



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Onerji (*levodopa / carbidopa*)

A plain-language overview of Onerji and why it is authorised in the EU

### What is Onerji and what is it used for?

Onerji is a medicine used in patients with advanced Parkinson's disease to treat changes in their ability to move (motor fluctuations) when these cannot be adequately controlled by other medicines taken by mouth.

Parkinson's disease is a progressive brain disorder that causes shaking, slow movement and muscle stiffness. Motor fluctuations happen when the effects of the medication taken by mouth wear off and symptoms return. Patients experience sudden switches between being 'on' and able to move and being 'off' and having difficulty moving about.

Onerji contains the active substances levodopa and carbidopa.

### How is Onerji used?

The medicine can only be obtained with a prescription.

Onerji is available as an infusion (drip) that is given continuously under the skin, 24 hours per day using a delivery pump. The infusion is given into the belly (abdomen), the areas on the sides of the body between the lower ribs and hips (flanks), or the outer thighs. If needed, the outer back of the upper arm can also be used.

A different infusion site must be used each day; patients must not use the same site again for at least two weeks. Onerji is given together with levodopa or other medicines for Parkinson's disease taken by mouth.

Patients and their caregivers may be able to use the medicine and the pump themselves at home if the doctor considers this appropriate and they have received training from their healthcare professional.

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

### How does Onerji 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.

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Onerji contains levodopa which is turned into dopamine in the brain; this helps to restore dopamine levels. The carbidopa in Onerji stops levodopa from being turned into dopamine before it reaches the brain.

### **What benefits of Onerji have been shown in studies?**

A main study showed that Onerji was more effective than carbidopa and levodopa taken by mouth at increasing the average daily duration during which patients experienced well-controlled Parkinson's symptoms ('on time') without involuntary movements. The study involved 259 adults with Parkinson's disease who experienced motor fluctuations which were not controlled by their current medication. After 12 weeks of treatment, patients taking Onerji had an increase in their daily 'on time' by around 1.72 hours compared with those taking carbidopa and levodopa by mouth.

They also had a reduction of about 1.4 hours per day in 'off time', the periods when a person's medication wears off and their motor symptoms return or worsen, compared with patients taking carbidopa and levodopa by mouth.

Studies carried out with Onerji are described in more detail in the medicine's assessment report.

### **What are the side effects and restrictions with Onerji?**

For the full list of side effects and restrictions with Onerji, see the package leaflet.

The most frequent side effects with Onerji (which may affect more than 1 in 10 people) include infusion site reactions such as nodules (lumps), haematoma (a collection of blood under the skin), pain, infection, erythema (reddening of the skin), eschar (a collection of dry, dead tissue within a wound) and dyskinesia (difficulty controlling movements).

Onerji must not be used in patients with narrow angle glaucoma (damage to the nerve in the eye caused by pressure inside the eye rising rapidly because fluid cannot drain out) or pheochromocytoma (a tumour of the adrenal glands). It must also not be used in patients taking certain medicines used to treat Parkinson's disease and depression known as non-selective monoamine oxidase inhibitors (MAOI) such as phenelzine and tranylcypromine, or in patients with thinking or memory problems or a history of certain medical conditions further specified in the package leaflet.

### **Why is Onerji authorised in the EU?**

Levodopa used in combination with carbidopa is the gold standard treatment for Parkinson's disease. However, long-term levodopa treatment taken by mouth, along with the natural progression of the disease, commonly leads to difficulty controlling movements. These complications occur because taking levodopa and carbidopa by mouth causes the blood levels to fluctuate which leads to periods when the disease symptoms are not well controlled. There is an unmet medical need for alternative treatment approaches that can provide continuous levodopa delivery which results in stable blood levels of the medicine. Onerji provides a continuous levodopa delivery and has been shown to be more effective than levodopa and carbidopa taken by mouth in controlling symptoms without motor complications. Regarding safety, local reactions represent a key concern, and measures have been implemented to minimise and manage these events.

The European Medicines Agency therefore decided that Onerji's benefits are greater than its risks and that it can be authorised for use in the EU.

## **What measures are being taken to ensure the safe and effective use of Onerji?**

The company that markets Onerji will provide an information pack for patients to ensure they understand how to set up the pump and to outline the risk of infusion site reactions with Onerji and how to manage them.

These materials may be made available by national competent authorities on their websites. A list of national repositories can be found on the [EMA website](#).

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

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

## **Other information about Onerji**

Onerji received a marketing authorisation valid throughout the EU on 27 April 2026.

Further information on Onerji, including the package leaflet and assessment report, can be found on the Agency's website: [ema.europa.eu/medicines/human/EPAR/onerji](https://ema.europa.eu/medicines/human/EPAR/onerji).

For information about the availability of this medicine in your country, contact your [national competent authority](#).

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