

DUODOPA®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Duodopa?

Duodopa contains the active ingredients levodopa and carbidopa. Duodopa is used to treat advanced Parkinson's disease.

For more information, see Section [1. Why am I using Duodopa?](#) in the full CMI.

2. What should I know before I use Duodopa?

Check the list of ingredients at the end of the CMI. Do not use Duodopa if you have ever had an allergic reaction to any of them.

Talk to your doctor before you use this medicine if he/she is not aware that you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Duodopa?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Duodopa and affect how it works. Duodopa may interfere with other medicines and affect how they work.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Duodopa?

- The Duodopa dose is calculated by your doctor based on your individual needs.
- Duodopa is given directly into the tummy using a pump and tube. The tube is inserted during a surgical operation.

More instructions can be found in Section [4. How do I use Duodopa?](#) in the full CMI.

5. What should I know while using Duodopa?

| Things you should do | |
|----------------------|---|
| | <ul style="list-style-type: none">• Tell your doctor if you have any problem with the pump or tube, including the skin where the tube is located. |

| | |
|------------------------------------|--|
| | <ul style="list-style-type: none"> • Tell your doctor if your Parkinson's symptoms get worse. • Tell your doctor if you become pregnant. • Remind any doctor or dentist you visit that you are using Duodopa. |
| Things you should not do | <ul style="list-style-type: none"> • Do not stop using this medicine suddenly. Always follow the directions provided from your doctor. |
| Driving or using machines | <ul style="list-style-type: none"> • Use caution when driving or operating machines. |
| Drinking alcohol | <ul style="list-style-type: none"> • There is no information on the effects of using Duodopa with alcohol. |
| Looking after your medicine | <ul style="list-style-type: none"> • Store Duodopa in the refrigerator. Do not allow it to freeze. • Use each cassette only once for a maximum of 16 hours. |

For more information, see Section [5. What should I know while using Duodopa?](#) in the full CMI.

6. Are there any side effects?

The most common side effects are nausea, uncontrollable twitching, jerking movements, weight loss, pain and redness at the location of the tube.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Duodopa[®] ('dew-oh-'doe-pah)

Active ingredient(s): *Levodopa* ((lee-voe-'doe-pah) and *Carbidopa* ('kah-bee-'doe-pah)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Duodopa. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Duodopa.**

Where to find information in this leaflet:

- [1. Why am I using Duodopa?](#)
- [2. What should I know before I use DuoDopa?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Duodopa?](#)
- [5. What should I know while using Duodopa?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Duodopa?

Duodopa contains the active ingredients levodopa and carbidopa.

Duodopa is used to treat advanced Parkinson's disease, helping you to gain control over your movements and posture.

2. What should I know before I use Duodopa?

Warnings

Do not use Duodopa if:

1. you are allergic to levodopa or carbidopa, or any of the ingredients listed at the end of this leaflet
2. you have a sudden fluid build-up inside the eye causing very high pressure (narrow angle glaucoma)
3. you have problems with your liver or kidneys
4. you have or have had melanoma, or if you have skin marks or sores that have not been checked by a doctor
5. you have any condition that affects the adrenal glands, the glands responsible for releasing hormones that control heart rate, metabolism, and blood pressure, e.g. a tumour on the gland called pheochromocytoma, or a condition called Cushings syndrome
6. you have an over-active thyroid.

Check with your doctor if you:

- have had a stroke or heart attack, or have other heart problems, such as blocked arteries, your heart beats too fast or too slowly
- have had severe asthma

- have or have had depression (low mood, a feeling of worthlessness) or you have had thoughts about suicide
- have or have had other mental health issues
- have had a stomach ulcer
- have ever had abdominal (tummy) surgery
- have or have had high pressure in one or both eyes
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Make sure your doctor is aware that you are pregnant or plan to become pregnant; or are breastfeeding or plan to do so.

3. What if I am taking other medicines?

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

Some medicines may interfere with Duodopa and affect how it works.

Check with your doctor before you use Duodopa if you are taking or have recently taken (in the last 2 weeks), any medicine to treat depression. There are

certain types of antidepressants that cannot be taken with Duodopa. These can include some monoamine oxidase (MAO) inhibitors. Examples include phenylzine, tranylcypromine.

Medicines that may increase the effect of Duodopa include:

- entacapone (sometimes added to therapy to reduce Parkinson's symptoms for a longer time)
- amantadine (used to treat certain viral infections).

Medicines that may reduce the effect of Duodopa include:

- some medicine used to treat certain mental and emotional conditions (e.g. chlorpromazine, thioridazine, haloperidol, risperidone)
- some medicines used to treat nausea or vomiting (e.g. metoclopramide)
- some medicines that work in the brain used to treat anxiety, and to relax muscles (e.g. diazepam, clonazepam)
- isoniazid (used to treat tuberculosis)
- phenytoin (used to treat convulsions or fits)
- papaverine (used to increase blood flow, and to treat problems with the stomach and gall bladder)
- iron supplements.

Medicines where Duodopa may increase their effect include:

- certain medicines used to treat high blood pressure.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Duodopa.

4. How do I use Duodopa?

How much to use

- The Duodopa dose is calculated by your doctor based on your individual needs.
- Follow all instructions given to you and use Duodopa until your doctor tells you to stop.

How to use Duodopa

- Duodopa is given directly into the tummy using a pump and tube. The tube is inserted during a surgical operation.
- Instructions on the use of the pump is supplied with the pump itself.
- Before you are fitted with a pump, your doctor may see if the medicine is right for you first. This is done by giving the medicine using a tube that goes up through the nose and into the stomach.

When to use Duodopa

- Your pump will be adjusted to give you 2 or more doses in each 24-hour period. This includes a larger morning “bolus” dose (given to build up the levels of the medicine in your system quickly), followed by a continuous dose throughout the day.

- From time-to-time your doctor may also prescribe additional bolus doses at certain times during the day, depending on how you respond.

If you forget to use Duodopa

Duodopa should be used every day.

If you miss your dose, start the pump with your usual dose as soon as you remember.

If you use too much Duodopa

You should immediately:

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there appear to be no signs of discomfort or poisoning.

5. What should I know while using Duodopa?

Things you should do

Call your doctor straight away if you:

- you have any problems with the pump or tube, including if you are finding it difficult to manage it
- you have any pain near the point where the tube is located, and you feel nauseous

- your Parkinson's disease symptoms get worse or it is harder to move than usual
- you become pregnant while using Duodopa.

Get regular skin cancer checks.

Keep all your doctor's appointments so that your progress can be checked.

Remind any doctor or dentist you visit that you are using Duodopa.

Things you should not do

- Do not stop using Duodopa suddenly. Use Duodopa until your doctor tells you to stop.

Driving or using machines

Use caution when driving or using any machines or tools while you are using Duodopa.

Duodopa may cause you to feel dizzy, lightheaded, or sleepy and may cause your vision to be blurred.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

- Store Duodopa in the refrigerator (Between 2°C and 8°C)
- Do not allow the medicine to freeze.
- Use each cassette only once for a maximum of 16 hours even if there is medicine left

- Keep your cassettes in the pack until it is time to use them

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, check with your pharmacy about options for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Bear in mind that with Parkinson's disease and its treatment, your carer may observe some symptoms more easily than you.

Less serious side effects

| Less serious side effects | What to do |
|---|---|
| <ul style="list-style-type: none">● Gut:● feeling sick in the stomach● vomiting● constipation (infrequent bowel motions)● diarrhoea● indigestion or heart burn● feeling bloated or passing wind● dry mouth● reduced appetite● loss of weight. <p>Skin and muscles:</p> <ul style="list-style-type: none">● pain or redness at the location of the tube● increased sweating● rash● neck pain● muscle contractions that cannot be controlled. <p>Brain and nerves:</p> <ul style="list-style-type: none">● headache | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

| Less serious side effects | What to do |
|---|-------------------|
| <ul style="list-style-type: none"> ● general tiredness or lack of energy ● feeling suddenly very tired ● difficulty sleeping or strange dreams ● dizziness or feeling lightheaded, especially when standing up quickly ● uncontrollable twitching, jerking movements or a worsening of your Parkinson's symptoms ● feeling sensitive to touch, tingling in hands or feet, numbness. | |

More serious side effects

| More serious side effects | What to do |
|--|---|
| <p>Infection:</p> <ul style="list-style-type: none"> ● frequent infections, with symptoms such as fever, lack of energy, skin sores, problems with teeth and gums, | <p>Call your doctor straight away, if you notice any of these more serious side effects.</p> |

| More serious side effects | What to do |
|--|-------------------|
| <p>burning when passing urine.</p> <p>Gut:</p> <ul style="list-style-type: none"> ● severe tummy-ache or cramping ● the tube has moved or appears to be blocked. <p>Skin:</p> <ul style="list-style-type: none"> ● Unusual marks or moles on your skin that appear or get worse. <p>Brain and nerves:</p> <ul style="list-style-type: none"> ● low mood or feeling a sense of worthlessness (depression) ● thoughts of suicide ● feeling confused or especially nervous ● seeing or hearing things that aren't real (hallucinations) ● sudden uncontrolled urges. | |

Very serious side effects

| Very serious side effects | What to do |
|--|--|
| <p>Allergic reaction:</p> <ul style="list-style-type: none">• swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing,• rash (hives). <p>Neuroleptic Malignant Syndrome:</p> <ul style="list-style-type: none">• Fast heartbeat,• sweating, and fever,• fast breathing,• muscle stiffness,• losing consciousness | <p>Go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p> |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. For NZ

Consumers, you can report any side effects to <https://nzphvc.otago.ac.nz/reporting/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Duodopa contains

| | |
|---|--|
| Active ingredient (main ingredient) | <ul style="list-style-type: none">• levodopa• carbidopa |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">• carmellose sodium• purified water |

Do not take this medicine if you are allergic to any of these ingredients.

What Duodopa looks like

Duodopa is a white to slightly yellow gel.

Duodopa gel is provided in 100 mL plastic bags inside individual hard plastic cassettes.

Duodopa is supplied in cartons of seven cassettes.

The carton includes the Australian registration number Aust R 133452.

Who distributes Duodopa?

Duodopa is distributed in Australia by:

AbbVie Pty Ltd

241 O’Riordan Street

MASCOT NSW 2020

Australia

Duodopa is distributed in New Zealand by:

AbbVie Limited

6th Floor, 156-158 Victoria Street

Wellington 6011

New Zealand

This leaflet was prepared in April 2020.