

Package leaflet: Information for the user

Duodopa 20 mg/ml + 5 mg/ml intestinal gel levodopa/carbidopa monohydrate

Read all of this leaflet carefully before you start using 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, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Duodopa is and what it is used for

Duodopa belongs to a group of medicines for Parkinson's disease.

Duodopa is a gel that goes through a pump and a tube into your gut (small intestine). In the gel there are two active substances:

- Levodopa.
- Carbidopa.

How Duodopa works

- In the body, levodopa is made into something called 'dopamine'. This adds to the dopamine already in your brain and spinal cord. Dopamine helps transfer signals between nerve cells.
- Too little dopamine causes Parkinson's disease signs like tremor, feeling stiff, slow movement, and problems keeping your balance.
- Treatment with levodopa increases the amount of dopamine in your body. This means it reduces these signs.
- Carbidopa improves the effect of levodopa. It also reduces the side effects of levodopa.

2. What you need to know before you use Duodopa

Do not use Duodopa if

- You are allergic to levodopa, carbidopa or any of the other ingredients of this medicine (listed in section 6).
- You have an eye problem called 'narrow-angle glaucoma'.
- You have severe heart problems.
- You have a severe uneven heart beat (arrhythmia).
- You have had a severe stroke.
- You are taking medicines for depression called selective MAO-A inhibitors and non-selective MAO-inhibitors such as moclobemide or phenelzine.
- You have a tumour of the adrenal gland (pheochromocytoma).
- You have hormone problems such as too much cortisol (Cushing's syndrome) or your thyroid hormone levels are too high (hyper-thyroidism).

- You have ever had skin cancer, or you have any unusual moles or marks on your skin which have not been looked at by your doctor.

Do not use Duodopa if any of the above apply to you. If you are not sure, talk to your doctor before having Duodopa.

Warnings and precautions

Talk to your doctor before using Duodopa if:

- You have ever had a heart attack, blocked blood vessels in your heart, or any other heart problems including an uneven heart beat (arrhythmia).
- You have a lung problem – such as asthma.
- You have ever had a hormone problem.
- You have ever had depression with thoughts of suicide or any other mental problems.
- You have an eye problem called ‘wide-angle glaucoma’.
- You have ever had a stomach ulcer.
- You have ever had fits (convulsions).
- You have ever had surgery in your upper stomach area (upper abdominal surgery).
- Progressive weakness, pain, numbness or loss of sensation in the fingers or feet (polyneuropathy) have been reported in patients treated with levodopa/carbidopa intestinal gel. Your doctor will check for the signs and symptoms of neuropathy before you start levodopa/carbidopa intestinal gel and periodically thereafter. Tell your doctor if you already have neuropathy or medical condition that is associated with neuropathy.

If any of the above apply to you (or you are not sure), talk to your doctor before having Duodopa.

Look out for side effects

Neuroleptic Malignant Syndrome

Do not stop having Duodopa or lower your dose unless a doctor tells you to. This is because suddenly stopping or lowering your Duodopa dose quickly may cause a serious problem called ‘Neuroleptic Malignant Syndrome’ (see section 4 ‘Serious side effects’).

Feeling sleepy or dizzy

If you suddenly fall asleep (sleep attacks) or feel very sleepy, or if you feel light-headed or dizzy:

- Do not drive or use any tools or machines until you feel fully awake again or you no longer feel light-headed or dizzy (see section 2 ‘Driving and using machines’).

Skin changes

Tell your doctor, pharmacist or nurse if you notice any unusual marks or moles on your skin that appear or get worse (see section 4 ‘Other side effects’).

Impulse control disorders – changes in your behaviour

Tell your doctor if you, your family or 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.
- Abnormally high sex drive or an increase in sexual thoughts or feelings.

Your doctor may need to review your treatments. They will discuss ways of managing or reducing these symptoms, with you (see section 4 ‘Impulse control disorders – changes in your behaviour’).

Dopamine Dysregulation Syndrome

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

Problems using the pump or tube

There may be some problems linked to using the pump and tube:

- You become less able to handle the pump and tube, your Parkinson's disease symptoms get worse or it is harder to move (bradykinesia), the pump and tube may not be working properly.
- You have pain in your stomach area, feel sick (nausea) and are sick (vomit) – tell your doctor straight away if this happens (see Section 4 'Serious side effects').
- You may get other side effects affecting your gut (intestine) and where the tube goes in (see section 4 'Problems using the pump or tube').

Duodopa and cancer

In the body, carbidopa (an active substance of Duodopa) is broken down into something called 'hydrazine'. It is possible that hydrazine could damage your genetic material which could lead to cancer. However, it is not known if the amount of hydrazine produced when taking a normal dose of Duodopa can cause this.

Tests or checks

Your doctor may do some blood tests if you are having this medicine.

Operations

Before you have an operation (including a dental operation), tell the doctor (or dentist) that you are having Duodopa.

Children and adolescents

Duodopa should not be used in children or young people under the age of 18 years.

Other medicines and Duodopa

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

Do not use Duodopa if you are taking:

- Medicines for depression called selective MAO-A inhibitors and non-selective MAO inhibitors such as moclobemide or phenelzine.

Talk to your doctor or pharmacist before starting Duodopa if you are taking other medicines for:

- Anaemia – such as iron tablets.
- Tuberculosis – such as isoniazid.
- Anxiety – such as benzodiazepines.
- Sickness – such as metoclopramide.
- High blood pressure – such as anti-hypertensives.
- Spasms in the blood vessels – such as papaverine.
- Fits (convulsions) or epilepsy – such as phenytoin.
- Parkinson's disease – such as tolcapone, entacapone, amantadine.
- Mental problems – such as anti-psychotics including phenothiazines, butyrophenones and risperidone.
- Severe allergic reactions, asthma, chronic bronchitis, heart disease and low blood pressure – such as anti-cholinergics and sympatho-mimetics.
- You are taking a medicine which may cause low blood pressure. This could cause something called 'orthostatic hypotension' – this can make you dizzy when getting up from a chair or bed. Duodopa can make this worse. Always change positions slowly.

Duodopa with food and drink

For some patients, Duodopa may not work well if it is taken with, or shortly after eating protein-rich food – such as meats, fish, dairy products, seeds and nuts. Talk to your doctor if you think this applies to you.

Pregnancy and breast-feeding

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before starting treatment with Duodopa.
- Do not use Duodopa if you are breast-feeding.

Driving and using machines

Do not drive or use any tools or machines until you are sure how Duodopa affects you.

- Duodopa may make you feel very sleepy, or you may sometimes find yourself suddenly falling asleep (sleep attacks).
- Duodopa may lower your blood pressure, which can make you feel light-headed or dizzy.

Do not drive or use any tools or machines until you feel fully awake again or you no longer feel light-headed or dizzy.

3. How to use Duodopa

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

About Duodopa gel and the pump

- Duodopa is a gel that goes through a pump and a tube into your gut (small intestine).
- The gel comes in a plastic cassette. The cassette is connected to a pump.
- The pump is connected to a tube which is placed into your gut (small intestine).
- The pump gives you a small dose throughout the day. This means that the level of the medicine in your blood stays the same. It also means some of the movement side effects are lower.

How much to use

- Your doctor will decide how much Duodopa you should use and for how long.
- Usually, a larger morning dose (called the 'bolus dose') is given. This allows you to quickly get the right amount of medicine in your blood. After that dose, a steady ('maintenance') dose is given.
- If needed, you may have extra doses – this will be decided by your doctor.

If you use more Duodopa than you should

If you have used more Duodopa than you should, talk to your doctor or go to a hospital straight away. Take the medicine pack with you. The following effects may happen:

- Problems opening your eyes.
- Muscle spasms you cannot control in your eyes, head, neck and body (dystonia).
- Movement you make without wanting to (dyskinesia).
- Unusual fast, slow or uneven heart beats (arrhythmia).

If you forget to use Duodopa

- Start your pump, with your normal dose, as soon as possible.
- Do not increase your dose to make up for a forgotten dose.

If you stop or lower your dose of Duodopa

Do not stop having Duodopa or lower your dose unless a doctor tells you to. This is because suddenly stopping or lowering your Duodopa dose quickly may cause a serious problem called 'Neuroleptic Malignant Syndrome'. This problem is more likely to happen if you are also taking a medicine called an 'anti-psychotic' (see section 4 'Serious side effects').

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

4. Possible side effects

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

Serious side effects from Duodopa

Stop using Duodopa and tell your doctor straight away, if you notice any of the following serious side effects. You might need urgent medical treatment:

- Acute pain in eyes, headache, blurred vision, nausea and vomiting. These may be signs of angle closure glaucoma. Uncommon: may affect up to 1 in 100 people.
- Fever, sore throat or mouth, or trouble passing water. These may be signs of a white blood cell problem called ‘agranulocytosis’. Your doctor will take a blood sample to check for this. Very rare: may affect up to 1 in 10,000 people.
- Swelling of the face, tongue or throat which may make it difficult to swallow or breathe, or nettle type skin rash. These may be signs of a severe allergic reaction (anaphylactic reaction). Frequency not known. Cannot be estimated from available data.

Tell your doctor straight away if you notice any of the following serious side effects:

- Neuroleptic Malignant Syndrome – the signs may include:
 - Fast heartbeat, changing blood pressure and sweating, followed by fever.
 - Faster breathing, muscle stiffness, lower consciousness and coma.
 - Higher levels of a protein in your blood (an enzyme called ‘creatine phosphokinase’). This is measured by your doctor.Rare: may affect up to 1 in 1,000 people.
See section 3 ‘If you stop or lower your dose of Duodopa’ for more information on Neuroleptic Malignant Syndrome.

Other side effects from Duodopa

Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

Very common: may affect more than 1 in 10 people

- Falling.
- Weight loss.
- Feeling sick (nausea), constipation.
- Anxiety, depression, not being able to sleep (insomnia).
- Movement you make without wanting to (dyskinesia), worsening of Parkinson’s disease symptoms.
- Feeling dizzy when you stand up or change positions (orthostatic hypotension) – this is from low blood pressure. Always change positions slowly – do not stand up quickly.
- Urinary tract infections

Common: may affect up to 1 in 10 people

- Weight gain.
- Uneven heartbeat.
- Not wanting to eat.
- Feeling tired, weak.
- High or low blood pressure.
- Anaemia – low levels of iron in the blood.
- Having pain, neck pain, muscle cramps, muscle weakness.
- Suddenly falling asleep (sleep attacks), feeling very sleepy, sleep disorders.
- Having higher levels of amino acids or homo-cysteine in the blood, having too little vitamin B6 and B12.
- Feeling dizzy or like you are going to faint, or fainting (syncope).
- Difficulty swallowing or dry mouth, change in taste (bitter taste).
- Headache.

- Progressive weakness or pain or numbness or loss of sensation in the fingers or feet (polyneuropathy).
- Rashes, itching, increased sweating, swelling caused by too much fluid (oedema).
- Difficulty passing water (retention of urine) or unable to control water flow (incontinence).
- Seeing, hearing or feeling things that are not there (hallucinations), confusion, abnormal dreams, feeling agitated, impulsive behaviour, psychotic disorder.
- Having a swollen stomach, diarrhoea, wind (flatulence), indigestion (dyspepsia), being sick (vomiting).
- Parkinson's disease symptoms coming back quickly or when not expected – this is called the 'on and off phenomenon'.
- Reduced sense of touch, muscle spasms you cannot control – affecting your eyes, head, neck and body (dystonia), shaking.

Impulse control disorders – changes in your behavior. These are common, may affect up to 1 in 10 people.

Some people are unable to resist the impulse to do something that could be harmful to themselves or others. This may include:

- A strong impulse to gamble too much, despite serious effects on you or your family.
- A change or increase in sexual thoughts and behaviour of significant concern to you or to others. This could include an increased sexual drive.
- Excessive shopping or spending too much which cannot be controlled.
- Binge eating – eating large amounts of food in a short time, or compulsive eating – eating more food than normal and more than your body needs.

Tell your doctor if you, your family or carer notice any of these behaviors. Your doctor may need to review your treatment. They will discuss ways of managing or reducing these symptoms with you.

Uncommon: may affect up to 1 in 100 people

- Dark urine.
- Hoarse voice, chest pain.
- Hair loss, red skin, hives.
- Having more saliva than usual.
- Swelling in your veins (phlebitis).
- A change in the way you walk.
- Trying to end your own life – suicide.
- Feeling tired or generally unwell.
- Fast and uneven beats of the heart (palpitations).
- Low number of white blood cells or changes in blood cell counts which may cause bleeding.
- Confusion, elevated mood (euphoric mood), increased sexual interest, nightmares, dementia, feeling of fear.
- Problems in controlling movements and making strong movements you cannot control.
- Problems opening your eyes, double vision, blurred vision, optic nerve damage (optic ischaemic neuropathy).

Rare: may affect up to 1 in 1,000 people

- Abnormal thinking.
- Uneven breathing pattern.
- Painful erection that will not go away.
- Unusual marks or moles on your skin that appear or get worse, or tumour of the skin (malignant melanoma).
- Dark saliva or sweat, burning feeling on your tongue, grinding of your teeth, hiccups.

Not Known: frequency cannot be estimated from the available data

- Craving for large doses of Duodopa 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 Duodopa.

Tell your doctor, pharmacist or nurse if you notice any of the side effects listed above.

Side effects from the pump or tube

The following side effects have been reported for the pump and tube, 'tube delivery system'. Tell your doctor or nurse if you notice any of these.

- If you become less able to handle the pump and tube, your Parkinson's disease symptoms get worse or it is harder to move (bradykinesia) – the pump and tube may not be working properly.
- If you have pain in your stomach area, feel sick (nausea) and are sick (vomit), tell your doctor straight away – you might have a problem with the pump or tube.

Very Common: may affect more than 1 in 10 people

- Stomach pain.
- Infection where the tube goes into your stomach – caused by surgery.
- Thick scarring where the tube goes in your stomach.
- Problems from having the tube put in – pain or swelling in the mouth or throat, difficulty swallowing, stomach discomfort, pain or swelling, injury to the throat, mouth or stomach, bleeding, being sick (vomiting), wind (flatulence), anxiety.
- Problems around where the tube goes into your stomach – red or raw skin, sores, discharge, pain or irritation.

Common: may affect up to 1 in 10 people

- Incision site infection, post procedural infection after the tube is placed in the intestine.
- Inflamed wall of stomach.
- Infection in the gut (intestine) or where the tube goes into your stomach.
- The tube moves around in the gut or gets blocked – which could cause lower amounts of medicine to be absorbed.
- Pain when breathing, feeling short of breath, chest infections (pneumonia, including aspiration pneumonia).

Uncommon: may affect up to 1 in 100 people

- Inflamed colon (colitis).
- Inflamed pancreas (pancreatitis).
- The tube goes through the wall of the large intestine.
- Blockage (obstruction), bleeding or ulcer in the gut.
- Sliding of one part of the gut into an adjacent part of the gut (intussusception).
- Food getting stuck around the tube causing it to block.
- Pocket of infection (abscess) – this could happen after the tube is placed in your stomach.

Not Known: it is not known how often these happen

- Reduced blood flow in the small intestine.
- The tube goes through the wall of the stomach or small intestine.
- Infection in the blood (sepsis).

Side effects when levodopa and carbidopa are taken by mouth

The following side effects have been reported with levodopa and carbidopa (the same active substances as in Duodopa) when taken by mouth. These side effects could also occur with Duodopa:

Rare: may affect up to 1 in 1,000 people

- Anaemia – low iron in the blood.
- An eye problem called 'Horner's syndrome'.
- Not being able to open your mouth all the way (trismus).

- Red or purple skin rash that looks like small bruises (Henoch-Schönlein purpura).
- Neuroleptic malignant syndrome (see section 4 ‘Serious side effects’).
- Widening of the pupil in your eye for a long period of time (mydriasis), decreased eye movement.

Very rare: may affect up to 1 in 10,000 people

- Changes in blood tests.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

5. How to store Duodopa

- 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 carton label after EXP.
- Store and transport refrigerated (2°C to 8°C). Keep the cassette in the outer carton in order to protect from light.
- A cassette of the gel may be used for up to 24 hours once it is out of the refrigerator.
- The medicine cassettes are for single use only. A cassette should not be used for longer than 24 hours even if some gel remains.
- Do not re-use an opened cassette.
- The gel might become slightly yellow – this does not affect the medicine.
- 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. Return used cassettes to your nearest pharmacy – do not re-use.

6. Contents of the pack and other information

What Duodopa contains

- The active substances are levodopa and carbidopa monohydrate. 1 ml of gel contains 20 mg levodopa and 5 mg carbidopa monohydrate.
- The other ingredients are carmellose sodium and purified water.

What Duodopa looks like and contents of the pack

Duodopa is available in cassettes (plastic bags of PVC with a protective hard plastic cover) containing 100 ml with 7 cassettes in each pack. The gel is off-white to slightly yellow.

Marketing Authorisation Holder

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

Duodopa

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For information in large print, tape, CD or Braille, phone
01628 561090 (UK) or 01 428 7900 (Ireland).

Other sources of information

Detailed information on this medicine is available on the web site of Health Products Regulatory Authority; www.hpra.ie.