

**Package leaflet: Information for the patient****Co-Careldopa 10 mg/100 mg Tablets****Co-Careldopa 12.5 mg/50 mg Tablets****Co-Careldopa 25 mg/100 mg Tablets****Co-Careldopa 25 mg/250 mg Tablets****Carbidopa/Levodopa****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 this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

**1. What this medicine is and what it is used for**

The name of your medicine is Co-Careldopa. It contains two different active ingredients Carbidopa and Levodopa.

Co-Careldopa improves the signs of Parkinson's disease. Parkinson's disease is a long-term illness where:

- you become slow and unsteady
- your muscles feel stiff
- you may develop shaking or trembling (called 'tremor').

If not treated, Parkinson's disease can make it hard for you to continue your normal daily activities.

Levodopa turns into a material called 'dopamine' in your brain. The dopamine helps to improve the signs of your Parkinson's disease.

Carbidopa belongs to a group of medicines called 'aromatic amino acid decarboxylase inhibitors'. It helps levodopa work more effectively by slowing the speed at which levodopa is broken down in your body.

**2. What you need to know before you take this medicine****Do not take this medicine if:**

- you are allergic (hypersensitive) to carbidopa or levodopa or any of the other ingredients of this medicine (listed in Section 6)
- you have ever had skin cancer or you have any unusual moles which have not been examined by your doctor
- you are taking certain medicines called 'MAOIs' (Monoamine Oxidase Inhibitors) used for depression. You need to stop using these medicines at least two weeks before you start this medicine (see also under 'Other medicines and Co-Careldopa below').
- you have a condition called 'narrow-angle glaucoma' that may cause a sudden build up of pressure in the eye
- you have a severe mental disorder
- you are pregnant, might become pregnant, or are breast-feeding.

Co-Careldopa should not be given in situations in which a sympathomimetic compound is contraindicated.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

**Warnings and precautions**

Check with your doctor or pharmacist before taking your medicine if:

- you have a history of fits (convulsions)
- you have had an ulcer in your gut (called 'duodenal' or 'peptic ulcer') or have vomited blood
- you have had a heart attack, heart beat problems, circulation or breathing problems
- you have had kidney, liver or hormonal problems
- you have had depression or other mental problems
- you have a condition called 'chronic wide-angle glaucoma' that may cause a build-up of pressure in the eye. You will need to have regular checks on the pressure in your eye.
- you sometimes have sudden sleep attacks or sometimes feel very sleepy
- you are due to have surgery.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

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

Tell your doctor if you or your family/carer notices you are developing addiction-like symptoms leading to craving for large doses of Co-careldopa and other medicines used to treat Parkinson's disease.

**Other medicines and Co-Careldopa**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription This includes herbal medicines. This is because Co-Careldopa can affect the way some other medicines work. Also some other medicines can affect the way Co-Careldopa works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines for Parkinson's disease containing levodopa:
  - If they are 'slow release', you will need to wait 24 hours after your last dose before starting Co-Careldopa.
  - If they are 'normal release', you will need to wait 12 hours after your last dose before starting Co-Careldopa.
  - Tell the doctor or pharmacist even if you have only taken them in the past.
- Medicines for Parkinson's disease which do not contain levodopa will usually be continued. However, your dose may be changed.
- Medicines for mental problems (including depression), tuberculosis (TB), high blood pressure, muscle spasms, epilepsy or, other diseases related to involuntary movements. Your dose may need to be changed.
- Medicines to treat low iron. Your dose may need to be changed.
- Medicines called 'MAOIs' (see also 'Do not take Co-Careldopa if').
- Anticholinergic medicines (such as orphenadrine, trihexyphenidyl, benztropine and procyclidine). Your dose may need to be changed.
- Phenytoin which is used to treat fits (convulsions).
- Papaverine which is used to treat impotence in men.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine. Your doctor or pharmacist has a more complete list of medicines to avoid while taking this medicine.

**Co-Careldopa with food and drink**

Try to avoid taking your tablets with a heavy meal. If your diet contains too much protein (meat, eggs, milk, cheese) this medicine may not work as well as it should.

**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.

- Any woman of childbearing potential who is receiving this medicine must practise effective contraception.
- Not enough is known about the use of Co-Careldopa during human pregnancies. It was shown to be harmful in animal experiments. Do not take this medicine if you are pregnant, or trying to conceive.
- Levodopa is excreted into breast milk. You must therefore not breastfeed during treatment with Co-Careldopa.

**Driving and using machines**

This medicine affects different people in different ways. Some people have side effects which affect their ability to drive or use tools or machines (see section 4). Do not drive or use tools or machines if you get these effects.

This medicine can also make you sleepy or cause 'sudden sleep attacks'. If this happens to you, you must not drive or use tools or machines. Your doctor will tell you if you can start driving again if these attacks stop.

**Laboratory tests**

This medication can affect some laboratory tests that your doctor may perform on blood or urine samples. Please remind your doctor if you are taking carbidopa/levodopa and are having any tests.

**3. How to take this medicine**

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

**Taking this medicine**

- Take this medicine by mouth.
- Although your medicine can have an effect after one day, it may take up to seven days to work.
- Take them at regular time intervals according to your doctor's instructions.
- Do not change the times at which you take your tablets or take any other medicines for Parkinson's disease without first consulting your doctor.
- Try to avoid taking your tablets with a heavy meal.

**If you have not had levodopa before**

The usual starting dose is:

- Co-Careldopa 12.5 mg/50 mg Tablets is one tablet three or four times a day.
- Co-Careldopa 25 mg/100 mg Tablets: one tablet three times a day.
- Co-Careldopa 10 mg/100 mg Tablets: one tablet three or four times a day.

**If you have had levodopa before**

Your doctor will ask you to stop taking your medicine for Parkinson's disease before you start taking this medicine.

The usual starting dose is:

- For Co-Careldopa 25 mg/100 mg Tablets and Co-Careldopa 25 mg/250 mg Tablets: one tablet three or four times a day.
- Co-Careldopa 10 mg/100 mg Tablets it will depend on what you were taking before.

More than one Co-Careldopa product may be prescribed by your doctor. If you have been given different Co-Careldopa tablets to take make sure that you are taking the correct one at the right time.

**Children under 18 years of age**

This medicine is not suitable for children under the age of 18 years.

**If you take more of this medicine than you should**

If you take too many tablets see your doctor immediately.

**If you forget to take this medicine**

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

XXXXXX

SAME SIZE ARTWORK

560 x180 mm

Front

FLAT DIMENSION = 180 x 560mm

FOLDED DIMENSION = 180 x 35mm

#### If you stop taking this medicine

Do not stop taking this medicine or change your dose without talking to your doctor first. When you stop taking this medicine the following can occur: stiff muscles, high temperature (fever) and mental changes.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

##### Stop taking this medicine and see your doctor straight away, if you notice any of the following side effects:

- allergic reaction, the signs may include hives (nettle rash), itching, rash, swelling of your face, lips, tongue or throat. This may cause difficulty in breathing or swallowing
- chest pain
- uneven (irregular) heart beat or palpitations
- dizziness on standing-up quickly
- bleeding from your gut which may be seen as blood in your faeces or darkened faeces (gastro-intestinal bleeding)
- blood problems, the signs may include pale skin (pallor), tiredness, fever, sore throat or mild bruising and prolonged bleeding after injury
- stiff muscles, high fever
- mental changes including delusions, hallucinations and depression
- fits (convulsions).

##### The most common side effects are

- abnormal movements such as twitching or spasms (which may or may not be like your Parkinson’s symptoms)
- nausea.

##### Other side effects include

- fainting, anorexia, high blood pressure
- inflammation of the veins, being sick (vomiting) diarrhoea, discoloration of urine, sweat or saliva
- on-off phenomenon, characteristic of some people with long-standing Parkinson’s disease. This is when you can have unpredictable changes from being mobile - “on” - to a sudden inability to move - “off”. “Off” to “on” can occur just as suddenly.
- dizziness; sleepiness (including excessive drowsiness or sudden sleep onset episodes), pins and needles
- dream abnormalities, confusion, feeling agitated, shortness of breath, hair loss

##### You may experience the following side effects:

- Craving for large doses of Co-Careldopa 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 Co-Careldopa.
- inability to resist the impulse to perform an action that could be harmful, which may include:
  - strong impulse to gamble excessively despite serious personal or 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; he/she will discuss ways of managing or reducing the symptoms.

##### Side effects that have been reported with medicines containing levodopa.

These may be experienced when taking Co-Careldopa.

##### Nervous system:

- loss of control over the voluntary movements of everyday life

- numbness, increased hand tremor, muscle twitching, muscle cramp, irregular movement of jaw muscles resulting in difficulty opening the mouth
- difficulty sleeping, feeling anxious or high, falling over and abnormal walking patterns
- headache

##### Eyes:

- drooping eyelid and dilated pupil
- changes in vision, irregular movement of the eye

##### Digestive system:

- indigestion, dry mouth, bitter taste
- swelling of the salivary glands, difficulty swallowing, grinding of the teeth
- hiccups, abdominal pain and distress, constipation, wind
- burning sensation of the tongue

##### Sexual:

- persistent abnormal erection of the penis

##### Urinary:

- difficulty passing urine or incontinence (inability to control urine flow)

Very common- Urinary tract infection

##### Skin:

- changed patches of pigmented skin, including, irritated or irregular moles, or moles in which you have noticed changes (melanoma)

##### General:

- weight gain or loss, swelling in the limbs
- flushing, hot flushes, increased sweating
- feeling weak, faint or tired
- hoarseness, general feeling of being unwell
- increased energy or activity, unusual breathing pattern

If any symptoms persist or you experience any other side effects please tell your doctor or pharmacist. It will help if you make a note of what you experienced, when it started and how long it lasted.

##### Reporting of side effects

If you get any side effect, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://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 this medicine

- Keep this medicine out of the sight and reach of children
- Store below 25°C.
- Do not use this medicine after the expiry date which is stated on the carton after {EXP.}. The expiry date refers to the last day of that month.
- 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 this medicine contains

- The active substances are carbidopa and levodopa.
- Each 10mg/100mg tablet contains 10.8 mg carbidopa monohydrate (equivalent to 10 mg of anhydrous carbidopa) and 100 mg levodopa.

- Each 12.5mg/50mg tablet contains 13.5 mg carbidopa monohydrate (equivalent to 12.5 mg of anhydrous carbidopa) and 50 mg levodopa.
- Each 25mg/100mg tablet contains 27.0 mg carbidopa monohydrate (equivalent to 25 mg of anhydrous carbidopa) and 100 mg levodopa.
- Each 25mg/250mg tablet contains 27.0 mg carbidopa monohydrate (equivalent to 25 mg of anhydrous carbidopa) and 250 mg levodopa.

- The other ingredients are:

10 mg/100 mg Tablets and 25mg /250mg Tablets:

Crospovidone (E1202), Indigo carmine lake (E132), Magnesium stearate (E572), Microcrystalline cellulose (E460), Pre gelatinised starch (maize)

12.5mg/50 mg Tablets and 25 mg/ 100 mg Tablets:

Crospovidone (E1202), Quinoline Yellow lake (E104), Magnesium stearate (E572), Microcrystalline cellulose (E460), Pre gelatinised starch (maize).

##### What this medicine looks like and contents of the pack

10mg /100 mg Tablets are round shaped, light blue coloured with ‘C’ on one side and ‘18’ on other side of tablet.

12.5 mg/50 mg Tablets are oval shaped, light yellow coloured, with ‘C’ on one side and ‘17’ on other side of tablet.

25 mg/100 mg Tablets are round shaped, light yellow coloured with ‘C’ on one side and ‘19’ on other side of tablet.

25 mg/250 mg Tablets are round shaped, light blue coloured with ‘C’ on one side and ‘20’ on other side of tablet.

Co-Careldopa tablets are available in:

10 mg/100 mg – Alu-Alu blister packs of 90 and 100 tablets

12.5 mg/50 mg – Alu-Alu blister packs of 30, 50, 90 and 100 tablets

25 mg/100 mg – Alu-Alu blister packs of 30, 50, 56, 60, 90, 98, 100, 196 and 200 tablets

25 mg/250 mg – Alu-Alu blister packs of 30, 50, 60, 90, 98, 100, 120, 196 and 200 tablets

Not all pack sizes may be marketed.

##### Marketing Authorisation Holder and Manufacturer

Name and address:

Bristol Laboratories Ltd,

Unit 3, Canalside, Northbridge Road, Berkhamsted, Hertfordshire,

HP4 1EG, United Kingdom

Telephone: 0044 (0)1442 200922

Email: [info@bristol-labs.co.uk](mailto:info@bristol-labs.co.uk)

##### Manufacturer

Bristol Laboratories Limited

Laporte Way, Luton,

LU4 8WL, United Kingdom

**Co-Careldopa 10mg/100mg tablets; PL 17907/0470**

**Co-Careldopa 12.5mg/50mg tablets; PL 17907/0471**

**Co-Careldopa 25mg/100mg tablets; PL 17907/0472**

**Co-Careldopa 25mg/250mg tablets; PL 17907/0473**

**This leaflet was last revised in June 2025.**

To request a copy of this leaflet in Braille, large print or audio format then please contact the marketing authorisation holder at the address (or telephone, email) above.

V15 28-05-25 D0

XXXXXX