Package leaflet: information for the patient

Levodopa/Carbidopa/Entacapone Sandoz 50/12,5/200 mg, filmomhulde tabletten
Levodopa/Carbidopa/Entacapone Sandoz 75/18,75/200 mg, filmomhulde tabletten
Levodopa/Carbidopa/Entacapone Sandoz 100/25/200 mg, filmomhulde tabletten
Levodopa/Carbidopa/Entacapone Sandoz 125/31,25/200 mg, filmomhulde tabletten
Levodopa/Carbidopa/Entacapone Sandoz 150/37,5/200 mg, filmomhulde tabletten
Levodopa/Carbidopa/Entacapone Sandoz 175/43,75/200 mg, filmomhulde tabletten
Levodopa/Carbidopa/Entacapone Sandoz 200/50/200 mg, filmomhulde tabletten

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 symptoms 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 [nationally completed name] is and what it is used for

[Nationally completed name] contains three active substances (levodopa, carbidopa and entacapone) in one film-coated tablet. [nationally completed name] 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 [nationally completed name]

Do not take [nationally completed name] if you

- are allergic to levodopa, carbidopa or 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)

- 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 [nationally completed name] if you have or have ever had:
- a heart attack or any other diseases of the heart including cardiac arrythmias, 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
- if you experience prolonged diarrhoea consult your doctor as it may be a sign of inflammation of the colon
- any form of severe mental disorder 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 [nationally completed name] may make these reactions worse.

Consult your doctor if during the treatment with [nationally completed name] 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 [nationally completed name]. 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
- experience progressive anorexia, asthenia (weakness, exhaustion) and weight decrease within a relatively short period of time. If this happens, a general medical evaluation including liver function should be considered
- feel the need to stop using [nationally completed name], see section 'If you stop taking [nationally completed name]'.

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 [nationally completed name].
Tell your doctor if you or your family/carer notices you are developing addiction-like symptoms

leading to craving for large doses of [Nationally completed name] and other medicines used to treat Parkinson's disease.

If you must undergo surgery, please tell your doctor that you are using [nationally completed name].

[nationally completed name] 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 [nationally completed name] in patients under 18 years is limited. Therefore, the use of [nationally completed name] in children is not recommended.

Other medicines and [Nationally completed name]
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 [nationally completed name] if you are taking certain medicines for treating depression (combinations of selective MAO-A and MAO-B inhibitors, or non-selective MAO inhibitors).

[nationally completed name] 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
- rimiterole and isoprenaline, used to treat respiratory diseases
- adrenaline, used for severe allergic reactions
- noradrenaline, dopamine and dobutamine, used to treat heart diseases and low blood pressure
- alpha-methyldopa, used to treat high blood pressure
- apomorphine, which is used to treat Parkinson's disease.

The effects of [nationally completed name] may be weakened by certain medicines. These include:
- dopamine antagonists used to treat mental disorders, nausea and vomiting
- phenytoin, used to prevent convulsions
- papaverine used to relax the muscles.

[Nationally completed name] may make it harder for you to digest iron. Therefore, do not take [nationally completed name] and iron supplements at the same time. After taking one of them, wait at least 2 to 3 hours before taking the other.

[Nationally completed name] with food and drink

[nationally completed name] may be taken with or without food. For some patients, [nationally completed name] 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, breast-feeding and fertility

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.

You should not breast-feed during treatment with [nationally completed name].

Driving and using machines

[Nationally completed name] 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.

[Nationally completed name] **contains lactose and sodium**

This medicine contains milk sugar (lactose). If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol (23 mg) sodium per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take [nationally completed name]

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 [nationally completed name] 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.
- If you are taking [nationally completed name] 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 [nationally completed name] 175mg/43.75mg/200mg tablets, do not take more than 8 tablets per day.
  - If you are taking [nationally completed name] 200 mg/50 mg/200mg tablets, do not take more than 7 tablets per day.

Talk to your doctor or pharmacist if you think the effect of [nationally completed name] is too strong or too weak, or if you experience possible side effects

If you take more [nationally completed name] than you should

If you have accidentally taken more [nationally completed name] tablets than you should, talk to your doctor or pharmacist immediately. In case of an overdose you may 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 [nationally completed name]

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 [nationally completed name] tablets, to avoid possible side effects.

If you stop taking [nationally completed name]

Do not stop taking [nationally completed name] 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 [nationally completed name] 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 [nationally completed name] experience the following symptoms, **contact your doctor immediately**:
- Your muscles get very rigid or jerk violently, you get tremors, agitation, confusion, fever, rapid pulse, or wide fluctuations in your blood pressure. 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).
- 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.

Very common (may affect more than 1 in 10 people)
- uncontrolled movements (dyskinesias)
- feeling sick (nausea)
- harmless reddish-brown discouloration 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, dizziness, drowsiness
- vomiting, abdominal pain and discomfort, heartburn, dry mouth, constipation
- inability to sleep, hallucinations, confusion, abnormal dreams (including nightmares), tiredness
- mental changes – including problems with memory, anxiety and depression (possibly with thoughts of suicide)
- heart or artery disease events (e.g. chest pain), irregular heart rate or rhythm
- more frequent falling
- shortness of breath

- increased sweating, rashes
- muscle cramps, swelling of legs
- blurred vision
- anaemia
- decreased appetite, decreased weight
- headache, joint pain
- urinary tract infection

Uncommon (may affect up to 1 in 100 people)
- heart attack
- bleeding in the gut
- changes in the blood cell count which may result in bleeding, abnormal liver function tests
- convulsions
- feeling agitated
- psychotic symptoms
- colitis (inflammation of the colon)
- discolourations other than urine (e.g. skin, nail, hair, sweat)
- swallowing difficulties
- inability to urinate

Not known (cannot be estimated from the available data)":
- Craving for large doses of [nationally completed name] in excess of that required to control motor symptoms, known as dopamine dysregulation syndrome. Some patients experience severe abnormal involuntary movements (dyskinesias), mood swings or other side effects after taking large doses of [nationally completed name].

The following side effects have also been reported:
- hepatitis (inflammation of the liver)
- itching

You may experience the following side effects:
- 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.

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 [nationally completed 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, bottle and the carton after "EXP".
The expiry date refers to the last day of that month.

Store below 25°C.
Only for blistered product:
Store in the original packaging in order to protect from moisture

Only for bottle product:
Storage conditions after first opening of the bottle:
Store in the original packaging and keep the bottle tightly closed in order to protect from moisture.

Shelf life after first opening:
Bottles: 3 months

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 to protect the environment.

6. Contents of the pack and other information

What [nationally completed name] 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 13.5mg 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.

50mg/12.5mg/200mg; 100mg/25mg/200mg; 150mg/37.5mg/200mg film coated tablets:
- The other ingredients are croscarmellose sodium (E 468), cellulose microcrystalline (E 460), poloxamer 188, hydroxypropyl cellulose (E 463), lactose monohydrate, magnesium stearate (E 470b) in the tablet core and hypromellose, type 2910, titanium Dioxide (E 171), glycerol (E 422), red iron oxide (E 172), yellow iron oxide (E 172), magnesium stearate (E 470b), polysorbate 80 (E 433), hydroxypropyl cellulose (E 463) in the film-coating.

75mg/18.75mg/200mg; 125mg/31.25mg/200mg; 175mg/43.75mg/200mg; 200mg/50mg/200mg film coated tablets:

- The other ingredients are croscarmellose sodium (E 468), cellulose microcrystalline (E 460), poloxamer 188, hydroxypropyl cellulose (E 463), lactose monohydrate, magnesium stearate (E 470b) in the tablet core and hypromellose, type 2910, titanium Dioxide (E 171), glycerol (E 422), red iron oxide (E 172), magnesium stearate (E 470b), polysorbate 80 (E 433), hydroxypropyl cellulose (E 463) in the film-coating.

What [nationally completed name] looks like and contents of the pack

50 mg/12.5 mg/200 mg film-coated tablets:
Brownish red coloured, round shaped, biconvex, film-coated tablets debossed `50' on one side and plain on the other side.

75 mg/18.75 mg/200mg film-coated tablets:
Light brownish red coloured, oval shaped, biconvex, film coated tablets debossed "75" on one side and plain on the other side.

100 mg/25 mg/200 mg film-coated tablets:
Brownish red coloured, oval, shaped, biconvex, film-coated tablets debossed `100' on one side and plain on the other side.

125 mg/31.25 mg/200 mg film-coated tablets:
Light brownish red coloured, oval shaped, biconvex, film-coated tablets debossed `125' on one side and plain on the other side.

150 mg/37.5 mg/200 mg *film-coated tablets*:
Brownish red coloured, oval shaped, biconvex, film-coated tablets debossed `150' on one side and plain on the other side.

175 mg/43.75 mg/200 mg *film-coated tablets*:
Light brownish red coloured, oval shaped, biconvex ,film-coated tablets debossed `175' on one side and plain on the other side.

200 mg/50 mg/200 mg *film-coated tablets*:
Dark brownish red coloured, oval shaped, biconvex, film-coated tablets debossed `200' on one side and plain on the other side.

The film-coated tablets are packed in OPA/Alu/PVC/Alu blisters or are packed in a HDPE bottle with an Aluminium Induction Seal Cap and Silica Gel Canister (as a loose component) in the bottle and inserted in a carton.

Pack sizes:
NL/H/3399/001-007:
Blister: 30 or 100 film-coated tablets.
Bottle: 30, 100 or 130 film-coated tablets

NL/H/3400-3401/001-007:
Blister: 30 film-coated tablets

Bottle: 30, 100 or 175 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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39179 Barleben
Duitsland

In het register ingeschreven onder:
Levodopa/Carbidopa/Entacapone Sandoz 50/12,5/200 mg, filmomhulde tabletten - RVG 116859
Levodopa/Carbidopa/Entacapone Sandoz 75/18,75/200 mg, filmomhulde tabletten - RVG 116860
Levodopa/Carbidopa/Entacapone Sandoz 100/25/200 mg, filmomhulde tabletten - RVG 116861
Levodopa/Carbidopa/Entacapone Sandoz 125/31,25/200 mg, filmomhulde tabletten - RVG 116862
Levodopa/Carbidopa/Entacapone Sandoz 150/37,5/200 mg, filmomhulde tabletten - RVG 116863
Levodopa/Carbidopa/Entacapone Sandoz 175/43,75/200 mg, filmomhulde tabletten - RVG 116864
Levodopa/Carbidopa/Entacapone Sandoz 200/50/200 mg, filmomhulde tabletten - RVG 116865

This medicinal product is authorised in the Member States of the EEA under the following names:
Nederland
Levodopa/Carbidopa/Entacapone Sandoz 50/12,5/200 mg, filmomhulde tabletten
Levodopa/Carbidopa/Entacapone Sandoz 75/18,75/200 mg, filmomhulde tabletten
Levodopa/Carbidopa/Entacapone Sandoz 100/25/200 mg, filmomhulde tabletten
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Levodopa/Carbidopa/Entacapone Sandoz 200/50/200 mg, filmomhulde tabletten

Duitsland
Levodopa/Carbidopa/Entacapon - 1 A Pharma 50 mg/12,5 mg/200 mg Filmtabletten
Levodopa/Carbidopa/Entacapon - 1 A Pharma 75 mg/18,75 mg/200 mg Filmtabletten
Levodopa/Carbidopa/Entacapon - 1 A Pharma 100 mg/25 mg/200 mg Filmtabletten
Levodopa/Carbidopa/Entacapon - 1 A Pharma 125 mg/31,25 mg/200 mg Filmtabletten
Levodopa/Carbidopa/Entacapon - 1 A Pharma 150 mg/37,5 mg/200 mg Filmtabletten
Levodopa/Carbidopa/Entacapon - 1 A Pharma 175 mg/43,75 mg/200 mg Filmtabletten
Levodopa/Carbidopa/Entacapon - 1 A Pharma 200 mg/50 mg/200 mg Filmtabletten

Deze bijsluiter is voor het laatst goedgekeurd in juni 2020