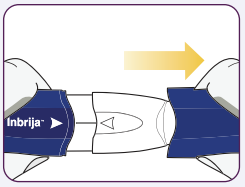
INBRIJA® (levodopa inhalation powder).

RAPID, RELIABLE, ANYTIME, ANYWHERE.[1-5]

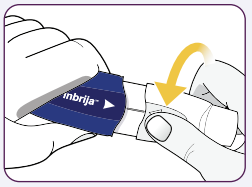
INBRIJA® is an on-demand medication that uses levodopa powder to help manage the return of Parkinson's symptoms during OFF-Episodes. Patients can use INBRIJA capsules with the inhaler when needed, for rapid and reliable relief.[1-5]

Remember to demonstrate these steps with your patients when prescribing INBRIJA®.

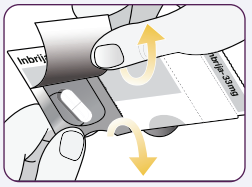
How to Prepare INBRIJA®



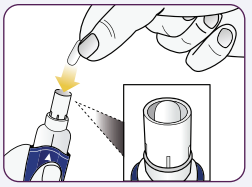
1 Pull off the blue cap



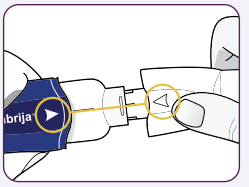
2 **TWIST** and pull to remove the white mouth-piece



3 Take one capsule out the foil packet



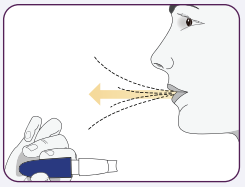
4 **LOAD** one capsule into the upright inhaler



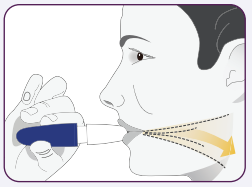
5 Reattach the mouthpiece firmly until there's a **CLICK**

Remember TWIST, LOAD, CLICK

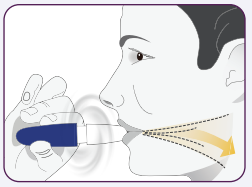
How to Inhale INBRIJA®



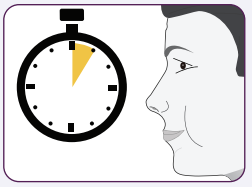
6 **BREATHE OUT** fully away from the inhaler



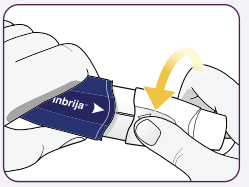
7 Close mouth around the mouthpiece and **BREATHE IN** slowly



8 Hear the **WHIRL**



9 Hold breath for 5 seconds and then breathe out



10 Remove the used capsule and throw it away

Remember BREATH OUT, BREATH IN, hear the WHIRL

2x **Repeat these steps with the second capsule** to get the full dose of the medication

INBRIJA® is indicated for intermittent treatment of OFF episodes in patients with Parkinson's disease (PD) treated with carbidopa/levodopa.

Inbrija® (levodopa inhalation powder)

Learn more

Clean & Store

1. Remove white mouthpiece
2. **CLEAN** holes inside with a dry cotton swab
3. Wipe the outer surface with a dry tissue
4. Place mouthpiece back onto the inhaler
5. Align white arrows together and push
6. **STORE** in a dry place away from children

Important information

Do's

- Always take TWO capsules per OFF-episode
- Always load one capsule at a time
- Only use INBRIJA® capsules with the inhaler
- Always check expiration dates and use a new capsule undamaged each time
- Always keep inhaler and capsules clean and dry

Don'ts

- Do not take more than 10 capsules a day
- Do not load two capsules at the same time
- Do not swallow INBRIJA® capsules or use without inhaler
- Do not use capsules past expiration date, preload capsules in advance and/or use if damaged
- Do not get inhaler or capsules wet or dirty

Date of preparation: June 2025 M-INB-HQ-0017

References: 1. LeWitt PA, Hauser RA, Pahwa R, et al; SPAN-PD Study Investigators. Safety and efficacy of CVT-301 (levodopa inhalation powder) on motor function during off periods in patients with Parkinson's disease: a randomised, double-blind, placebo-controlled phase 3 trial. Lancet Neurol. 2019;18:145-154. 2. Luinstra M, Rutgers W, van Laar T, et al. Pharmacokinetics and tolerability of inhaled levodopa from a new dry-powder inhaler in patients with Parkinson's disease. Ther Adv Chronic Dis. 2019;10: 2040622319857617. 3. Safirstein BE, Ellenbogen A, Zhao P, Henney HR 3rd, Kegler-Ebo DM, Oh C. Pharmacokinetics of inhaled levodopa administered with oral carbidopa in the fed state in patients with Parkinson's disease. Clin Ther. 2020;42:1034-1046. 4. Cohen R, Zhao P, Marini R, Blank B, Grosset DG. Subgroup analyses of effect of treatment with levodopa inhalation powder (CVT-301) 84 mg by severity of OFF symptoms in people with Parkinson's Disease, as assessed by the Unified Parkinson's Disease Rating Scale Part III (UPDRS-III). Presented at the American Academy of Neurology Annual Meeting; April 22-27, 2023; Boston MA, USA and virtual. Poster #P13-11-012.Clin Ther. 2020;42:1034-1046. 5. Isaacson SH, Zhao P, Blank B. SPAN-PD: subgroup analyses by baseline characteristics of patients treated with levodopa inhalation powder 84 mg or placebo to treat OFF symptoms in patients with Parkinson's disease. Presented at the 4th Pan American Parkinson's Disease and Movement Disorders Congress; May 22-28, 2022; Miami, FL, USA. Poster #112.

Inbrija 33 mg inhalation powder, hard capsules (levodopa) Indication: Intermittent treatment of episodic motor fluctuations (OFF episodes) in adult patients with Parkinson's disease (PD) treated with a levodopa/dopa-decarboxylase inhibitor. **Dosage:** Patients should be on a stable levodopa/dopa-decarboxylase inhibitor regimen before starting Inbrija. Patients selected for treatment with Inbrija should be able to recognize the onset of their ‚OFF' symptoms and be capable of preparing the inhaler or else have a responsible care giver able to prepare the inhaler for them when required. Inbrija should be inhaled when symptoms, motor or non-motor, of an OFF period start to return. The recommended dose of Inbrija is 2 hard capsules up to 5 times per day each delivering 33 mg levodopa. The maximum daily dose of Inbrija should not exceed 10 capsules. It is not recommended to take more than 2 capsules per OFF period. Abrupt dose reduction or withdrawal of any levodopa medicinal product should be carefully observed, particularly in patients who are also receiving neuroleptics. It is recommended to administer Inbrija cautiously to patients with severe renal disease or severe hepatic impairment. The safety and efficacy of Inbrija in children under 18 years of age have not been established. **Method of administration:** For inhalation use only. Inbrija hard capsules must not be swallowed. The Inbrija inhaler is to be thrown away after all the capsules have been used. The capsules must only be removed from the blister immediately before use. The physician or other healthcare professional should instruct the patient how to administer the product correctly. Detailed instructions for use for the patients are included in the package leaflet. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Narrow-angle glaucoma. Phaeochromocytoma. Co-administration with non-selective monoamine oxidase (MAO) inhibitors. These inhibitors should already be discontinued for at least two weeks prior to initiating therapy due to the established underlying levodopa therapy. A previous history of neuroleptic malignant syndrome (NMS) and/or non-traumatic rhabdomyolysis. **Warnings and precautions for use:** Because of the risk of bronchospasm, use of levodopa inhalation powder in patients with asthma, chronic obstructive pulmonary disease (COPD), or other chronic underlying lung disease is not recommended. Levodopa has been associated with somnolence and episodes of sudden sleep onset. Patients must be informed of this and advised to exercise caution while driving or operating machines during treatment. Abrupt dose reduction or withdrawal of any levodopa medicinal product should be carefully observed, particularly in patients who are also receiving neuroleptics. Patients with a major psychotic disorder or a history of psychotic disorder must be treated cautiously with a levodopa/dopa-decarboxylase inhibitor because of the risk of exacerbating psychosis. In addition, concomitant use of antipsychotics should be monitored carefully for worsening of Parkinson's motor symptoms especially when D2-receptor antagonists are used. Patients should be regularly monitored for the development of impulse control disorders. Inbrija may cause dyskinesia. Adjustment of levodopa therapy or other medicinal products used for the treatment of Parkinson's disease may be considered. Inbrija should be administered with caution in patients with severe cardiovascular disease. Levodopa should be administered cautiously to patients with a history of peptic ulcer disease. Patients with chronic glaucoma may be treated cautiously with levodopa provided the intraocular pressure is well-controlled and the patient is monitored carefully for changes in intraocular pressure during therapy. Periodic skin examinations are recommended to monitor for melanoma in patients receiving Inbrija. Abnormalities in laboratory tests have been reported. Caution should be exercised when interpreting the plasma and urine levels of catecholamines and their metabolites in patients on levodopa or levodopa/dopadecarboxylase inhibitor therapy. Levodopa can cause orthostatic hypotension. There is limited data available on the use of Inbrija during a respiratory infection. Treatment should be continued or discontinued based on individual assessments. **Interactions:** The use of non-selective MAO inhibitors with levodopa is contraindicated. The use of selective MAO-B inhibitors with levodopa may be associated with orthostatic hypotension. Dopamine D2 receptor antagonists and isoniazid may reduce the effectiveness of levodopa. Patients who are taking these medicinal products should be monitored for worsening Parkinson's symptoms. Dose adjustment of antihypertensive medicinal products may be required during concomitant use of Inbrija. Anticholinergic medicinal products may impair the effect of oral levodopa medicinal products, due to a delayed absorption. A dose adjustment of levodopa may be required. A dose adjustment of levodopa may be required with concomitant use of COMT inhibitors. There have been rare reports of adverse reactions, including hypertension and dyskinesia, resulting from the concomitant use of tricyclic antidepressants and a levodopa/dopa-decarboxylase inhibitor. Psychotic reactions have been observed in patients receiving amantadine and levodopa. Interactions of Inbrija with local or systemic pulmonary medicinal products were not investigated because Inbrija is not recommended in patients with asthma, chronic obstructive pulmonary disease (COPD), or other chronic underlying lung disease. **Pregnancy and breastfeeding:** Inbrija is not recommended during pregnancy and in women of childbearing potential not using contraception. Breast-feeding should be discontinued during treatment with Inbrija. **Effects on ability to drive and use machines:** Patients treated with levodopa and presenting with somnolence and/or sudden sleep episodes must be informed to refrain from driving or engaging in activities where impaired alertness may put themselves or others at risk of serious injury or death, until such recurrent episodes and somnolence have resolved. **Undesirable effects:** Very common(>1/10):Cough. Common (>1/100 to <1/10): Dyskinesia, Upper respiratory tract infection, Sputum discoloured, Nasal discharge discolouration, Throat irritation, Nausea, Vomiting, Fall. **Reported with oral levodopa:** not known: Malignant melanoma, Anaemia, Agranulocytosis, Thrombocytopenia, Leukopenia, Allergic oedema, Decreased appetite, Confusional state, Hallucination, Depression, Anxiety, Abnormal dreams, Insomnia, Psychotic disorder, Impulse-control disorder, Agitation, Suicide attempt, Disorientation, Dopamine dysregulation syndrome, Euphoric mood, Libido increased, Bruxism, Paranoia, Delusion, Dystonia, On and off phenomenon, Somnolence, Dizziness, Worsening of Parkinson's disease, Paraesthesia, Headache, Tremor, Seizure, Sudden onset of sleep, Restless legs syndrome, Neuroleptic malignant syndrome, Ataxia, Dysgeusia, Cognitive disorder, Horner's syndrome, Dementia, Vision blurred, Diplopia, Mydriasis, Oculogyric risis, Blepharospasm, Cardiac rhythm disordersa, Palpitations, Orthostatic hypotension, Hypertension, Syncope, Thrombophlebitis, Hot flush, Dyspnoea, Respiration abnormal, Dysphonia, Hiccups, Abdominal pain, Constipation, Diarrhoea, Dry mouth, Gastrointestinal haemorrhage, Peptic ulcer, Dysphagia, Dyspepsia, Glossodynia, Flatulence, Saliva discolouration, Salivary hypersecretion, Angioedema, Hyperhidrosis, Rash, Pruritus, Henoch-Schonlein purpura, Urticaria, Alopecia, Sweat discolouration, Muscle spasms, Trismus, Urinary retention, Chromaturia, Urinary incontinence, Priapism, Oedema peripheral,Asthenia,Fatigue,Malaise,Gait disturbance,Chest pain, Aspartate aminotransferase increased,Alanine aminotransferase increased,Blood lactate dehydrogenase increased,Blood bilirubin increased,Blood glucose increased,Blood creatinine increased,Blood uric acid increased,Haemoglobin decreased,Haematocrit decreased,Blood urine present,Blood urea increased,Blood alkaline phosphatase increased,Coombs test positive,White blood cells urine positive,Bacterial test positive,Weight decreased,Weight increased. **Packages, prices and reimbursement:** Prescription Only Medicine. Inbrija is approved in the EU by EMA Central Procedure but not distributed or available on the Finnish market. **For further information:** Marketing Authorization Holder: Acorda Therapeutics Ireland Limited 10 Earlsfort Terrace Dublin 2, D02 T380 Ireland Tel: +353 (0)1 231 4609. Local representative in Finland: Merz Therapeutics Nordics AB, Gustav III:s Boulevard 32, 169 73 Solna, Sweden. Please consult the Summary of Product Characteristics before prescribing. This text is based on the Summary of Product Characteristics 01/2025.

Inbrija®
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