

INBRIJA®

Innovation Factsheet

INBRIJA® (levodopa) is an U.S. Food and Drug Administration (2018) and European Medicines Agency (2019) approved, inhaled prescription levodopa medication used to treat the return of motor fluctuation symptoms in Parkinson's disease (PD), known as "OFF" episodes, that occur while the patient is taking their usual treatment of levodopa/dopa-decarboxylase inhibitor.¹ It represents a breakthrough in particle engineering and inhalation drug delivery, making it one of the few inhaled powders developed for systemic therapy. As **INBRIJA** is delivered directly to the lung, absorption of the medicine is not affected by meals or other PD-associated conditions in the gut that can impact oral medications.¹

Key facts

- Developed using proprietary **ARCUS®** spray-drying technology, first pioneered at MIT and Harvard.
- Each capsule contains a high dose of 42 mg levodopa in a single inhalation.¹
- Around 60% of the dose reaches the lungs, independent of inhalation strength.¹
- On-demand dosing flexibility, up to five doses per day depending on patient need
 - maximum daily dose should not exceed 10 capsules.¹

How it works

In PD, the cells in the brain that produce dopamine, a neurotransmitter important for controlling movement, begin to die and the amount of dopamine in the brain decreases.² **INBRIJA** contains levodopa which converts into dopamine in the brain and helps to restore dopamine levels, improving the symptoms of the disease. **INBRIJA** is inhaled directly into the lungs, bypassing the gut, where it is rapidly absorbed into the bloodstream. This provides fast, reliable relief of OFF symptoms such as stiffness and slowness of movement. With its large-capacity capsule and breath-actuated inhaler, **INBRIJA** requires fewer inhalations than traditional lactose-based dry powder inhalers, easing use for people with PD.¹



ARCUS technology

ARCUS is an inhalation technology that enables the delivery of high-dose, highly respirable dry powder medications directly to the lungs. It uses spray-drying to produce low-density, porous particles that are easy to inhale, even for patients with reduced lung function. High doses of medicine can be delivered efficiently, using a simple breath-actuated device, which results in fast absorption, consistent drug levels, and ease of use.



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Clinical impact

71%

of patients reported improvements of motor symptoms of PD during OFF episodes, such as slowness, stiffness, or difficulty moving vs 46% on placebo³

Patients experienced meaningful improvement in symptoms **within 10–30 minutes** of inhalation³

Provides an on-demand, non-oral option that complements existing levodopa therapy³



Looking ahead

The acquisition of **INBRIJA** by Merz Therapeutics from Acorda Therapeutics in 2024 established the foundation for a PD franchise. With continued investment in innovation and manufacturing scale-up, **INBRIJA** is set to bring better function, faster relief, and improved quality of life to more PD patients globally.

Mandatory Safety Information

Inbrija 33 mg inhalation powder, hard capsules.

Active substance: Levodopa. **Prescription only!**

Qualitative and quantitative composition:

Active substance: Each hard capsule contains 42 mg levodopa. Each delivered dose contains 33 mg levodopa.

Excipients: **Capsule content:** Colfosceril palmitate (DPPC), Sodium chloride. **Capsule shell:** Hypromellose, Titanium dioxide (E 171), Carrageenan, Potassium chloride, Carnauba wax, Maize starch. **Ink:** Shellac, Black iron oxide (E 172), Propylene glycol, Potassium hydroxide.

Therapeutic indications: Inbrija is indicated for the intermittent treatment of episodic motor fluctuations (OFF episodes) in adult patients with Parkinson's disease (PD) treated with a levodopa/dopa-decarboxylase inhibitor.

Contraindications: Hypersensitivity to the active substance or to any of the excipients, Narrow-angle glaucoma, Pheochromocytoma, Co-administration with non-selective monoamine oxidase (MAO) inhibitors, a previous history of neuroleptic malignant syndrome (NMS) and/or non-traumatic rhabdomyolysis.

Undesirable effects: *Very common (m1/10):* Cough.

Common (m1/100 bis <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 crisis, Blepharospasm, Cardiac rhythm disorders, 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.

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Further information is provided in the Summary of Product Characteristics and the Package Leaflet.

REFERENCES:

1. European Medicines Agency. Inbrija (levodopa), An overview of Inbrija and why it is authorised in the EU. <https://www.ema.europa.eu/en/medicines/human/EPAR/inbrija> Last accessed: 20.10.2025
2. Parkinson's Europe. Understanding Parkinson's – Causes. <https://parkinsonseurope.org/understanding-parkinsons/causes/>. Last accessed: 20.10.2025.
3. 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 randomized, double-blind, placebo-controlled phase 3 trial. *Lancet Neurol* 2019; 18: 145-154.