

Package leaflet: Information for the patient

Levodopa/Carbidopa/Entacapone Mylan 50 mg/12.5 mg/200 mg film-coated tablets
Levodopa/Carbidopa/Entacapone Mylan 75 mg/18.75 mg/200 mg film-coated tablets
Levodopa/Carbidopa/Entacapone Mylan 100 mg/25 mg/200 mg film-coated tablets
Levodopa/Carbidopa/Entacapone Mylan 125 mg/31.25 mg/200 mg film-coated tablets
Levodopa/Carbidopa/Entacapone Mylan 150 mg/37.5 mg/200 mg film-coated tablets
Levodopa/Carbidopa/Entacapone Mylan 175 mg/43.75 mg/200 mg film-coated tablets
Levodopa/Carbidopa/Entacapone Mylan 200 mg/50 mg/200 mg film-coated tablets

levodopa/carbidopa/entacapone

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

1. What Levodopa/Carbidopa/Entacapone Mylan is and what it is used for

Levodopa/Carbidopa/Entacapone Mylan contains three active substances (levodopa, carbidopa and entacapone) in one film-coated tablet. Levodopa/Carbidopa/Entacapone Mylan is used for the treatment of Parkinson's disease.

Parkinson's disease is caused by low levels of a substance called dopamine in the brain. Levodopa increases the amount of dopamine and hence reduces the symptoms of Parkinson's disease. Carbidopa and entacapone improve the antiparkinson effects of levodopa.

2. What you need to know before you take Levodopa/Carbidopa/Entacapone Mylan

Do not take Levodopa/Carbidopa/Entacapone Mylan if you:

- are allergic to levodopa, carbidopa, entacapone, or any of the other ingredients of this medicine (listed in section 6)
- have narrow-angle glaucoma (an eye disorder)
- have a tumour of the adrenal gland
- are taking certain medicines for treating depression (combinations of selective MAO-A and MAO-B inhibitors, or non-selective MAO-inhibitors e.g. phenelzine, tranylcypromine)
- have ever had neuroleptic malignant syndrome (NMS – this is a rare reaction to medicines used to treat severe mental disorders)

- have ever had non-traumatic rhabdomyolysis (a rare muscle disorder)
- have a severe liver disease.

Warnings and precautions

Talk to your doctor or pharmacist before taking Levodopa/Carbidopa/Entacapone Mylan if you have or have ever had:

- a heart attack or any other diseases of the heart including cardiac arrhythmias, or of the blood vessels
- asthma or any other disease of the lungs
- a liver problem, because your dose may need to be adjusted
- kidney or hormone-related diseases
- stomach ulcers or convulsions
- any form of serious mental health issues like psychosis
- chronic wide-angle glaucoma, because your dose may need to be adjusted and the pressure in your eyes may need to be monitored.

Consult your doctor if you are currently taking:

- antipsychotics (medicines used to treat psychosis)
- a medicine which may cause low blood pressure when rising from a chair or bed. You should be aware that Levodopa/Carbidopa/Entacapone Mylan may make these reactions worse.

Consult your doctor if during the treatment with Levodopa/Carbidopa/Entacapone Mylan you:

- notice that your muscles get very rigid or jerk violently, or if you get tremors, agitation, confusion, fever, rapid pulse, or wide fluctuations in your blood pressure. If any of this happens, **contact your doctor immediately**
- feel depressed, have suicidal thoughts, or notice unusual changes in your behaviour
- find yourself suddenly falling asleep, or if you feel very drowsy. If this happens, you should not drive or use any tools or machines (see also section 'Driving and using machines')
- notice that uncontrolled movements begin or get worse after you started to take Levodopa/Carbidopa/Entacapone Mylan. If this happens, your doctor may need to change the dose of your antiparkinson medicine
- experience diarrhoea: monitoring of your weight is recommended in order to avoid potentially excessive weight loss
- if you experience prolonged diarrhoea consult your doctor as it may be a sign of inflammation of the colon
- experience progressive anorexia (loss of appetite), asthenia (weakness, exhaustion) and weight decrease within a relatively short period of time. This may be a sign of problems with your liver and your doctor may wish to carry out tests.
- feel the need to stop using Levodopa/Carbidopa/Entacapone Mylan, see section 'If you stop taking Levodopa/Carbidopa/Entacapone Mylan'.

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 a preoccupation with an increase in sexual thoughts or feelings. Your doctor may need to review your treatments.

Your doctor may take some regular laboratory tests during a long term treatment with Levodopa/Carbidopa/Entacapone Mylan.

If you must undergo surgery, please tell your doctor that you are using Levodopa/Carbidopa/Entacapone Mylan.

Levodopa/Carbidopa/Entacapone Mylan is not recommended to be used for treatment of extrapyramidal symptoms (e.g. involuntary movements, shaking, muscle rigidity and muscle contractions) caused by other medicines.

Children and adolescents

Experience with levodopa/carbidopa/entacapone in patients under 18 years is limited. Therefore, the use of Levodopa/Carbidopa/Entacapone Mylan in children is not recommended.

Other medicines and Levodopa/Carbidopa/Entacapone Mylan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription and herbal medicines.

Do not take Levodopa/Carbidopa/Entacapone Mylan if you are taking certain medicines for treating depression (combinations of selective MAO-A and MAO-B inhibitors, or non-selective MAO inhibitors e.g. phenelzine, tranylcypromine) (see above “Do not take Levodopa/Carbidopa/Entacapone Mylan if you”).

Levodopa/carbidopa/entacapone may increase the effects and side effects of certain medicines. These include:

- medicines used to treat depression such as moclobemide, amitryptiline, desipramine, maprotiline, venlafaxine and paroxetine
-
- medicines used to treat high blood pressure

The effects of levodopa/carbidopa/entacapone may be weakened by certain medicines. These include:

- dopamine antagonists used to treat mental health conditions, or prevent nausea (feeling sick) and vomiting (being sick)
- phenytoin, used to prevent convulsions
- papaverine used to relax the muscles.

Levodopa/carbidopa/entacapone may make it harder for you to digest iron. Therefore, do not take Levodopa/Carbidopa/Entacapone Mylan and iron supplements at the same time. After taking one of them, wait at least 2 to 3 hours before taking the other.

Levodopa/Carbidopa/Entacapone Mylan with food and drink

For some patients, levodopa/carbidopa/entacapone may not be well absorbed if it is taken with, or shortly after eating protein-rich food (such as meats, fish, dairy products, seeds and nuts). Consult your doctor if you think this applies to you.

Pregnancy and breast-feeding

Pregnancy

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

Levodopa/Carbidopa/Entacapone Mylan is not recommended during pregnancy unless the benefits for the mother outweigh the possible risks to the baby.

Breast-feeding

You should not breast-feed during treatment with Levodopa/Carbidopa/Entacapone Mylan.

Driving and using machines

Levodopa/carbidopa/entacapone may lower your blood pressure, which may make you feel light-headed or dizzy. Therefore, be particularly careful when you drive or when you use any tools or machines.

If you feel very drowsy, or if you sometimes find yourself suddenly falling asleep, wait until you feel fully awake again before driving or doing anything else that requires you to be alert. Otherwise, you may put yourself and others at risk of serious injury or death.

Levodopa/Carbidopa/Entacapone Mylan contains lactose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Levodopa/Carbidopa/Entacapone Mylan

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

For adults and elderly:

- Your doctor will tell you exactly how many tablets of Levodopa/Carbidopa/Entacapone Mylan to take each day.
- The tablets are not intended to be split or broken into smaller pieces.
- You should take only one tablet each time.
- Depending on how you respond to treatment, your doctor may suggest a higher or lower dose.
- Levodopa/Carbidopa/Entacapone Mylan may be taken with or without food. For some patients, this medicine may not be well absorbed if it is taken with, or shortly after eating protein-rich food (see section 2 “Levodopa/Carbidopa/Entacapone Mylan with food and drink”).
- If you are taking Levodopa/Carbidopa/Entacapone Mylan 50 mg/12.5 mg/200 mg, 75 mg/18.75 mg/200 mg, 100 mg/25 mg/200 mg, 125 mg/31.25 mg/200 mg or 150 mg/37.5 mg/200 mg tablets, do not take more than 10 tablets per day.
 - If you are taking Levodopa/Carbidopa/Entacapone Mylan 175 mg/43.75 mg/200 mg tablets, do not take more than 8 tablets per day.
 - If you are taking Levodopa/Carbidopa/Entacapone Mylan 200 mg/50 mg/200 mg tablets, do not take more than 7 tablets per day.

Talk to your doctor or pharmacist if you think the effect of Levodopa/Carbidopa/Entacapone Mylan is too strong or too weak, or if you experience possible side effects

If you take more Levodopa/Carbidopa/Entacapone Mylan than you should

If you have accidentally taken more Levodopa/Carbidopa/Entacapone Mylan tablets than you should, talk to your doctor or pharmacist immediately. In case of an overdose you may experience changes in your breathing, feel confused or agitated, your heart rate may be slower or faster than normal or the colour of your skin, tongue, eyes or urine may change.

If you forget to take Levodopa/Carbidopa/Entacapone Mylan

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

If it is more than 1 hour until your next dose:

Take one tablet as soon as you remember, and the next tablet at the normal time.

If it is less than 1 hour until your next dose:

Take a tablet as soon as you remember, wait 1 hour, then take another tablet. After that carry on as normal.

Always leave at least an hour between Levodopa/Carbidopa/Entacapone Mylan tablets, to avoid possible side effects.

If you stop taking Levodopa/Carbidopa/Entacapone Mylan

Do not stop taking Levodopa/Carbidopa/Entacapone Mylan unless your doctor tells you to. In such a case your doctor may need to adjust your other antiparkinson medicines, especially levodopa, to give sufficient control of your symptoms. If you suddenly stop taking Levodopa/Carbidopa/Entacapone Mylan and other antiparkinsonian medicines it may result in unwanted side effects.

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. If you experience any of these side effects, talk to your doctor as soon as possible. Many of the side effects can be relieved by adjusting the dose.

If you during the treatment with Levodopa/Carbidopa/Entacapone Mylan you experience the following symptoms, **contact your doctor immediately or go to the nearest hospital casualty department straight away:**

Common (may affect up to 1 in 10 people)

- heart condition which can cause chest pain (angina pectoris), shortness of breath and swelling of the feet or legs due to fluid retention

Uncommon (may affect up to 1 in 100 people)

- heart attack. You may experience severe chest pain, tingling or feeling clammy
- bleeding in the gut. You may become sick and notice blood or you pass stools which are bloody or black

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

- serious allergic reaction, the signs may include hives (nettle rash), itching, rash, swelling of your face, lips, tongue or throat. This may cause difficulties in breathing or swallowing.

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

- your muscles get very rigid or jerk violently, you get tremors, agitation, confusion, fever, rapid pulse, or wide fluctuations in your blood pressure or red-brown discoloration of the urine due to destruction of muscle fibres. These can be symptoms of neuroleptic malignant syndrome (NMS, a rare severe reaction to medicines used to treat disorders of the central nervous system) or rhabdomyolysis (a rare severe muscle disorder).
- fits (convulsions)
- suicidal thoughts or behaviour

Tell your doctor straight away, if you experience any of the following:

Common (may affect up to 1 in 10 people)

- suddenly falling asleep
- depression

Uncommon (may affect up to 1 in 100 people)

- severe mental condition in which you lose contact with reality and is unable to think and judge clearly
- difficulty passing urine or emptying the bladder

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

- yellowing of the whites of the eyes or skin, dark urine, pale coloured bowel movements, itching due to problems with your liver
- inability to resist the impulse to perform an action that could be harmful, which may include:
 - strong impulse to gamble excessively despite serious or personal 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.

Other possible side effects

Very common (may affect more than 1 in 10 people)

- uncontrolled movements (dyskinesias)
- feeling sick (nausea)
- harmless reddish-brown discolouration of urine
- muscle pain
- diarrhoea

Common (may affect up to 1 in 10 people)

- light-headedness or fainting due to low blood pressure, high blood pressure
- worsening of Parkinson's symptoms, such as slow or instable movement, shaking, uncontrollable muscle spasms affecting the eyes, head, neck and body, loss of memory
- dizziness, drowsiness
- vomiting, abdominal pain and discomfort, heartburn, dry mouth, constipation,
- inability to sleep
- seeing, feeling or hearing things that are not there (hallucinations), confusion, abnormal dreams (including nightmares)
- tiredness or unusual weakness
- mental changes – including problems with memory and anxiety irregular heart rate or rhythm
- more frequent falling
- shortness of breath
- increased sweating
- rash
- muscle cramps
- swelling of legs

- disturbances in the manner of walking
- blurred vision
- a reduction in the number of red blood cells (anaemia)
- decreased appetite, decreased weight
- headache
- joint pain
- urinary tract infection

Uncommon (may affect up to 1 in 100 people)

- changes in the blood cell count which may result in bleeding or bruising for longer than normal or unexpectedly due to reduced number of platelets, abnormal liver function tests seen in a blood test
- feeling agitated
- inflammation of the colon (colitis) which may cause persistent stomach cramps and diarrhoea
- discolourations other than urine (e.g. skin, nail, hair, sweat)
- swallowing difficulties
- generally feeling unwell

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

- itchy red rash

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Levodopa/Carbidopa/Entacapone Mylan

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 and the carton after EXP.

The expiry date refers to the last day of that month.

Shelf life after first opening the container: 3 months

Store below 25°C.

Only for blistered product: Store in the original package in order to protect from moisture

Only for bottle product: Store in the original packaging and 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 Levodopa/Carbidopa/Entacapone Mylan contains

- The active substances are levodopa, carbidopa and entacapone.
- Each film-coated tablet contains 50 mg of levodopa, 12.5 mg of carbidopa anhydrous (as 13.5 mg carbidopa monohydrate) and 200 mg of entacapone.
- Each film-coated tablet contains 75 mg of levodopa, 18.75 mg of carbidopa anhydrous (as 20.24 mg carbidopa monohydrate) and 200 mg of entacapone.
- Each film-coated tablet contains 100 mg of levodopa, 25 mg of carbidopa anhydrous (as 27 mg carbidopa monohydrate) and 200 mg of entacapone.
- Each film-coated tablet contains 125 mg of levodopa, 31.25 mg of carbidopa anhydrous (as 33.74 mg carbidopa monohydrate) and 200 mg of entacapone.
- Each film-coated tablet contains 150 mg of levodopa, 37.5 mg of carbidopa anhydrous (as 40.48 mg carbidopa monohydrate) and 200 mg of entacapone.
- Each film-coated tablet contains 175 mg of levodopa, 43.75 mg of carbidopa anhydrous (as 47.23 mg carbidopa monohydrate) and 200 mg of entacapone.
- Each film-coated tablet contains 200 mg of levodopa, 50 mg of carbidopa anhydrous (as 54 mg carbidopa monohydrate) and 200 mg of entacapone.
- The other ingredients in the tablet core are croscarmellose sodium E 468, cellulose microcrystalline E 460, poloxamer 188, hydroxypropyl cellulose E 463, lactose monohydrate, magnesium stearate E470b.
- The ingredients in the film-coating are

50mg/12.5mg/200mg; 100mg/25mg/200mg; 150mg/37.5mg/200mg:

Hypromellose, type 2910, Titanium Dioxide E 171, Glycerol E 422, Red Iron Oxide E172, Yellow Iron Oxide E172, Magnesium Stearate E 470b, Polysorbate 80 E433, Hydroxypropyl cellulose E 463.

75mg/18.75mg/200mg; 125mg/31.25mg/200mg; 175mg/43.75mg/200mg:

Hypromellose, type 2910, Titanium Dioxide E 171, Glycerol E 422, Red Iron Oxide E172, Magnesium Stearate E 470b, Polysorbate 80 E433, Hydroxypropyl cellulose E 463.

200mg/50mg/200mg:

Hypromellose, type 2910, Titanium Dioxide E 171, Glycerol E 422, Red Iron Oxide E172, Magnesium Stearate E 470b, Polysorbate 80 E433, Hydroxypropyl cellulose E 463.

What Levodopa/Carbidopa/Entacapone Mylan looks like and contents of the pack

Levodopa/Carbidopa/Entacapone Mylan 50 mg/12.5 mg/200 mg: brownish red coloured, round shaped, biconvex, film-coated tablets debossed “50” on one side and plain on the other side.

Levodopa/Carbidopa/Entacapone Mylan 75 mg/18.75 mg/200mg: light brownish red coloured, oval shaped, biconvex, film coated tablets debossed “75” on one side and plain on the other side.

Levodopa/Carbidopa/Entacapone Mylan 100 mg/25 mg/200 mg: brownish red coloured, oval, shaped, biconvex, film-coated tablets debossed “100” on one side and plain on the other side.

Levodopa/Carbidopa/Entacapone Mylan 125 mg/31.25 mg/200 mg: light brownish red coloured, oval shaped, biconvex, film-coated tablets debossed “125” on one side and plain on the other side.

Levodopa/Carbidopa/Entacapone Mylan 150 mg/37.5 mg/200 mg: brownish red coloured, oval shaped, biconvex, film-coated tablets debossed “150” on one side and plain on the other side.

Levodopa/Carbidopa/Entacapone Mylan 175 mg/43.75 mg/200 mg: light brownish red coloured, oval shaped, biconvex, film-coated tablets debossed “175” on one side and plain on the other side.

Levodopa/Carbidopa/Entacapone Mylan 200 mg/50 mg/200 mg: dark brownish red coloured, oval shaped, biconvex, film-coated tablets debossed “200” on one side and plain on the other side.

Levodopa/Carbidopa/Entacapone Mylan comes in different pack sizes as HDPE bottle with an Aluminium Induction Seal-Cap and Silica Gel Canister (as a loose component) in the HDPE bottle and Blister (Aluminium-Aluminium) containing 30 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Generics [UK] Limited, Station Close, Potters Bar, Hertfordshire EN6 1TL, United Kingdom.

Manufacturers

Wessling Hungary Kft., Budapest, Fóti út. 56, 1047, Hungary.

Mylan Hungary Kft., Mylan utca 1, Komárom, H-2900, Hungary.

This medicinal product is authorised in the Member States of the EEA under the following names:

Czech Republic	LEVODOPA/CARBIDOPA/ENTACAPONE MYLAN 50 mg/12,5 mg/200 mg, 100 mg/25 mg/200 mg, 150 mg/37,5 mg/200 mg, 200 mg/50 mg/200 mg potahované tablety
France	Levodopa/Carbidopa/Entacapone Mylan 50 mg/12.5 mg/200 mg, 75 mg/18.75 mg/200 mg, 100 mg/25 mg/200 mg, 125 mg/31.25 mg/200 mg, 150 mg/37.5 mg/200 mg, 175 mg/43.75 mg/200 mg, 200 mg/50 mg/200 mg filmomhulde tabletten
Greece	LEVODOPA/CARBIDOPA/ENTACPONE Mylan 50 mg/12.5 mg/200 mg, 75 mg/18.75 mg/200 mg, 100 mg/25 mg/200 mg, 125 mg/31.25 mg/200 mg, 150 mg/37.5 mg/200 mg, 200 mg/50 mg/200 mg film-coated tablets
Ireland	Levodopa/Carbidopa/Entacapone Mylan 50 mg/12.5 mg/200 mg, 75 mg/18.75 mg/200 mg, 100 mg/25 mg/200 mg, 125 mg/31.25 mg/200 mg, 150 mg/37.5 mg/200 mg, 175 mg/43.75 mg/200 mg, 200 mg/50 mg/200 mg film-coated tablets
Italy	LEVODOPA/CARBIDOPA/ENTACPONE MYLAN
Slovakia	Levodopa/Carbidopa/Entacapone Mylan 50 mg/12.5 mg/200 mg, 100 mg/25 mg/200 mg, 150 mg/37.5 mg/200 mg
Spain	LEVODOPA/CARBIDOPA/ENTACPONA Mylan 50 mg/12.5 mg/200 mg, 75 mg/18.75 mg/200 mg, 100 mg/25 mg/200 mg, 125 mg/31.25 mg/200 mg, 150 mg/37.5 mg/200 mg, 200 mg/50 mg/200 mg comprimidos recubiertos
The Netherlands	Levodopa/Carbidopa/Entacapone Mylan 50 mg/12.5 mg/200 mg, 75 mg/18.75 mg/200 mg, 100 mg/25 mg/200 mg, 125 mg/31.25 mg/200 mg, 150 mg/37.5 mg/200 mg, 175 mg/43.75 mg/200 mg, 200 mg/50 mg/200 mg filmomhulde tabletten
United Kingdom	Levodopa/Carbidopa/Entacapone Mylan 50 mg/12.5 mg/200 mg, 75 mg/18.75 mg/200 mg, 100 mg/25 mg/200 mg, 125 mg/31.25 mg/200 mg, 150 mg/37.5 mg/200 mg, 175 mg/43.75 mg/200 mg, 200 mg/50 mg/200 mg film-coated tablets

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