

Package leaflet: Information for the user

Tremopen 12.5 mg/50 mg tablets
Tremopen 10 mg/100 mg tablets
Tremopen 25 mg/100 mg tablets
Tremopen 25 mg/250 mg tablets
carbidopa/levodopa

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <invented name> is and what it is used for
2. What you need to know before you take <invented name>
3. How to take <invented name>
4. Possible side effects
5. How to store <invented name>
6. Contents of the pack and other information

1. What <invented name> is and what it is used for

<invented name> contains the active substances carbidopa and levodopa which are anti-Parkinson substances.

<invented name> 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 <invented name> works:

- levodopa turns into a material called 'dopamine' in your brain. The dopamine helps to improve the signs of your Parkinson's disease.
- carbidopa belongs to a group of medicines called 'aromatic amino acid decarboxylase inhibitors'. It helps levodopa work more effectively by slowing the speed at which levodopa is broken down in your body.

2. What you need to know before you take <invented name>

Do not take <invented name>:

- if you are allergic to carbidopa or levodopa or any of the other ingredients of this medicine (listed in section 6).
- if you are taking certain medicines called 'MAOIs' (Monoamine Oxidase Inhibitors, such as selegiline) used for depression. You need to stop using these medicines at least two weeks before you start taking <invented name>.

- if you have a condition called ‘narrow-angle glaucoma’ that may cause a sudden build up of pressure in the eye
- if you have suspicious undiagnosed skin lesions or a history of skin cancer
- if you have attacks of hypertension induced by tumor of the adrenal medulla (pheochromocytoma)
- overproduction of cortisol or thyroid hormone
- if you have severe heart disease

Do not take <invented name> if any of the above apply to you.

If you are not sure, talk to your doctor or pharmacist before taking the medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking <invented name>:

- if you have drug-induced movement disorders
- if you have lung problems, such as bronchial asthma
- if you have liver, kidney or gland-problems
- if you have a history of an ulcer in your guts (called ‘peptic ulcer’)
- if you have a history of heart attacks (myocardial infarction)
- if you are taking a medicine which may cause low blood pressure when rising from a chair or bed (orthostatic hypotension)
- if you have had depression or other mental problems
- if you have been taking levodopa alone previously
- if you have a history of severe involuntary movements or psychotic episodes
- if you have a history of fits (convulsions)
- if you have a condition called ‘chronic wide-angle glaucoma’ that may cause a build-up of pressure in the eye. You will need to have regular checks on the pressure in your eye.
- if you sometimes have sudden sleep attacks or sometimes feel very sleepy
- if you are due to have surgery

Tell your doctor if you or your family/carer notices you are developing urges or cravings to behave in ways that are unusual for you or you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These behaviours are called impulse control disorders and can include addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings. Your doctor may need to review your treatments.

Tell your doctor if you or your family/carer notices you are developing addiction-like symptoms leading to craving for large doses of <invented name> and other medicines used to treat Parkinson’s disease.

This medication can affect some laboratory tests that your doctor may perform on blood or urine samples. Please remind your doctor if you are taking <invented name> and are having any tests.

Children and adolescents

<invented name> is not recommended for children or adolescents under 18 years.

Other medicines and <invented name>

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because <invented name> can affect the way some other medicines work. Also some other medicines can affect the way <invented name> works.

In particular tell your doctor or pharmacist if you are taking:

- medicines to treat high blood pressure (antihypertensive drugs). Dosage adjustment of the antihypertensive agent may be required.
- medicines to treat depressions (antidepressants, such as tricyclic antidepressants and non-selective monoamine oxidase inhibitors)
- anticholinergic agents. An adjustment of the dose of Carbidopa/Levodopa may be needed.

- medicines to treat Parkinson's disease (COMT-inhibitors, such as tolcapone, entacapone, amantadine or medicines containing selegiline). The dose of Carbidopa/Levodopa may need adjustment.
- medicines to treat anemia (such as iron preparations). Administration of <invented name> and iron preparations should be separated by the longest possible interval in time
- medicines to treat severe allergic reactions, asthma, chronic bronchitis, heart diseases and low blood pressure (such as sympathomimetics).
- medicines to treat convulsive fits (such as phenytoin)
- medicines to treat mental problems (such as phenothiazines, butyrophenons and risperidone)
- medicines to treat tuberculosis (such as isoniazide)
- medicines to treat erectile dysfunction (such as papaverine).

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

<invented name> with food and drink

Try to avoid taking <invented name> with a meal containing proteins (such as, meat, eggs, milk, cheese) since the function of <invented name> may decrease.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

<invented name> is not recommended during pregnancy or in women of childbearing potential not using contraception unless the benefits for the mother outweigh the possible risk to the unborn baby.

Do not take <invented name> if you are breast-feeding.

Driving and using machines

<invented name> may lower your blood pressure, which can make you feel light-headed or dizzy. Therefore, be particularly careful when you drive or when you use any tools or machines.

<invented name> can also make you sleepy or cause 'sudden sleep attacks'. If this happens to you, you must not drive or use tools or machines until such reoccurring 'sudden sleep' attacks and sleepiness have disappeared.

3. How to take <invented name>

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual daily dose may be variable and is individually determined by the doctor depending on the severity of the disease and the response to the treatment. During the dose adjustment period, the patient should pay special attention to symptoms such as involuntary movements, and inform your doctor immediately if this occurs. Your doctor will adjust your dosage as necessary.

More than one strength of <invented name> may be prescribed by your doctor. If you have been given different strengths of <invented name>, make sure that you are taking the correct tablet at the right time.

For doses not realisable/practicable with this medicinal product, other medicinal products are available.

How to take this medicine

- Take this medicine by mouth by swallowing the tablet. The tablet shall be taken whole and should not be divided, because the tablets do not contain a score line.
- Although your medicine can have an effect after one day, it may take up to seven days to work.
- Take the tablet at regular time intervals according to your doctor's instructions.
- Do not change the times at which you take your tablets or take any other medicines for Parkinson's disease without first consulting your doctor.
- Try to avoid taking your tablets with a protein-rich meal (see section 2 “<invented name> with food and drink“)

If you take more <invented name> than you should

If you or your child take too many tablets, see a doctor immediately.

If you forget to take <invented name>

Do not take a double dose to make up for a forgotten dose.

If you stop taking <invented name>

Do not stop taking <invented name> or change your dose until your doctor tells you to. If you stop taking <invented name> abruptly, the following can occur: stiff muscles, high temperature (fever) and mental changes.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking <invented name> and see your doctor straight away, if you notice any of the following side effects:

- chest pain
- uneven (irregular) heartbeat or palpitations
- bleeding from your gut which may be seen as blood in your faeces or darkened faeces (gastro-intestinal bleeding)
- muscle stiffness, severe inability to sit still, high fever, sweating, increased salivation, and impaired consciousness (malignant neuroleptic syndrome)
- mental changes including delusions, hallucinations, and depression (with very rare suicidal tendencies)
- fits (convulsions)
- sudden build-up of fluid in the skin and mucous membranes (e.g. throat and tongue), breathing difficulties and/or itching and skin rash, often appearing as an allergic reaction (angioedema)
- a very serious blood disorder (lack of white blood cells) accompanied by sudden high fever, severe sore throat and mouth ulcers (agranulocytosis)

Other side effects that may occur:

Very Common (: may affect more than 1 in 10 people):

- urinary tract infections

Common (may affect up to 1 in 10 people):

- loss of appetite (anorexia)

- confusion, dizziness, nightmares, sleepiness, tiredness, insomnia, feeling of well-being (euphoria), dementia, feeling of stimulation, dream abnormalities
- movement disorders (dyskinesia), a disorder characterised by sudden involuntary movements (chorea), muscle tone disorder (dystonia), movement disorders caused from outside the nervous system, sudden changes in Parkinson's symptoms ("on-off" symptoms), slowdown in movements during "on-off" periods (bradykinesia)
- feeling of too fast heartbeat (palpitations), irregular heartbeat
- a drop in blood pressure caused e.g. by getting up too quickly from a sitting or lying position, sometimes accompanied by dizziness (orthostatic hypotension), tendency to faint
- nausea, vomiting, dry mouth, bitter taste

Uncommon (may affect up to 1 in 100 people):

- weight loss or weight gain
- disturbance of muscle coordination (ataxia), increase in hand tremors
- increase in blood pressure (hypertension)
- hoarseness
- constipation, diarrhoea, wind
- increased salivation (sialorrhoea), difficulties in swallowing (dysphagia)
- fluid accumulation (oedema)
- muscle spasms
- dark urine
- loss of strength (asthenia), weakness
- feeling of being unwell (malaise)
- hot flushes

Rare (may affect up to 1 in 1,000 people):

- a blood disorder (lack of white blood cells) accompanied by an increased susceptibility to infections (leukopenia), anaemia, a blood disorder (lack of blood platelets) accompanied by bruising and a tendency to bleed (thrombocytopenia)
- excitement (agitation), fear, impaired ability to think, disorientation, headache, increased sexual desire, numbness, fits/seizures
- episodes of serious mental illness, during which control over one's own conduct and behaviour is impaired
- feelings of prickling, tingling and itchiness without any apparent cause (paraesthesia),
- more frequent falling, gait disorders, lockjaw (trismus)
- blurred vision, spasm of the orbicularis oculi muscle surrounding the eye (blepharospasm, this may be a sign of overdose), activation of a pre-existing Horner's syndrome (an eye disorder), double vision, dilated pupils, a deterioration in eye movements
- inflammation of the veins (phlebitis)
- breathlessness (dyspnoea), abnormal breathing patterns
- impaired digestion with symptoms such as feelings of fullness in the upper abdomen, upper abdominal pain, belching, nausea, vomiting and heartburn (dyspepsia), stomach and intestinal pain, dark saliva, grinding of teeth (bruxism), hiccups, stomach and intestinal bleeding, burning tongue, duodenal ulcers
- skin rash with severe itching and the formation of wheals (urticaria), itching, facial redness, hair loss, skin rash, increased sweating, dark sweat
- in children, allergy-related bleeding in the skin and gastrointestinal tract wall (Schönlein- Henoch purpura)
- urine retention, involuntary passing of urine, persistent erection (priapism)

Very rare (may affect up to 1 in 10,000 people):

- drowsiness and constant daytime fatigue/sudden attacks of sleep

Not known (frequency cannot be estimated from the available data):

- muscle twitching
- Craving for large doses of <invented name> in excess of that required to control motor symptoms

(dopamine dysregulation syndrome). Some patients experience severe abnormal involuntary movements, mood swings or other side effects after taking large doses of <invented name> of the medicinal product.

- Inability to resist the impulse to perform an action that could be harmful, which may include:
 - Strong impulse to gamble excessively despite serious personal or family consequences.
 - Altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive.
 - uncontrollable excessive shopping or spending
 - binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger)

Tell your doctor if you experience any of these behaviours; they will discuss ways of managing or reducing the symptoms.

If any symptoms persist or if you experience any other side effects, please tell your doctor or pharmacist. It will help if you make a note of what you experienced, when it started and how long it lasted.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V*](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <invented name>

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What <invented name> contains

- The active substances are carbidopa and levodopa.
 - Each tablet contains 12.5 mg carbidopa (as carbidopa monohydrate) and 50 mg levodopa.
 - Each tablet contains 10 mg carbidopa (as carbidopa monohydrate) and 100 mg levodopa.
 - Each tablet contains 25 mg carbidopa (as carbidopa monohydrate) and 100 mg levodopa.
 - Each tablet contains 25 mg carbidopa (as carbidopa monohydrate) and 250 mg levodopa.

- The other ingredients are:

10 mg/100 mg and 25 mg/250 mg: crospovidone [Type B] (E1202), indigo carmine aluminium lake (E132), magnesium stearate (E470b), cellulose microcrystalline (E460), pregelatinized starch [maize]
12.5mg/50 mg and 25 mg/100 mg: crospovidone [Type B] (E1202), quinoline yellow aluminium lake (E104), magnesium stearate (E470b), cellulose microcrystalline (E460), pregelatinized starch [maize]

What <invented name> looks like and contents of the pack

12.5 mg/50 mg: light yellow colored, round shaped, with a diameter of 6 mm, with “C” on one side and “17” on other side of tablet.

<invented name>10 mg/100 mg: light blue colored, round shaped, with a diameter of 8 mm, with “C” on one side and “18” on other side of tablet.

<invented name>25 mg/100 mg: light yellow colored, round shaped, with a diameter of 8 mm, with “C” on one side and “19” on other side of tablet.

<invented name>25 mg/250 mg: light blue colored, round shaped, with a diameter of 10.40 mm, with “C” on one side and “20” on other side of tablet.

Pack-sizes:

12.5 mg/50 mg: 20, 100 or 200 tablets in aluminium blisters in a carton box.

10 mg /100mg: 20, 100 or 200 tablets in aluminium blisters in a carton box.

25 mg /100mg: 20, 50, 100 or 200 tablets in aluminium blisters in a carton box.

25 mg /250mg: 20, 50, 60, 100, 120 or 200 tablets in aluminium blisters in a carton box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<To be completed nationally>

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