

INBRIJA®

Differentiation Factsheet

INBRIJA® (levodopa) is a significant advancement for people living with Parkinson's disease (PD) as it provides an on-demand, inhalable form of levodopa, offering an effective way to manage "OFF" episodes (times when the patient has more difficulty moving about) in adult patients with PD who are already being treated with a levodopa/dopa-decarboxylase inhibitor.¹



The first and only inhalable on-demand levodopa to be approved by regulators.¹



INBRIJA delivers levodopa directly to the lungs via oral inhalation using a specialized, breath actuated inhaler device.¹



The inhaled formulation enables levodopa to bypass the gastrointestinal (GI) tract and, instead, rapidly enter the bloodstream through the respiratory system.^{1,2}



This method of delivery is especially valuable for people who need an on-demand, rapid relief from their symptoms that oral intake cannot reliably provide.¹



Dosing is straightforward and can be administered on the go, enabling patients to self-manage their symptoms when OFF episodes occur.²

- Patients can use **INBRIJA** as needed
 - up to five times per day
 - to manage symptoms returning.¹



As **INBRIJA** is delivered directly to the lung, absorption of the medicine is not affected by meals or other conditions in the gut that can impact oral medications.



In a large phase 3 clinical trial (N=351), **INBRIJA** started improving motor symptoms in as early as 10 minutes and significant relief in motor symptoms was seen in 30 minutes of inhaling **INBRIJA**.²



The inhalable on-demand administration offers a non-stigmatizing option for managing OFF episodes.



PD can change how well medicine is absorbed by the body:³

- It can slow the movement of food and pills through the gut.
- Meals, especially foods high in protein, can interfere with the absorption of orally administered levodopa from the intestine into the brain.
- There are other factors that can lower the amount of oral levodopa that enters the bloodstream and brain.



The most common side effects of **INBRIJA** are cough, dyskinesia, upper respiratory tract infection, sputum and nasal discharge discoloration, throat irritation, nausea, vomiting and fall.^{1,2}



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.