

Prescribing information and adverse event information

INBRIJA® (levodopa) 33 mg inhalation powder, hard capsules Prescribing Information (PI) M-INB-UK-0126.

Please refer to the Summary of Product Characteristics (SmPC) for further information.

Indication: 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.

Dosage and Administration: Patients should be on a stable levodopa/dopa-decarboxylase inhibitor (e.g. carbidopa or benserazide) regimen before starting Inbrija. Inbrija should be inhaled when symptoms, motor or non-motor, of an OFF period start to return. The recommended dose is 2 hard capsules up to 5 times per day each delivering 33 mg levodopa. The maximum daily dose should not exceed 10 capsules (330 mg). It is not recommended to take more than 2 capsules per OFF period. Exceeding the recommended dose may lead to increased levodopa associated adverse reactions. Abrupt dose reduction or withdrawal of any levodopa medicinal product should be carefully observed, particularly in patients who are also receiving neuroleptics.

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

Special warnings and precautions: Bronchospasm in patients with lung disease: 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. Central Nervous System (CNS) effects and mental disturbances: 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. Patients who have experienced somnolence and/or an episode of sudden sleep onset must refrain from driving or operating machines. Furthermore, a reduction of dose or termination of therapy may be considered. Withdrawal-emergent hyperpyrexia and confusion: A symptom complex that resembles neuroleptic malignant syndrome (characterised by elevated temperature, muscular rigidity, altered consciousness, and autonomic instability), with no other obvious aetiology, has been reported in association with rapid dose reduction, withdrawal of, or changes in the background dopaminergic therapy. Therefore, any abrupt dose reduction or withdrawal of any levodopa medicinal product should be carefully observed, particularly in patients who are also receiving neuroleptics. Mental disturbances: Patients may experience new or worsening mental status and behavioural changes, which may be severe, including psychotic-like and suicidal behaviour during levodopa treatment or after starting or increasing the dose of levodopa. Impulse control disorders: Patients should be regularly monitored for the development of impulse control disorders. Review of treatment is recommended if such symptoms develop. Dyskinesia: Inbrija may cause dyskinesia. Adjustment of levodopa therapy or other medicinal products used for the treatment of Parkinson's disease may be considered. Cardiovascular ischaemic events: Inbrija should be administered with caution in patients with severe cardiovascular disease. Care should be exercised when Inbrija is administered to patients with a history of myocardial infarction who have residual atrial, nodal, or ventricular arrhythmias. Cardiac function should be monitored during the initiation of treatment with Inbrija. Peptic ulcer disease: Levodopa should be administered cautiously to patients with a history of peptic ulcer disease. Glaucoma: Levodopa may cause increased intraocular pressure in patients with glaucoma. Patients with chronic glaucoma may be treated cautiously with levodopa provided the intraocular pressure is well-controlled and the patient is monitored carefully during therapy. Melanoma: Epidemiological studies have shown that patients with PD have a higher risk of developing melanoma than the general population. Periodic skin examinations are recommended in patients receiving Inbrija. Laboratory monitoring: Abnormalities in laboratory tests may include elevations of liver function tests. Abnormalities in blood urea nitrogen (BUN) and positive Coombs test have also been reported. Interference with test: Levodopa may cause a false-positive reaction for urinary ketone bodies when a test tape is used for determination of ketonuria. False-negative tests may result with the use of glucose-oxidase methods of testing for glucosuria. Cases of falsely diagnosed pheochromocytoma in patients on levodopa/dopa-decarboxylase inhibitor therapy have been reported very

rarely. Caution should be exercised when interpreting the plasma and urine levels of catecholamines and their metabolites in patients on levodopa or levodopa/dopa-decarboxylase inhibitor therapy. Orthostatic hypotension: Levodopa can cause orthostatic hypotension. Inbrija should be used with caution in case of concomitant use of medicinal products that may cause orthostatic hypotension. Intercurrent respiratory infection: There is limited data available on the use of Inbrija during a respiratory infection. Based on individual assessments of the severity of the intercurrent respiratory infection Inbrija may be continued or discontinued until the respiratory symptoms resolve.

Drug interactions: Non-selective Monoamine Oxidase (MAO) inhibitors: use with levodopa is contraindicated. Any non-selective MAO inhibitors should be discontinued at least 14 days prior to initiating levodopa. Selective Monoamine Oxidase (MAO) inhibitors (e.g. rasagiline, selegiline, and safinamide): use with levodopa may be associated with orthostatic hypotension. Patients taking these medicinal products should be monitored closely. Dopamine D2 receptor antagonists (e.g. phenothiazines, butyrophenones, risperidone, metoclopramide) and isoniazid: may reduce the effectiveness of levodopa. Patients taking these medicinal products should be monitored for worsening Parkinson's symptoms. Antihypertensives: Symptomatic postural hypotension has occurred when levodopa and a dopa-decarboxylase inhibitor are used in patients receiving certain antihypertensives. Dose adjustment of the antihypertensive may be required. Anticholinergics: Concurrent use can cause a worsening of involuntary motor disorders. 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. COMT inhibitors: The addition of entacapone to a levodopa/dopa-decarboxylase inhibitor has been demonstrated to increase the levodopa bioavailability by 30%. A dose adjustment of levodopa may be required. Tricyclic antidepressants: 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. Amantadine: Concurrent administration of levodopa and amantadine may increase confusion, hallucinations, nightmares, gastro-intestinal disturbances, or other atropine-like side effects. Psychotic reactions have been observed. Local or systemic pulmonary medicinal products: Interactions of Inbrija with local or systemic pulmonary medicinal products were not investigated.

Pregnancy and lactation: There are no or limited data from the use of levodopa in pregnant women. Studies in animals have shown reproductive toxicity. Inbrija is not recommended during pregnancy and in women of childbearing potential not using contraception. Levodopa is excreted in human milk. There is insufficient information on the effects of levodopa in newborns/infants. Breast-feeding should be discontinued during treatment with Inbrija.

Effects on ability to drive and use machines: Levodopa may have a major influence on the ability to drive and use machines.

Undesirable effects: Very common ($\geq 1/10$): Cough. Common ($\geq 1/100$ to $< 1/10$): Dyskinesia, upper respiratory tract infections, sputum discoloured, nasal discharge discolouration, throat irritation, nausea, vomiting, and falls. See Summary of Product Characteristics full list of undesirable effects.

Legal classification: POM. **Pack size and list price:** 92 capsules £413.95.

Marketing Authorisation number: PL 61157/0001 **Marketing Authorisation Holder:** Merz Therapeutics GmbH, Eckenheimer Landstraße 100, 60318 Frankfurt am Main, Germany. **Date of preparation:** December 2025.

Additional Information Available in the Summary of Product Characteristics or on request from: Merz Pharma UK Ltd, Ground Floor Suite B Breakspear Park, Breakspear Way, Hemel Hempstead, Hertfordshire, England, HP2 4TZ

Adverse events should be reported. Reporting forms and information for United Kingdom can be found at <https://yellowcard.mhra.gov.uk/>. Adverse events should also be reported to Merz Pharma UK Ltd by email to txmedical.information@merz.com or on +44 (0) 333 200 4143.