Patient leaflet in accordance with the Pharmacists Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Ongentys 50 mg
hard capsules

Active ingredient:
Each hard capsule of Ongentys 50 mg contains opicapone 50 mg.

For Inactive ingredients and allergens in this medicine see section 2 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.
Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Ongentys 50 mg is used as adjunctive therapy in adults with Parkinson's disease who are taking medicines containing levodopa/DOPA decarboxylase inhibitors and who are not sufficiently controlled.

Therapeutic group: Anti-Parkinson drugs, other dopaminergic agents.

Treatment with Ongentys 50 mg increases the effectiveness of levodopa and helps relieve the symptoms of Parkinson's disease and movement problems.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient opicapone or to any of the other ingredients this medicine contains (see section 6 'Additional information');
- you have a tumour of the adrenal gland (known as phaeochromocytoma), or of the nervous system (known as paraganglioma), or any other tumour which increases the risk of severe high blood pressure;
- you have ever suffered from neuroleptic malignant syndrome which is a rare reaction to antipsychotic medicines;
- you have ever suffered from a rare muscle disorder called rhabdomyolysis which was not caused by injury;
- you are taking certain antidepressants called monoamine-oxidase inhibitors (MAOI) (e.g. phenelzine, tranylcypromine or moclobemide). Ask your doctor or pharmacist if you can take your antidepressant together with Ongentys 50 mg.

Special warnings about using this medicine
Before treatment with Ongentys 50 mg, tell your doctor:

- if you have severe liver problems and suffered from loss of appetite, weight loss, weakness, or exhaustion within a short period of time. Your doctor may need to reconsider your treatment.
- Talk to your doctor or pharmacist 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 you or others. These behaviours are called 'impulse control disorders' and can include addictive gambling, an abnormally high sex drive or an increased preoccupation with sexual thoughts or feelings. Behaviours such as these have been reported in patients using other medicines for Parkinson's disease.

Your doctor may need to review your treatments.

Children and adolescents
This medicine is not intended for children and adolescents under the age of 18 years. This medicine has not been studied in these age groups since treatment of Parkinson's disease is not relevant in children and adolescents.

Drug interactions
If you are taking, or have recently taken, other medicines including non-prescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking**:**

- medicines for treatment of depression or anxiety such as venlafaxine, maprotiline and desipramine. Taking Ongentys 50 mg with these medicines may increase the risk of side effects. Your doctor may need to adjust your treatment;
- safinamide used for Parkinson's disease. There is no experience taking Ongentys 50 mg and safinamide together. Your doctor may need to adjust your treatment;
- medicines to treat asthma such as rimiterole or isoprenaline. Ongentys 50 mg may increase their effect;
- medicines used to treat allergic reactions such as adrenaline. Ongentys 50 mg may increase their effect;
- medicines used to treat heart failure such as dobutamine, dopamine or dopexamine. Ongentys 50 mg may increase their effect;
- medicines for high cholesterol such as rosuvastatin, simvastatin, atorvastatin or pravastatin. Ongentys 50 mg may increase their effect;
- medicines that affect the immune system such as methotrexate. Ongentys 50 mg may increase their effect;
- medicines containing quinidine, that are used to treat abnormal heart rhythm or malaria. Taking Ongentys 50 mg and quinidine at the same time may decrease the effect of Ongentys 50 mg.

Pregnancy, breast-feeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, contact your doctor or pharmacist before taking this medicine.

Ongentys 50 mg is not recommended for use during pregnancy. You should use effective contraception if you might become pregnant.
It is not known if Ongentys 50 mg passes into breast milk in humans. Since the risk to the baby cannot be excluded, you should stop breast-feeding during treatment with Ongentys 50 mg.

Driving and using machines
Ongentys 50 mg taken with levodopa may make you feel light-headed, dizzy, or sleepy. Do not drive or operate machinery if you feel any of these side effects.

Important information about some of this medicine's ingredients
Lactose - If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
Sodium - This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium free'.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine.

The recommended dosage is 50 mg once daily. The medicine should preferably be taken at bedtime.
Take Ongentys 50 mg at least one hour before or after taking your levodopa medicine.

Doses of other medicines to treat Parkinson's disease
The dose of other medicines to treat Parkinson's disease may need to be adjusted when you start taking Ongentys 50 mg. Follow the instructions that your doctor has given you.

Do not exceed the recommended dose

Method of administration
Ongentys 50 mg is intended for oral administration. Swallow the capsule whole, with a glass of water.

If you have accidentally taken a higher dose
If you take Ongentys 50 mg at a higher quantity than required, or if a child has accidentally swallowed some medicine, immediately contact a doctor or pharmacist, or go to the hospital and bring the medicine package with you. This will help the doctor identify the medicine you took.

If you forget to take the medicine
If you forget to take one dose, you should continue the treatment and take the next dose as scheduled. Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment as recommended by your doctor. Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop taking this medicine
Do not stop taking Ongentys 50 mg unless your doctor tells you to as your symptoms may get worse. If you stop taking Ongentys 50 mg your doctor may need to adjust the dose of other medicines that you are taking to treat Parkinson's disease.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them. If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Ongentys 50 mg may cause side effects in some users.
Do not be alarmed by reading the list of side effects, you may not suffer from any of them.

Side effects caused by Ongentys 50 mg are usually mild to moderate and occur mostly within the first weeks of treatment. Some side effects may be caused by the increased effects of using Ongentys 50 mg together with levodopa.

Contact your doctor straight away if you experience any side effects at the start of treatment. Many of the side effects can be managed by your doctor adjusting your levodopa medicine.

Contact your doctor as soon as possible if you notice any of the following side effects:

Very common side effects: occurring in more than one in ten users
- involuntary and uncontrollable, or difficult or painful body movements

Common side effects: occurring in 1-10 in 100 users
- constipation
- dry mouth
- nausea
- vomiting
- increased levels of the enzyme creatine kinase in your blood
- muscle spasm
- dizziness
- headache
- sleepiness
- difficulty falling or staying asleep
- strange dreams

- seeing or experiencing things which do not exist (hallucinations)
- a fall in blood pressure on standing up which causes dizziness or fainting.

Uncommon side effects: occurring in 1-10 in 1,000 users
- palpitations or irregular heartbeat
- blocked ear
- dry eye
- pain or swelling of the abdomen
- indigestion
- weight loss
- loss of appetite
- increased levels of triglycerides (fats) in your blood
- muscle twitching, stiffness or pain
- pain in arms or legs
- altered sense of taste
- excessive body movements
- fainting
- anxiety
- depression
- hearing things which do not exist
- nightmares
- sleep disorder
- abnormal colour of urine
- need to wake and pass urine at night
- shortness of breath
- high or low blood pressure
- falls
- feeling low in energy or tired

If you experience any side effect, if any side effect gets worse or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
Storage conditions:
There are no special storage conditions. It is recommended to store at room temperature.
Keep in the original blister in order to protect from moisture.

6. Additional information

In addition to the active ingredient, this medicine also contains:
lactose monohydrate, sodium starch glycolate (Type A), pregelatinized starch and magnesium stearate.

The capsule shell contains:
gelatine, titanium dioxide (E 171), indigo carmine aluminium lake (E 132), erythrosine (E 127) and printing ink (shellac galze, titanium dioxide (E 171), propylene glycol, ammonia solution, simethicone).

What the medicine looks like and contents of the pack:
Dark blue hard capsules. 19 mm length, with “OPC 50” and “Bial” printed on them.
The capsules are packaged in blisters
The packs contain 10, 30 or 90 capsules.
Not all pack sizes may be marketed.

Registration holder’s name and address:
Truemed Ltd., 10 Beni Gaon St., Poleg Industrial Park, P.O. Box 8105, Netanya 4250499

Manufacturer’s name and address:
BIAL - Portela & Cª, S.A., À Av. da Siderurgia Nacional 4745-457 S. Mamede do Coronado, Portugal

Revised in September 2024

Registration number of the medicine in the Ministry of Health’s National Drug Registry: 170-17-37081

PL-1060 02-09.24