DUODOPA®

Levodopa/carbidopa monohydrate (‘lee-voe-‘doe-pah’/’kah-bee-‘doe-pah’) Gel

Consumer Medicine Information

What is in this CMI

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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.

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


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.
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 anti-hypertensives
• 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 light-headed 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.

Tell 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.

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**Product description**

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**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.

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**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.

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**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
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