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Inbrija (*levodopa*)

An overview of Inbrija and why it is authorised in the EU

What is Inbrija and what is it used for?

Inbrija is a medicine used to treat adults with Parkinson's disease (a progressive brain disease that causes shaking and muscle stiffness and slows movement).

Inbrija is used to treat symptoms during 'off' periods (times when the patient has more difficulty moving about) that occur while the patient is taking their usual treatment of a combination of levodopa and an inhibitor of dopa-decarboxylase.

Inbrija contains the active substance levodopa.

How is Inbrija used?

Inbrija is available as capsules containing a powder for inhalation and can only be obtained with a prescription.

Inbrija should be inhaled using the Inbrija inhaler device when the patient recognises the symptoms of an 'off' period. The recommended dose is 2 capsules in each 'off' period up to a maximum of 10 capsules per day.

For more information about using Inbrija, see the package leaflet or contact your doctor or pharmacist.

How does Inbrija work?

In patients with Parkinson's disease, 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.

Inbrija contains levodopa which converts into dopamine in the brain and helps to restore dopamine levels, thereby improving the symptoms of the condition. Because Inbrija is inhaled, it can supply extra levodopa (and hence dopamine) quickly when needed during an 'off' period.

What benefits of Inbrija have been shown in studies?

Two main studies have shown that Inbrija is effective at improving patients' symptoms during 'off' periods. Effects were measured using a standard symptom scale known as the unified Parkinson's disease rating scale, UPDRS, part III.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

The first study involved 226 patients who had 12 weeks of standard treatment with levodopa and a dopa-decarboxylase inhibitor. In this study, patients who took Inbrija during their 'off' periods had an average improvement of 10 points on the scale 30 minutes later, compared with 6 points for patients taking placebo (a dummy treatment). Of patients treated with Inbrija, 71% reported that their symptoms were improved, compared with 46% of patients on placebo.

In the second study involving 77 patients who had 4 weeks of standard treatment, patients who took Inbrija during 'off' periods had an average improvement of 10 points on the scale 10 to 60 minutes later, compared with 3 points for patients taking placebo.

What are the risks associated with Inbrija?

The most common side effect with Inbrija is cough (which may affect more than 1 in 10 people). Other common side effects, which may affect up to 1 in 10 people, are falls, upper respiratory tract infection (nose and throat infection), dyskinesia (difficulty controlling movement) and discoloured sputum (phlegm).

Allergic oedema (swelling) and gastrointestinal haemorrhage (bleeding in the gut) have been reported for other medicines containing levodopa. Medicines containing levodopa and a dopa-decarboxylase inhibitor have shown side effects of symptoms like neuroleptic malignant syndrome (a nervous disorder) and rhabdomyolysis (breakdown of muscle fibres).

Inbrija must not be used in patients with narrow angle glaucoma (an eye disorder) or pheochromocytoma (a tumour of the adrenal glands). It must also not be used in patients taking medicines known as non-selective monoamine oxidase (MAO) inhibitors or in patients with a history of neuroleptic malignant syndrome or rhabdomyolysis. For the full list of side effects and restrictions, see the package leaflet.

Why is Inbrija authorised in the EU?

Studies show that Inbrija is effective at reducing symptoms during 'off' periods in patients with Parkinson's disease on levodopa/dopa-decarboxylase-inhibitor treatment. The safety of the medicine is in line with other similar medicines. Because it is inhaled, Inbrija provides rapid relief of symptoms, which improves patients' quality of life. The European Medicines Agency therefore decided that Inbrija's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Inbrija?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Inbrija have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Inbrija are continuously monitored. Side effects reported with Inbrija are carefully evaluated and any necessary action taken to protect patients.

Other information about Inbrija

Inbrija received a marketing authorisation valid throughout the EU on 19 September 2019.

Further information on Inbrija can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Inbrija.

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