○ Carton	● PIL	○ Label	○ Cliché
Part No:	12030497	**Version:**	3
Part Description:	ONGENTYS 50,FOLHETO INFORM (DE/EN - AT/DE/IE/UK)-Insert		
Laetus Code:	497		
Dimension:	626x316 mm		
Colours:	● Pantone 281		
Total:	1		
Date:	2024.10.08		
		Proof number:	5

FIBER ORIENTATION

Ongentys

Package leaflet: Information for the patient

Ongentys 50 mg hard capsules
opicapone

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

1. What Ongentys is and what it is used for

Ongentys contains the active substance opicapone. It is used to treat Parkinson's disease and associated movement problems. Parkinson's disease is a progressive disease of the nervous system that causes shaking and affects your movement.

Ongentys is for use in adults who are already taking medicines containing levodopa and DOPA decarboxylase inhibitors. It increases the effects of levodopa and helps to relieve the symptoms of Parkinson's disease and movement problems.

2. What you need to know before you take Ongentys

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

Warnings and precautions
Talk to your doctor or pharmacist before taking Ongentys:
- 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 Parkinsons´s disease.
Your doctor may need to review your treatments.

Children and adolescents
Children and adolescents under the age of 18 years must not take this medicine. It has not been studied in these age groups since treatment of Parkinson's disease is not relevant in children and adolescents.

Other medicines and Ongentys
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking:
- medicines for depression or anxiety such as venlafaxine, maprotiline and desipramine. Taking Ongentys 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 and safinamide together. Your doctor may need to adjust your treatment;
- medicines to treat asthma such as rimiterole or isoprenaline. Ongentys may increase their effect;
- medicines used to treat allergic reactions such as adrenaline. Ongentys may increase their effect;
- medicines used to treat heart failure such as dobutamine, dopamine or dopexamine. Ongentys may increase their effects;
- medicines for high cholesterol such as rosuvastatin, simvastatin, atorvastatin or pravastatin Ongentys may increase their effects;
- medicines that affect the **immune system** such as methotrexate. Ongentys may increase its effect
- medicines containing **quinidine,** a medicine used to treat abnormal heart rhythms or malaria. Taking Ongentys and quinidine together, i.e. at the same time, may decrease the effect of Ongentys.

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

Ongentys is not recommended if you are pregnant. You should use effective contraception if you might become pregnant.

It is not known if Ongentys passes into breast milk in humans. Since the risk to the baby/infant cannot be excluded, you should stop breast-feeding during treatment with Ongentys.

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

Ongentys contains lactose and sodium
- Lactose: If you have been told by your doctor that you have 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 take Ongentys

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

The recommended dose is 50 mg once daily.

Ongentys should be taken preferably at bedtime.

Take Ongentys 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. Follow the instructions that your doctor has given you.

Method of administration
Ongentys is for oral use.

Swallow the capsule whole with a glass of water.

If you take more Ongentys than you should
If you take more Ongentys than you should, tell your doctor or pharmacist, or go to a hospital immediately. Take the medicine package and this leaflet with you. This will help the doctor identify what you have taken.

If you forget to take Ongentys
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.

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

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.

Side effects caused by Ongentys 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 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.

Tell your doctor as soon as possible if you notice any of the following side effects: Very common: may affect more than 1 in 10 people
- involuntary and uncontrollable, or difficult or painful body movements

Common: may affect up to 1 in 10 people
- constipation
- dry mouth
- feeling sick (nausea)
- vomiting (being sick)
- increased levels of the enzyme (creatine kinase) in your blood
- muscle spasm
- dizziness
- headache
- sleepiness
- difficulty falling or staying asleep
- strange dreams
- experiencing or seeing things which do not exist (hallucinations)
- a fall in blood pressure on standing up which causes dizziness, light-headedness or fainting

Uncommon: may affect up to 1 in 100 people
- 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
- feeling confused
- nightmares
- sleep disorder
- abnormal colour of urine
- need to wake and pass urine at night
- shortness of breath
- high or low blood pressure
- having falls
- feeling low in energy or tired

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:

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

United Kingdom
Yellow Card Scheme Website:
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ongentys

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 bottle/blister/carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions. Blisters: Store in the original blister in order to protect from moisture.
Bottles: Keep the bottle tightly closed in order to protect from moisture.

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 Ongentys contains
- The active substance is opicapone. Each hard capsule contains 50 mg of opicapone.
- The other ingredients are:
  - capsule content: lactose monohydrate, sodium starch glycolate (Type A), pregelatinized maize starch and magnesium stearate
  - capsule shell: gelatine, indigo carmine aluminium lake (E 132), erythrosine (E 127) and titanium dioxide (E 171)
  - printing ink: shellac, titanium dioxide (E 171), propylene glycol, ammonia solution, concentrated, simeticone

What Ongentys looks like and contents of the pack
Ongentys 50 mg hard capsules are dark blue, approximately 19 mm length, with "OPC 50" and "Bial" printed on the capsules.

The capsules are packaged in bottles or blisters.

Bottles: 10, 30 or 90 capsules.
Blisters: 10, 30 or 90 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Bial - Portela & Cª, S.A.
À Av. da Siderurgia Nacional
4745-457 S. Mamede do Coronado
Portugal
tel: +351 22 986 61 00
fax: +351 22 986 61 90
e-mail: info@bial.com

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Ireland
BIAL - Portela & Cª, S.A.
Tel.: + 351 22 986 61 00

United Kingdom
BIAL - Portela & Cª, S.A.
Tel.: + 351 22 986 61 00

This leaflet was last revised in April 2025.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

12030497.3

Bial
À Av. da Siderurgia Nacional
4745-457 S. Mamede do Coronado
PORTUGAL

Ongentys

Ongentys 50 mg hard capsules
opicapone

Ongentys 50 mg Hartkapseln
Opicapon