, risperidone, chlorpromazine, fluphenazine decanoate, phenothiazine, butyrophenone, or trifluoperazine;
- metoclopramide to treat nausea;
- isoniazid, an antibiotic to treat tuberculosis;

2. What you need to know before you use Inbrija

- medicines for high blood pressure, as the dose may need to be adjusted;
- medicines for depression called tricyclic antidepressants such as clomipramin, desipramin, or doxepin;
- amantadine to treat flu or your Parkinson's disease.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Treatment with Inbrija is not recommended during pregnancy and in women of childbearing age who do not use contraception.

2. What you need to know before you use Inbrija

Women should not breast-feed during treatment with Inbrija.

Driving and using machines

Inbrija can cause **excessive drowsiness, dizziness and sudden sleep attacks**. If this happens to you, do not drive or use tools or machines. You must be sure that you do not get sudden sleep attacks, dizziness and drowsiness before you drive again or use machines. You could put yourself or others at risk of serious injury or death.

3. How to use Inbrija

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Before starting Inbrija, you must be taking regular treatment for Parkinson's disease combining a so-called dopa-decarboxylase inhibitor with levodopa.

The recommended dose of Inbrija is **2 capsules** to treat each off period. Do not use more than 2 capsules for each off period.

You can use 2 capsules up to five times a day.

3. How to use Inbrija

The maximum dose of Inbrija is 10 capsules per day.

Important information before you use Inbrija:

- **Inbrija capsules must not be swallowed.**
- This medicine is for **use by inhalation only**.
- The capsules must only be removed from the blister pack immediately before use.
- Two capsules of medicine should be inhaled to get the full dose.
- The medicine must be used only with the Inbrija inhaler device.

3. How to use Inbrija

- When you open a new carton, always use the new inhaler supplied.
- Your doctor or pharmacist will show you how to use your medicine correctly.

Please see the “**Instructions for use**” at the end of this leaflet on how to use your medicine with the provided inhaler.

If you use more Inbrija than you should

If you use more Inbrija than you should (or someone accidentally swallows Inbrija) **get medical help immediately**. You may feel confused or agitated, and your heart rate may be slower or faster than normal.

3. How to use Inbrija

If you forget to use Inbrija

Use Inbrija only during an off period. If the off period has passed, do not use Inbrija until the next off period.

If you stop using Inbrija

Do not stop using Inbrija without checking with your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Get urgent medical help if you have an allergic oedema with symptoms including hives (nettle rash), itching, rash, swelling of your face, lips, tongue, or throat. This may cause difficulties in breathing or swallowing.

Get urgent medical help if your muscles get very rigid or jerk violently, you get tremors, agitation, confusion, fever, rapid pulse, or wide fluctuations in your blood pressure. These can be symptoms of neuroleptic malignant syndrome (NMS, a rare severe reaction to medicines used to treat disorders of the central nervous system) or rhabdomyolysis (a rare severe muscle disorder).

4. Possible side effects

Get urgent medical help if you have bleeding in your stomach or intestines which may be seen as blood in your faeces or darkened faeces.

The following side effects may happen with this medicine:
Very common (may affect more than 1 in 10 people):

- cough

Common (may affect up to 1 in 10 people):

- new or increased abnormal body movements (dyskinesia);
- infections of nose, sinuses, throat or lungs;
- change in colour of your mucus;

4. Possible side effects

- discoloured (i.e. not clear) nasal mucus;
- irritation in throat or itchy throat;
- feeling sick (nausea); vomiting;
- being prone to falls.

Other side effects you may experience of which the frequency is not known include:

- sensation of choking associated with the drug powder impacting the back of the throat, immediately after use;
- skin cancer;
- lack of red blood cells so you are pale and feel tired; being more prone to infections because of a lack of white blood cells; lack of blood platelets which can lead to bruising and a tendency to bleed;

4. Possible side effects

- decreased appetite;
- confusion; hallucinations; depression; anxiety; bad dreams; unable to sleep; abnormal thinking and perceptions, losing touch with reality; feeling agitated; suicidal; being disorientated; exaggerated feeling of happiness; increased sex drive; grinding of teeth; feeling paranoid and delusional;
- movement disorder in which a person's muscles contract uncontrollably; sudden, sometimes unpredictable changes in symptoms, due to the return of Parkinson's disease symptoms; sleepiness; dizziness; worsening of Parkinson's disease; pins and needles; headache; tremors; seizure; sudden onset of sleep; restless legs syndrome; ataxia (disorder affecting co-ordination, balance and speech); distorted sense of taste; mental health disorders that affecting learning, memory, perception, and problem solving; Horner's syndrome (an eye disorder); dementia;

4. Possible side effects

- blurred vision; double vision; widening pupil; prolonged rolling eyes upwards; involuntary tight closure of the eyelids;
- heart problems, a noticeably rapid, strong, or irregular heartbeat;
- low blood pressure soon after standing up; high blood pressure; fainting; blood clot in a vein; hot flushes;
- shortness of breath; difficulty in breathing; difficulty in speaking; hiccups;
- stomach pains; constipation; diarrhoea; dry mouth; stomach and intestinal bleeding; stomach ulcer; difficulty in swallowing; indigestion; burning sensation in the mouth; passing wind; change in colour of saliva; more saliva than normal;

4. Possible side effects

- swelling of face, lips, tongue, limbs and genitals; excessive sweating; rash; severe itching of the skin; condition called Henoch-Schoenlein purpura, the symptoms of which include a purple spotted skin rash; allergic reaction causing a rash of round, red welts on the skin that itch intensely; hair loss; discoloured sweat;
- muscle spasms; lockjaw;
- difficulty in emptying the bladder; abnormal urine colour; loss of bladder control;
- painful, abnormally long-lasting erection;
- swelling of lower legs or hands; feeling weak and having no energy; feeling tired; lack of energy; difficulty in walking; chest pain;
- abnormal blood investigation results; weight loss; weight gain.

4. Possible side effects

You may experience the following side effects:

- inability to resist the impulse to perform an action that could be harmful, which may include:
 - strong impulse to gamble excessively despite serious personal or family consequences;
 - altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive;
 - uncontrollable excessive shopping or spending;
 - binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger).

4. Possible side effects

Tell your doctor if you experience any of these behaviours; they will discuss ways of managing or reducing the symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Inbrija

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blisters and carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Store in the original package in order to protect from light and moisture and only remove immediately before use.

Do not use any capsule that looks crushed, damaged or wet.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Inbrija contains

- The active substance is levodopa. Each hard capsule contains 42 mg levodopa. The dose that leaves the mouthpiece of the inhaler (delivered dose) is 33 mg of levodopa.
- The other ingredients comprising the powder and capsule are colfosceril palmitate (DPPC), sodium chloride, hypromellose, titanium dioxide (E 171), carrageenan, potassium chloride, carnauba wax, maize starch, shellac, black iron oxide (E 172), propylene glycol and potassium hydroxide.

6. Contents of the pack and other information

What Inbrija looks like and contents of the pack

Inbrija inhalation powder, hard capsules consist of a white powder for inhalation filled into white opaque hard capsules with "A42" printed in black on the cap of the capsule and two black bands printed on the body of the capsule.

In this pack, you will find an inhaler together with peel-off blisters containing 4 hard capsules each.

The pack sizes are:

- a carton containing 16 hard capsules (4 blister strips) and one inhaler
- a carton containing 32 hard capsules (8 blister strips) and one inhaler

6. Contents of the pack and other information

- a carton containing 60 hard capsules (15 blister strips) and one inhaler
- a carton containing 92 hard capsules (23 blister strips) and one inhaler

Not all pack sizes may be marketed.

6. Contents of the pack and other information

Marketing Authorisation Holder

Acorda Therapeutics Ireland Limited
10 Earlsfort Terrace
Dublin 2, D02 T380
Ireland
Tel: +353 (0)1 231 4609

Manufacturer

ADOH B.V.
Godfried Bomansstraat 31
6543 JA Nijmegen
Netherlands

This leaflet was last revised in December 2024.

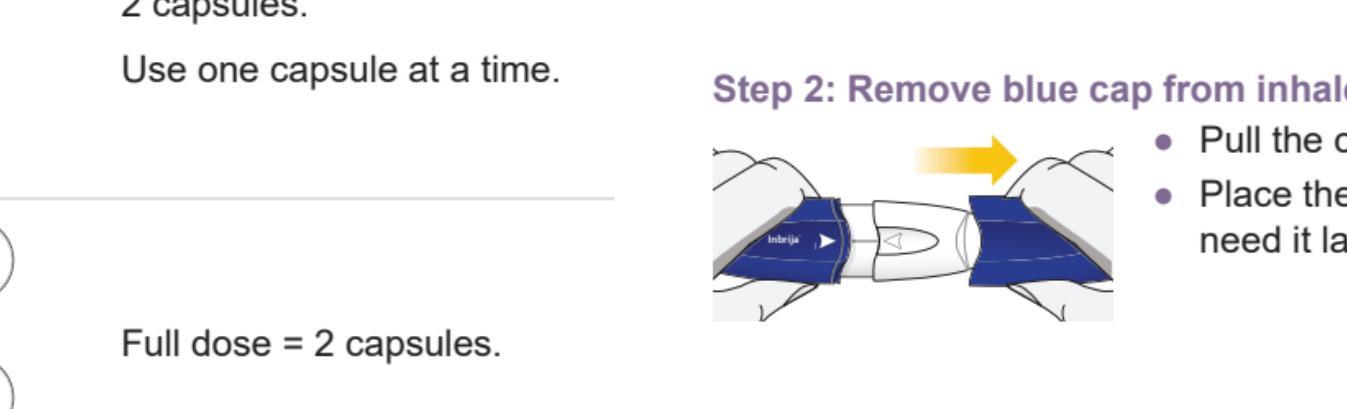
Instructions for use:

Read these instructions before you start using Inbrija.

Overview

- Make sure your hands are clean and dry when using the inhaler and capsules.
- Only remove the capsules from the blister immediately before use.
- A complete dose is 2 capsules used one after the other.
- Load 1 capsule into the Inbrija inhaler, close your lips firmly around the mouthpiece, then breathe in (inhale) and hold that breath for 5 seconds. You should hear the capsule "whirl". Then, remove the used capsule and load a second capsule into the inhaler. Close your lips firmly around the mouthpiece and breathe in, again holding your breath for 5 seconds.

Parts of your Inbrija inhaler



Blue Handle Alignment Arrows Capsule Chamber White Mouthpiece Blue Cap

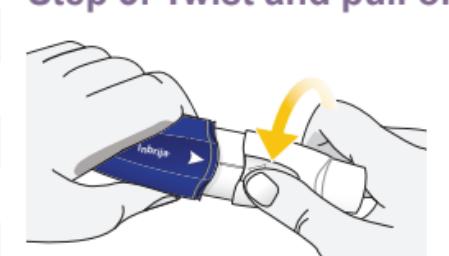
Instructions for use:

- You should inhale the contents of the second capsule within 10 minutes of the first one.
- Do not load 2 capsules at the same time.
- Dispose of all used capsules immediately after use.
- Dispose of the inhaler after you are finished all of the capsules in the carton.

Each carton includes blisters of 4 capsules.

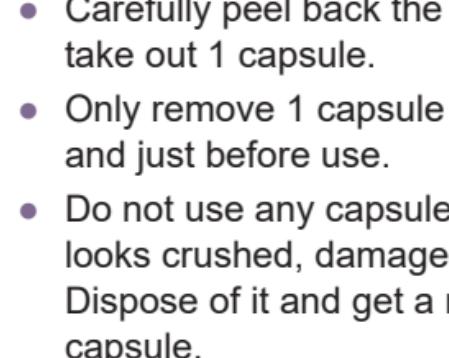
Capsules

Step 1: Gather supplies



- Hold the inhaler upright using the handle.
- Find a clean and dry surface.
- Make sure your hands are clean and dry.
- Release the mouthpiece and handle together until you hear a click. This punctures the capsule.
- Do not push the handle and mouthpiece together more than once.
- Get inhaler and strip of capsules.
- Do not load 2 capsules at the same time.
- Tear off package of 2 capsules.

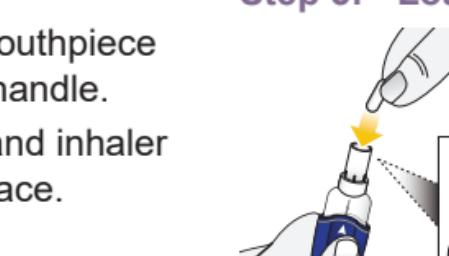
Step 2: Remove blue cap from inhaler



- Release the mouthpiece.
- Pull the cap straight off.
- Line up the white arrows on the handle and mouthpiece.

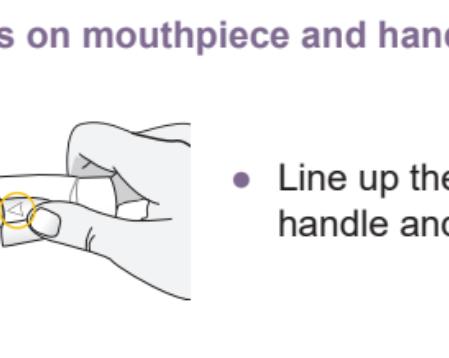
Full dose = 2 capsules.

Step 3: Twist and pull off white mouthpiece



- Twist and pull off the mouthpiece to separate it from the handle.
- Release the mouthpiece and handle together until you hear a click. This punctures the capsule.
- Do not push the handle and mouthpiece together more than once.

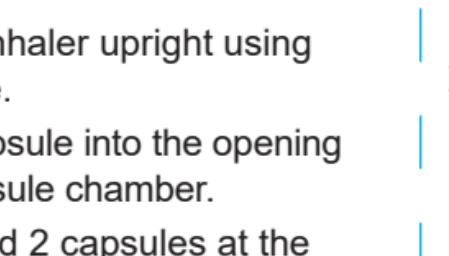
Step 4: Remove 1 capsule from package



Prepare and use a total of 2 capsules.

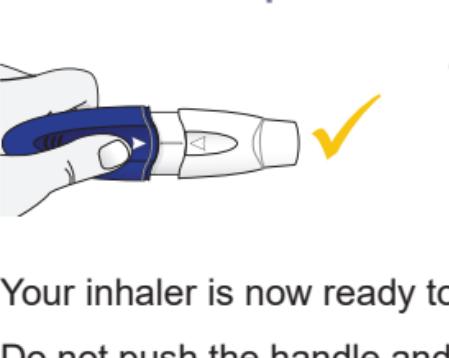
A full dose is 2 capsules.

Step 5: Load capsule



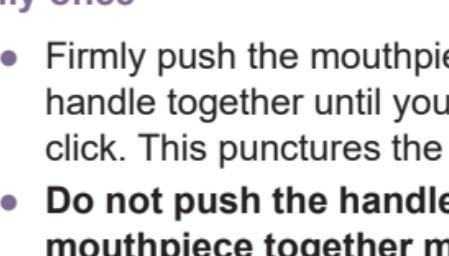
- Hold the inhaler upright using the handle.
- Find a clean and dry surface.
- Release the mouthpiece and handle together until you hear a click. This punctures the capsule.
- Do not push the handle and mouthpiece together more than once.
- Get inhaler and strip of capsules.
- Do not load 2 capsules at the same time.
- Tear off package of 2 capsules.

Step 6: Attach white mouthpiece



- Release the mouthpiece.
- Align arrows on mouthpiece and handle.
- Line up the white arrows on the handle and mouthpiece.

Step 7: Hold inhaler away and breathe out



- Stand it upright.
- Hold the inhaler level away from your mouth.
- Breathe out completely.
- Do not breathe into mouthpiece.

Your inhaler is now ready to use.

Do not push the handle and mouthpiece together more than once. This may damage the capsule, and you may not get your full dose if this happens starting at Step 4 using a new capsule.

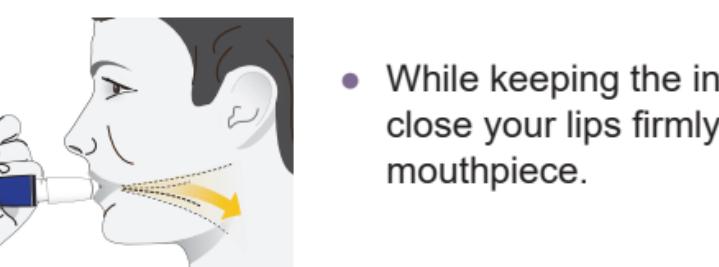
1

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Step 8: Breathe in deeply to inhale powder



- While keeping the inhaler level, close your lips firmly around the mouthpiece.

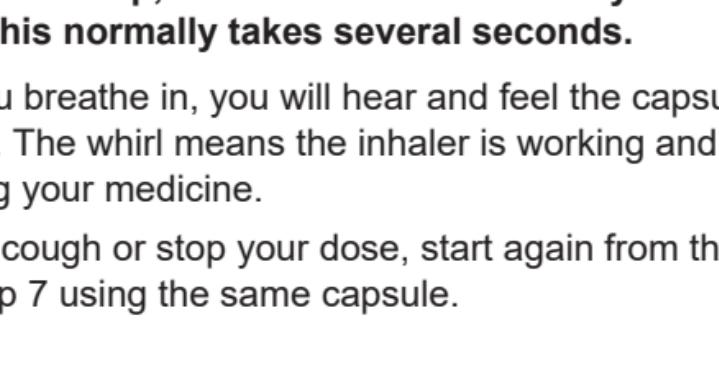
Take in a deep, comfortable breath until your lungs feel full. This normally takes several seconds.

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 7 using the same capsule.

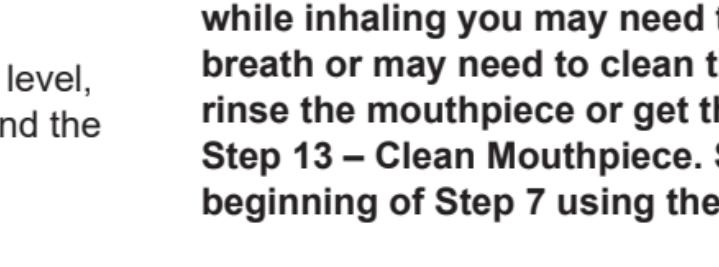
Important: If you did not hear or feel the capsule "whirl" while inhaling you may need to take a deeper, longer breath or may need to clean the mouthpiece (Do not rinse the mouthpiece or get the inhaler wet). Refer to Step 13 – Clean Mouthpiece. Start again from the beginning of Step 7 using the same capsule.

Step 9: Hold breath for 5 seconds, then breathe out



- Take the inhaler out of your mouth and hold your breath for 5 seconds.
- Then breathe out.

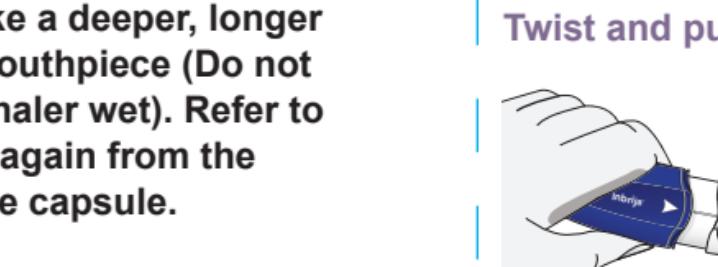
Step 10: Remove capsule from inhaler



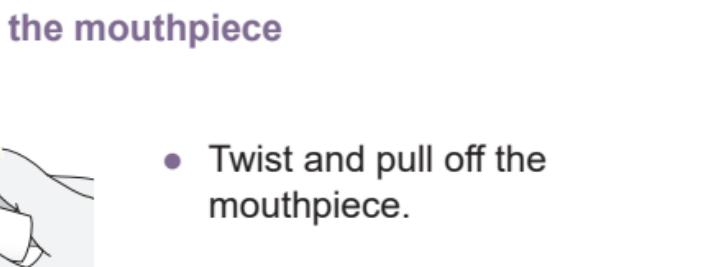
Twist and pull off the mouthpiece

- Repeat Steps 4 to 10 with the second capsule to finish the full dose.
- Do not clean any other parts of the inhaler.**
- Do not rinse the mouthpiece or get the inhaler wet.**
- You should inhale the contents of the second capsule within 10 minutes of the first one.**

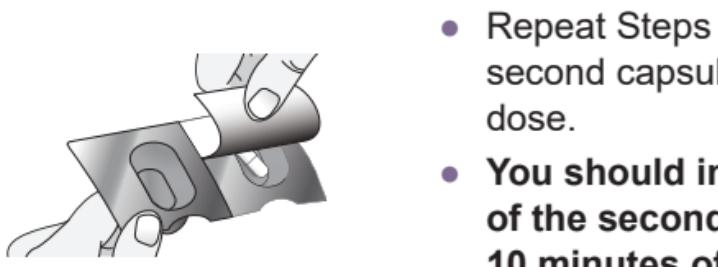
Step 11: Dose with 2nd capsule



Step 12: Dispose of used capsules



Step 13: Clean Mouthpiece

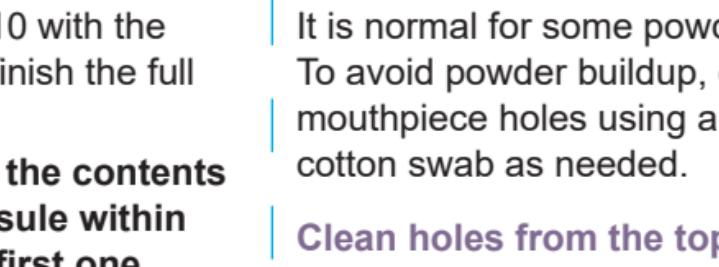


Cleaning the inhaler

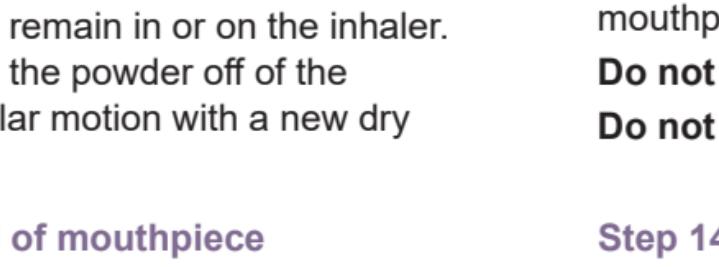
- It is normal for some powder to remain in the inhaler.
- To avoid powder buildup, clean the powder off the mouthpiece holes using a circular motion with a new dry cotton swab as needed.
- You can also use a dry tissue to wipe the inside or outside of the inhaler mouthpiece.
- Do not clean any other parts of the inhaler.**
- Do not rinse the mouthpiece or get the inhaler wet.**
- Dispose of used capsules in accordance with local requirements.**
- Your inhaler is now ready to store.**

Step 14: Store inhaler

Make sure there are no capsules in the inhaler



Step 15: Ready for storage



5

6

7

8

Measurement details Booklet + User part

Booklet 193,675 x 82,55 mm (margins 6,35 mm)

User part 723,9 x 82,55 mm (margins 12,7 mm)

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