

Package leaflet: Information for the user

Co-careldopa 12.5 mg/50 mg tablets

Co-careldopa 10 mg/100 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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Co-careldopa is and what it is used for

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. Co-careldopa contains two different active substances called: levodopa and carbidopa.

- 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 Co-careldopa

Do not take Co-careldopa:

- if you are allergic to carbidopa or levodopa or any of the other ingredients of this medicine (listed in section 6).
- if you have ever had skin cancer or you have any unusual moles which have not been examined by your doctor.
- if 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 Co-careldopa (see also under 'Other medicines and Co-careldopa' below).
- if you have a condition called 'narrow-angle glaucoma' that may cause a sudden build up of pressure in the eye
- if you have a severe mental disorder
- if you are pregnant, might become pregnant or are breast-feeding.

Do not take Co-careldopa if any of the above apply to you.

If you are not sure, talk to your doctor or pharmacist before taking Co-careldopa.

Warnings and precautions

Talk to your doctor or pharmacist before taking Co-careldopa:

- if you have a history of fits (convulsions)
- if you have had an ulcer in your gut (called 'duodenal' or 'peptic ulcer') or have vomited blood
- if you have had a heart attack, heart beat problems, circulation or breathing problems
- if you have had kidney, liver or hormonal problems
- if you have had depression or other mental problems
- if 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.
- if you sometimes have sudden sleep attacks or sometimes feel very sleepy
- if 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 Co-careldopa.

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.

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.

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 Co-careldopa and are having any tests.

Children and adolescents

Co-careldopa is not suitable for children under the age of 18 years.

Other medicines and Co-careldopa

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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, other diseases related to involuntary movements or to treat low iron. Your dose may need to be changed.

- Medicines called 'MAOIs' (see also 'Do not take Co-careldopa').
- 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 Co-careldopa.

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) Co-careldopa may not work as well as it should.

Pregnancy and breast-feeding

Do not take Co-careldopa if you are pregnant, might become pregnant or are breast-feeding. Levodopa, one of the substances in Co-careldopa, is passed into human milk.

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.

Driving and using machines

- Co-careldopa 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 Possible side effects). Do not drive or use tools or machines if you get these effects.
- Co-careldopa 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.

3. How to take Co-careldopa

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

Taking this medicine

- If the tablet breaks when you remove it from the blister pack, make sure you have all of the tablet pieces (the full dose). If you do not have all the pieces of a broken tablet, throw away the pieces and take another tablet from the blister pack.
- Taking only part of a tablet (a partial dose) may cause symptoms to get worse.
- 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.

The usual starting dose:

- for Co-careldopa 12.5 mg/50 mg and 10 mg/100 mg Tablets: will depend on what you were taking before.
- for Co-careldopa 25 mg/100 mg Tablets and Co-careldopa 25 mg/250 mg Tablets: is one tablet three or four times a day.

If you have not had levodopa before

The usual starting dose is:

- for Co-careldopa 12.5 mg/50 mg Tablets: one tablet three or four times a day.
- for 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 Co-careldopa.

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.

Use in children and adolescents

Co-careldopa is not suitable for children under the age of 18 years.

If you take more Co-careldopa than you should

If you take too many tablets see your doctor immediately.

If you forget to take Co-careldopa

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

If you stop taking Co-careldopa

Do not stop taking Co-careldopa or change your dose without talking to your doctor first.

When you stop taking Co-careldopa the following can occur: stiff muscles, high temperature (fever) and mental changes.

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

4. Possible side effects

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

Stop taking Co-careldopa 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
- urinary tract infections (frequency: very common).

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)

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 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 Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Co-careldopa

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the blister and 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 Co-careldopa contains

– The active substances are carbidopa and levodopa.

Each tablet of Co-careldopa contains 13.5 mg carbidopa monohydrate (equivalent to 12.5 mg of anhydrous carbidopa) and 50 mg levodopa.

Each tablet of Co-careldopa contains 10.8 mg carbidopa monohydrate (equivalent to 10 mg of anhydrous carbidopa) and 100 mg levodopa.

Each tablet of Co-careldopa contains 27 mg carbidopa monohydrate (equivalent to 25 mg of anhydrous carbidopa) and 100 mg levodopa.

Each tablet of Co-careldopa contains 27 mg carbidopa monohydrate (equivalent to 25 mg of anhydrous carbidopa) and 250 mg levodopa.

– The other excipients are:

10 mg/100 mg & 25 mg/250 mg: crospovidone, indigo carmine lake (E132), magnesium stearate, cellulose microcrystalline, pre-gelatinized starch

12.5mg/50 mg & 25 mg/100 mg: crospovidone, quinine yellow lake (E104), magnesium stearate, cellulose microcrystalline, pre-gelatinized starch

What Co-careldopa looks like and contents of the pack

Co-careldopa 12.5 mg/50 mg tablets are round shaped, light yellow coloured, with C on one side and 17 on other side of tablet. Co-careldopa 10 mg/100 mg tablets are round shaped, light blue coloured, with C on one side and 18 on other side of tablet.

Co-careldopa 25 mg/100 mg tablets are round shaped, light yellow coloured, with C on one side and 19 on other side of tablet. Co-careldopa 25 mg/250 mg tablets are round shaped, light blue coloured, with C on one side and 20 on other side of tablet.

Pack-sizes:

12.5 mg/50 mg: 50 or 90 tablets

10 mg /100mg & 25 mg /100mg & 25 mg /250mg: 100 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Somex Pharma, Ilford, Essex, IG3 8BS

Manufacturer

Somex Pharma, Ilford, Essex, IG3 8RA

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