

DUODOPA®

'dew-oh-'doe-pah\

Levodopa/carbidopa monohydrate (\'lee-voe-'doe-pah\ \'kah-bee-'doe-pah\ Gel

Consumer Medicine Information

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Product Description

This CMI answers some common questions about Duodopa intestinal gel.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Duodopa against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Duodopa is used for

Duodopa intestinal gel is used to control severe involuntary movements of advanced Parkinson's disease.

Parkinson's disease is a condition where you lose control of your limbs and posture. Loss of control may be mild and can become severe.

Duodopa intestinal gel belongs to a group of medicines called Anti-Parkinson medications. These medicines work by increasing the amount of a chemical called dopamine which the brain requires to work properly. This helps you to gain control over your movements and posture again.

Duodopa may be used alone, or in combination with other medicines to treat your condition.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is no evidence that Duodopa is addictive.

This medicine is only available with a doctor's prescription.

Duodopa is not recommended for use in children under 18 years as its safety and effectiveness in that age group have not been established.

Before you use it

When you must not use it

Do not use Duodopa if you have an allergy to:

- any medicine containing levodopa, carbidopa
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to Duodopa may include:

- shortness of breath, wheezing or difficulty breathing

- swelling of the face, lips, tongue or other part of the body
- rash, itching or hives on the skin

Do not use Duodopa if you are taking a medicine called a monoamine oxidase inhibitor (MAOI) or have been taking it within the last 14 days.

Duodopa can however be used with MAOIs which target MAO type B (e.g. Selegiline hydrochloride). Talk to your doctor or pharmacist if you have any questions. Taking Duodopa with, or within 14 days, of taking any other type of MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

If you are taking or have recently taken antidepressant medicines and are unsure about whether you can use Duodopa, check with your doctor.

Do not use Duodopa if you have or have had, any of the following medical conditions:

- an eye problem called 'narrow-angle glaucoma' which involves a change in vision and/or severe eye pain/headache
- severe liver and kidney insufficiency
- a tumour of the adrenal gland (pheochromocytoma)
- hormonal problems such as too much cortisol (Cushing's syndrome) or your thyroid hormone levels are too high (hyperthyroidism)
- any unusual skin lumps or moles which have not been examined by your doctor

- melanoma (a type of skin cancer)

If you are unsure if any of the above conditions apply to you, ask your doctor.

Take special care with Duodopa

Before starting treatment with Duodopa tell your doctor about any medical problems that you have or have had, especially any of the following:

- a heart attack, blocked blood vessels in your heart, or any other heart problems including an uneven heart beat (arrhythmia)
- serious lung problems
- bronchial asthma
- depression with thoughts of suicide or any other mental problems
- change in vision or severe eye pain/headache or if you have been diagnosed with an eye problem called 'wide-angle glaucoma'
- stomach ulcer
- a history of fits (convulsions)
- surgery in your upper stomach area (upper abdominal surgery)
- liver or kidney problems

Tell your doctor if you are pregnant, think you may be pregnant, or intend to become pregnant.

Your doctor will discuss the risks and benefits of using it if you are pregnant.

Do not breastfeed while using this medicine.

This medicine may pass into the breast milk and therefore there is the possibility that the breast-fed baby may be affected.

Do not take this medicine after the expiry date printed on the pack or if the packaging is damaged or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Talk to your doctor about getting regular skin checks performed by a specialist, such as a dermatologist.

It's important that you regularly get your skin checked for any signs of melanoma.

Do not swim or bathe whilst being treated with Duodopa.

The pump cannot be taken into water. The pump should not be disconnected to go swimming or bathing either, as doing so may cause your symptoms to worsen or you may find it harder to move without warning.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Duodopa may interfere with each other. These include:

- some medicines used to treat high blood pressure - such as antihypertensives
- a medicine which may cause low blood pressure. This could cause something called 'orthostatic hypotension' - this can make you dizzy when standing up. Duodopa can make this worse. Always change positions slowly.
- some medicines used to treat depression
- some medicines used to treat mental (psychiatric) problems - such as phenothiazines, butyrophenones and risperidone
- phenytoin, a medicine used to treat fits (convulsions)
- benzodiazepines, medicines that act as relaxants and are used to treat problems relating to anxiety and sleeping disorders such as insomnia (difficulty in falling asleep)

- papaverine, a medicine used to treat erectile dysfunction
- metoclopramide, a medicine used to treat symptoms involving the stomach, including nausea, vomiting, heartburn and loss of appetite
- isoniazid, a medicine used to treat tuberculosis
- amantadine, entacapone and selegiline, other medicines used to treat Parkinson's disease
- iron supplements or medications containing iron used to treat anaemia

These medicines may be affected by Duodopa or may affect how well the intestinal gel works. You may need different amounts of your medicine or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Duodopa.

If you have not told your doctor about any other medicines you are taking, tell him/her before you start using Duodopa.

How to use it

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to use

The total amount of Duodopa used each day includes three individually adjusted doses: the morning bolus dose, the continuous maintenance dose, and extra bolus doses.

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 are prescribed Duodopa, your doctor or nurse will program the right dose amounts for you into your pump.

How to use it

Duodopa is a gel for continuous intestinal use. In long-term use the gel is normally pumped directly into the small intestine by a portable pump and a permanent tube.

A manual with instructions for using the portable pump is delivered together with the pump.

When to use it

Duodopa is for use daily, from the time you wake up in the morning till the time you go to bed.

How long to use it

Continue using your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep using your medicine even if you feel well.

If you forget to use it

If you forget to use Duodopa, start using it as soon as you remember.

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or nurse.

If you use too much (overdose)

If you have used too large a dose of the drug always contact a doctor or go to a hospital straight away. Take the medicine pack with you.

You may need urgent medical attention.

Symptoms of an overdose may include:

- 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)
- fits (convulsions)

While you are using it

Things you must do

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are using Duodopa.

Tell any other doctors, dentists, and pharmacists who treat you that you are using Duodopa.

If you are going to have surgery or emergency treatment, tell the surgeon or anaesthetist that you are using Duodopa.

It may affect other medicines used during surgery.

If you need to have any medical tests while you are using Duodopa, tell your doctor.

Duodopa may affect the results of some tests.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may want to take some tests from time to time. This helps prevent unwanted side effects.

Things you must not do

Do not use Duodopa to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they seem to have the same condition as you.

Do not stop using your medicine or change your dose unless your doctor tells you to.

If you stop using it suddenly or change your dose, your condition may worsen or you may have unwanted side effects such as:

- muscular rigidity
- increased body temperature
- mental change (agitation, confusion, coma)
- movement you make without wanting to (dyskinesia)

If possible, your doctor will gradually reduce the amount you use each day before stopping the medicine completely.

Problems using the pump or tube

Should complete failure of the intestinal tube or pump occur, you must continue your treatment by starting oral levodopa/carbidopa until the problem is solved.

Tell your doctor if you notice any of the following symptoms:

- you become less able to handle the pump and tube, your Parkinson's disease symptoms get worse or it is harder to move (bradykinesia)
- you have pain in your stomach area or feel sick (nausea and/or vomiting)

Things to be careful of

Be careful driving or operating machinery until you know how Duodopa affects you.

As with other medicines, Duodopa may cause dizziness, light-headedness, tiredness, drowsiness, sudden sleep, blurred vision or other effects in some people. Make sure you know how you react to Duodopa before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy, light-headed, or your vision is affected.

Do not drive or use any tools or machines until you feel fully

awake again or you no longer feel lightheaded or dizzy.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Duodopa.

This medicine helps most people with advanced Parkinson's disease, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Many of the side effects can be relieved by adjusting the dose.

Tell your doctor if you notice any of the following and they worry you:

- abnormal uncontrolled movements, including muscle twitching or spasms, which may or may not resemble your usual Parkinson's symptoms (dyskinesia)
- dizziness, or light-headedness when standing quickly
- neck pain
- feeling sick (nausea/vomiting), loss of appetite, weight loss
- discoloured saliva
- dream abnormalities
- drowsiness, tiredness or sudden sleep
- trouble sleeping
- slow movements, more difficulty in moving
- twitching or spasm of the eyelids
- any raw or red skin, thick scarring, sores, bleeding,

discharge, pain or irritation at the site where the tube goes into your stomach

- discomfort or swelling in the stomach
- passing of wind (flatulence), diarrhoea
- confusion, anxiety, abnormal dreams and feeling agitated
- developing urges or cravings to behave in ways that are unusual for you (e.g. increased sex drive), unable to resist the impulse to do something of significant concern to you or others (e.g. desire to gamble, excessive spending or binge eating)

These are possible side effects of Duodopa and have normally been mild. They could also be an indication that the pump and tube may not be working properly.

Tell your doctor immediately if you notice any of the following:

- abnormal changes to the colour of your urine (chromaturia)
- any new dark pigmented skin lesions, or changes to a mole including growing bigger, bleeding, itching, or getting darker
- pain, bleeding or swelling in the mouth or throat, difficulty swallowing
- difficult or painful urination
- changes in mood such as depression
- signs of anaemia, such as tiredness, short of breath, and looking pale
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bruising or bleeding more easily than normal, nose bleeds
- fainting
- stomach aches, pain, cramping
- skin rash, itchiness
- numbness or tingling in the hands or feet

- change in vision or severe eye pain/headache

These are serious side effects. You may need urgent medical attention. Serious side effects are generally rare.

Tell your doctor immediately or go to accident and emergency at your nearest hospital if you notice any of the following:

- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing
- itchy swellings on the skin (hives or nettle rash)
- bleeding from the back passage, black sticky bowel motions (stools), an urgency to pass stools, pain when passing stools or diarrhoea containing blood and mucus
- severe stomach aches that may come and go, nausea and vomiting
- vomiting blood or material that looks like coffee grounds
- chest pain
- fast or irregular heartbeats (palpitations)
- muscle stiffness accompanied by fever
- mental changes such as feeling very fearful or paranoid
- developing unusual behaviours (e.g. seeing, hearing or feeling things that are not there - hallucinations)
- shortness of breath

These are all serious side effects that need urgent medical attention. Serious side effects are generally rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Some side effects can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by this list of side effects.

You may not experience any of them.

After using it

Storage

Keep your hard plastic cassettes of Duodopa intestinal gel in the refrigerator until it is time to use them.

Each cassette is for single use only and should not be used for longer than one day (up to 16 hours) even if some medicine is left.

Use before the expiry date printed on the carton.

Used cassettes should not be reused but returned to the nearest pharmacy.

Keep your gel in a cool dry place where the temperature stays between 2°C and 8°C (Refrigerate. Do not freeze).

Cassettes should be stored before use in the carton to protect from light.

Keep it where children cannot reach it.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Duodopa gel is a white to slightly yellow gel.

Duodopa gel is provided in 100 mL PVC (polyvinyl chloride) bags each inside individual hard plastic cassettes.

Duodopa gel is supplied in cartons of seven cassettes.

Ingredients

Active Ingredients:

- levodopa
- carbidopa monohydrate

Other Ingredients:

- carmellose sodium
- purified water

Duodopa does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

DUODOPA® is supplied in Australia by:

AbbVie Pty Ltd
241 O'Riordan Street
Mascot NSW 2020
Australia
Telephone: 1800 043 460

DUODOPA® is supplied in New Zealand by:

AbbVie Limited
6th Floor, 156-158 Victoria Street
Wellington 6011
New Zealand
Telephone: 0800 900 030

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