

Summary Public Assessment Report

Tremopen (carbidopa monohydrate, levodopa)

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Tremopen
levodopa, carbidopa (monohydrate)

Tablet, 12,5 mg/50 mg, 10 mg/100 mg, 25 mg/100 mg, 25 mg/250 mg

This is a summary of the public assessment report (PAR) for Tremopen. It explains how Tremopen was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Tremopen.

For practical information about using Tremopen, patients should read the package leaflet or contact their doctor or pharmacist.

What is Tremopen and what is it used for?

Tremopen is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Sinemet.

Tremopen is used in the treatment of Parkinson's disease. Tremopen improves the signs of parkinsonism (but not for drug-induced extrapyramidal symptoms) in adults. Parkinson's disease is a long-term illness where:

- you become slow and unsteady
- your muscles feel stiff
- you may develop shaking or trembling (called 'tremor').

If not treated, Parkinson's disease can make it hard for you to continue your normal daily activities.

How does Tremopen work?

Tremopen contains the active substances carbidopa and levodopa which are anti-Parkinson substances.

- levodopa turns into a material called 'dopamine' in your brain. Dopamine is involved in nerve cell signaling within the body. Low dopamine levels in parts of the brain causes Parkinson's disease symptoms. Therefore, dopamine improves the signs of Parkinson's disease. Since dopamine itself cannot reach the brain from other parts of the body, levodopa is given which is converted into dopamine within the brain cells.
- carbidopa belongs to a group of medicines called 'aromatic amino acid decarboxylase inhibitors'. Carbidopa prevents levodopa from being converted to dopamine in other parts of the body, allowing the conversion to mainly take place in the brain. This helps levodopa work more effectively and reduces adverse effects on the other organs of the body.

How is Tremopen used?

The pharmaceutical form of Tremopen is tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Tremopen have been shown in studies?

Because Tremopen is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Sinemet.

Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Tremopen?

Because Tremopen is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Tremopen approved?

It was concluded that, in accordance with EU requirements, Tremopen has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine Sinemet. Therefore, the Swedish Medical Products Agency decided that, as for Sinemet, the benefits are greater than its risks and recommended that it can be approved for use.

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

A risk management plan has been developed to ensure that Tremopen is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Tremopen, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Tremopen

The full PAR for Tremopen can be found on the following website:
<http://mri.medagencies.org/Human/>. For more information about treatment with Tremopen

This summary was last updated in 2022-01.