Package leaflet: Information for the patient

Levodopa/Carbidopa/Entacapone Holsten 50 mg/12.5 mg/200 mg film-coated tablets
Levodopa/Carbidopa/Entacapone Holsten 75 mg/18.75 mg/200 mg film-coated tablets
Levodopa/Carbidopa/Entacapone Holsten 100 mg/25 mg/200 mg film-coated tablets
Levodopa/Carbidopa/Entacapone Holsten 125 mg/31.25 mg/200 mg film-coated tablets
Levodopa/Carbidopa/Entacapone Holsten 150 mg/37.5 mg/200 mg film-coated tablets
Levodopa/Carbidopa/Entacapone Holsten 175 mg/43.75 mg/200 mg film-coated tablets
Levodopa/Carbidopa/Entacapone Holsten 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 <invented name> is and what it is used for

<invented name> contains three active substances (levodopa, carbidopa and entacapone) in one film-coated tablet. <invented 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 <invented name>

Do not take <invented name>:
- If you are allergic to levodopa, carbidopa or entacapone, or any of the other ingredients of this medicine (listed in section 6)
- If you have narrow-angle glaucoma (an eye disorder)
- If you have a tumour of the adrenal gland
- If you are taking certain medicines for treating depression (combinations of selective MAO-A and MAO-B inhibitors, or non-selective MAO-inhibitors)
- If you have ever had neuroleptic malignant syndrome (NMS – this is a rare reaction to medicines used to treat severe mental disorders)
- If you have ever had non-traumatic rhabdomyolysis (a rare muscle disorder)
- If you have a severe liver disease.

Warnings and precautions
Talk to your doctor or pharmacist before taking <invented 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 <invented name> may make these reactions worse.

Consult your doctor if during the treatment with <invented 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 <invented 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 <invented name>, see section 'If you stop taking <invented name>'.

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.

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 <invented name>.

If you must undergo surgery, please tell your doctor that you are using <invented name>.

<invented 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 levodopa/carbidopa/entacapone in patients under 18 years is limited. Therefore, the use of <invented name> in children is not recommended.

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

Do not take <invented name> if you are taking certain medicines for treating depression (combinations of selective MAO-A and MAO-B inhibitors, or non-selective MAO inhibitors).

<invented 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 <invented 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.

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

<invented name> with food and drink
<invented name> may be taken with or without food. For some patients, <invented 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 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.

You should not breast-feed during treatment with <invented name>.

Driving and using machines
<invented 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.

[50 mg/12.5 mg/200 mg, 75 mg/18.75 mg/200 mg, 125 mg/31.25 mg/200 mg, 175 mg/43.75 mg/200 mg and 200 mg/50 mg/200 mg]

<invented name> 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.

<invented name> 100 mg/25 mg/200 mg contains lactose and allura red (E129).
If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.
Allura red (E129) may cause allergic reactions.

<invented name> 150 mg/37.5 mg/200 mg contains lactose and carmoisine (E122).
If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Carmoisine (E122) may cause allergic reactions.

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.

For adults and elderly:
- Your doctor will tell you exactly how many tablets of <invented 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 <invented 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 <invented name> 175 mg/43.75 mg/200 mg tablets, do not take more than 8 tablets of this strength per day.
- If you are taking <invented name> 200 mg/50 mg/200 mg tablets, do not take more than 7 tablets of this strength per day.

Talk to your doctor or pharmacist if you think the effect of <invented name> is too strong or too weak, or if you experience possible side effects

If you take more <invented name> than you should
If you have accidentally taken more <invented 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 color of your skin, tongue, eyes or urine may change.

If you forget to take <invented 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 <invented name> tablets, to avoid possible side effects.

If you stop taking <invented name>
Do not stop taking <invented 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 <invented 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. Many of the side effects can be relieved by adjusting the dose.

If you during the treatment with <invented 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 discoloration 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 <invented 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 <invented 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 <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 bottle and the carton after EXP.
The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Shelf life after first opening of the bottle: 175 days.

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 <invented name> contains

The active substances of <invented name> are levodopa, carbidopa and entacapone.
- Each <invented name> 50 mg/12.5 mg/200 mg film-coated tablet contains 50 mg of levodopa, 12.5 mg of carbidopa and 200 mg of entacapone.
- The other ingredients in the tablet core are microcrystalline cellulose, lactose, low-substituted hydroxypropylcellulose, povidone (K-30), colloidal anhydrous silica and magnesium stearate
- The ingredients in the film-coating are titanium dioxide (E171), hypromellose, glycerol (E422), yellow iron oxide (E172), polysorbate 80, red iron oxide (E172), black iron oxide (E172) and magnesium stearate.

The active substances of <invented name> are levodopa, carbidopa and entacapone.
- Each <invented name> 75 mg/18.75 mg/200 mg film-coated tablet contains 75 mg of levodopa, 18.75 mg of carbidopa and 200 mg of entacapone.
- The other ingredients in the tablet core are microcrystalline cellulose, lactose, low-substituted hydroxypropylcellulose, povidone (K-30), colloidal anhydrous silica and magnesium stearate
- The ingredients in the film-coating are titanium dioxide (E171), hypromellose, glycerol (E422), yellow iron oxide (E172), polysorbate 80, red iron oxide (E172) and magnesium stearate.

The active substances of <invented name> are levodopa, carbidopa and entacapone.
- Each <invented name> 100 mg/25 mg/200 mg film-coated tablet contains 100 mg of levodopa, 25 mg of carbidopa and 200 mg of entacapone.
- The other ingredients in the tablet core are microcrystalline cellulose, lactose, low-substituted hydroxypropylcellulose, povidone (K-30), colloidal anhydrous silica and magnesium stearate

- The ingredients in the film-coating are titanium dioxide (E171), hypromellose, glycerol (E422), polysorbate 80, allura red aluminium lake (E129), carmine (E120) and magnesium stearate.

The active substances of <invented name> are levodopa, carbidopa and entacapone.
- Each <invented name> 125 mg/31.25 mg/200 mg film-coated tablet contains 125 mg of levodopa, 31.25 mg of carbidopa and 200 mg of entacapone.
- The other ingredients in the tablet core are microcrystalline cellulose, lactose, low-substituted hydroxypropylcellulose, povidone (K-30), colloidal anhydrous silica and magnesium stearate
- The ingredients in the film-coating are titanium dioxide (E171), hypromellose, glycerol (E422), yellow iron oxide (E172), polysorbate 80, red iron oxide (E172) and magnesium stearate.

The active substances of <invented name> are levodopa, carbidopa and entacapone.
- Each <invented name> 150 mg/37.5 mg/200 mg film-coated tablet contains 150 mg of levodopa, 37.5 mg of carbidopa and 200 mg of entacapone.
- The other ingredients in the tablet core are microcrystalline cellulose, lactose, low-substituted hydroxypropylcellulose, povidone (K-30), colloidal anhydrous silica and magnesium stearate
- The ingredients in the film-coating are titanium dioxide (E171), hypromellose, glycerol (E422), polysorbate 80, red iron oxide (E172), carmoisine aluminium lake (E122) and magnesium stearate.

The active substances of <invented name> are levodopa, carbidopa and entacapone.
- Each <invented name> 175 mg/43.75 mg/200 mg film-coated tablet contains 175 mg of levodopa, 43.75 mg of carbidopa and 200 mg of entacapone.
- The other ingredients in the tablet core are microcrystalline cellulose, lactose, low-substituted hydroxypropylcellulose, povidone (K-30), colloidal anhydrous silica and magnesium stearate
- The ingredients in the film-coating are titanium dioxide (E171), hypromellose, glycerol (E422), yellow iron oxide (E172), polysorbate 80, red iron oxide (E172), black iron oxide (E172) and magnesium stearate.

The active substances of <invented name> are levodopa, carbidopa and entacapone.
- Each <invented name> 200 mg/50 mg/200 mg film-coated tablet contains 200 mg of levodopa, 50 mg of carbidopa and 200 mg of entacapone.
- The other ingredients in the tablet core are microcrystalline cellulose, lactose, low-substituted hydroxypropylcellulose, povidone (K-30), colloidal anhydrous silica and magnesium stearate
- The ingredients in the film-coating are titanium dioxide (E171), hypromellose, glycerol (E422), yellow iron oxide (E172), polysorbate 80, red iron oxide (E172), black iron oxide (E172) and magnesium stearate.

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

<invented name> 50 mg/12.5 mg/200 mg: Round, biconvex, light brown film-coated tablet, marked with “50” on one side, plain on the other. Dimension: approx. 14 mm diameter.
<invented name> 75 mg/18.75 mg/200 mg: Oval, biconvex, light orange film-coated tablet, marked with “75” on one side, plain on the other. Dimensions: approx. 16x10 mm.
<invented name> 100 mg/25 mg/200 mg: Oblong, biconvex, pale red film-coated tablet, marked with “100” on one side, plain on the other. Dimensions: approx. 17x9 mm.
<invented name> 125 mg/31.25 mg/200 mg: Round, biconvex, yellowish brown film-coated tablet, marked with “125” on one side, plain on the other. Dimension: approx. 14 mm diameter.
<invented name> 150 mg/37.5 mg/200 mg: Oval, biconvex, dark red film-coated tablet, marked with “150” on one side, plain on the other. Dimensions: approx. 16x10 mm.
<invented name> 175 mg/43.75 mg/200 mg: Ellipse, biconvex, pale brown film-coated tablet, marked with “175” on one side, plain on the other. Dimensions: approx. 17x10 mm
<invented name> 200 mg/50 mg/200 mg: Oblong, biconvex, brown film-coated tablet, marked with “200” on one side, plain on the other. Dimensions: approx. 17x9 mm.

<invented name> is available in pack sizes of 10, 28, 30, 50, 60, 90, 98, 100, 130, 150, 175, 200 or 250 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer
TEVA Gyógyszergyár Zrt.
(TEVA Pharmaceutical Works Private Limited Company)
H-4042 Debrecen, Pallagi út 13,
Hungary

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

Austria	Levodopa/Carbidopa/Entacapon Rivopharm® 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 Filmtabletten
Denmark	Levodopa/Carbidopa/Entacapone Holsten
Sweden	Levodopa/Carbidopa/Entacapone Holsten

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