

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 Comtan?

Comtan contains the active ingredient entacapone. Comtan is used to treat the symptoms of Parkinson's disease in people who are already taking a medicine called levodopa.

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

2. What should I know before I use Comtan?

Do not use if you have ever had an allergic reaction to entacapone or any of the ingredients listed at the end of the CMI.

Talk to your doctor if 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 Comtan?](#) in the full CMI.

3. What if I am taking other medicines?

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

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 Comtan?

- Take one tablet (200 mg) of Comtan each time you take a dose of levodopa.
- People with moderate to severe Parkinson's disease usually take from 4 to 7 tablets of Comtan each day. The maximum dose is 10 tablets each day.

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

5. What should I know while using Comtan?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Comtan.• If you become pregnant, tell your doctor immediately.• Before having any surgery or other hospital treatment, tell the anaesthetist or the doctor in charge that you are taking Comtan.
Things you should not do	<ul style="list-style-type: none">• Do not give this medicine to anyone else, even if their condition seems similar to yours.• Do not use it to treat any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking Comtan until you know how it affects you.• This medicine may increase the dizziness, light headedness or sleepiness that sometimes happens when you take levodopa. Very rarely it can cause extreme sleepiness and sudden onset of sleep in the middle of daytime activities, sometimes without warning.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in the original container until it is time to take it.

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

6. Are there any side effects?

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

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects. Some of the side effects listed below are more common at the beginning of treatment and may disappear as treatment continues.

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.

Comtan®

Active ingredient(s): *entacapone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Comtan. **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 Comtan.**

Where to find information in this leaflet:

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

1. Why am I using Comtan?

Comtan contains the active ingredient entacapone.

Comtan is used to treat the symptoms of Parkinson's disease in people who are already taking a medicine called levodopa. When levodopa on its own does not control the symptoms, Comtan can be added.

Parkinson's disease is a disorder of the nervous system. It is caused by a lack of dopamine, a natural substance that is produced in the brain. Dopamine relays messages in the part of the brain that controls muscle movement. When too little dopamine is produced, problems with movement result.

Comtan is always used together with levodopa. Levodopa works by increasing the level of dopamine in the brain and Comtan works by making the effect of levodopa last longer. Together, Comtan and levodopa help to relieve symptoms such as shaking of the limbs, stiffness and slowness of movement, which make it difficult to perform normal daily activities. Other medicines can also be added to help treat this 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 purpose.

There is not enough information to recommend this medicine for children under 18 years of age.

2. What should I know before I use Comtan?

Warnings

Do not use Comtan if:

- you are allergic to entacapone, or any of the ingredients listed at the end of this leaflet. Always

check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

- you have or ever had any of the following health problems / medical conditions:
 - a problem with your liver
 - a tumour of the adrenal gland (called pheochromocytoma), which could cause your blood pressure to rise to a dangerous level
 - a serious condition called neuroleptic malignant syndrome (NMS), with symptoms such as a sudden increase in body temperature, sweating, fast heart beat, muscle stiffness and fluctuating blood pressure
 - a condition called rhabdomyolysis, with symptoms of severe muscle weakness, that was not due to an injury
- the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether any of the above conditions apply to you, your doctor can advise you.

Check with your doctor if you:

- have any other medical conditions, including:
 - severe kidney disease that requires dialysis treatment. Your doctor may need to adjust the dose of Comtan in this case.
 - heart attack or any other diseases of the heart.
- take any medicines for any other condition
- have allergies to any other medicines, foods, dyes or preservatives. Your doctor will want to know if you are prone to allergies.
- have an intolerance to sucrose. This medicine contains sucrose.

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

Do not take Comtan if you are pregnant.

There is not enough information to recommend its use during pregnancy.

Do not breast-feed while you are taking Comtan.

It is not known if the active ingredient in Comtan passes into breast milk and could affect your baby.

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.

Tell your doctor if you are taking a medicine called a monoamine-oxidase inhibitor (MAOI).

Taking Comtan together with some, but not all, MAOI medicines may cause serious side effects. Your doctor will know whether or not the MAOI medicine you are taking can be safely taken with Comtan.

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

- other medicines for Parkinson's disease
- some medicines for depression
- methyl dopa, a medicine for high blood pressure
- medicines containing iron, such as iron tablets or multiple vitamins
- warfarin, a medicine used to prevent blood clots

You may need to take different amounts of your medicines or to take different medicines while you are taking Comtan. Your doctor and pharmacist have more information.

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

4. How do I use Comtan?

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

These directions may differ from the information contained in this leaflet.

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

How much to take

- **Take one tablet (200 mg) of Comtan each time you take a dose of levodopa.**
- People with moderate to severe Parkinson's disease usually take from 4 to 7 tablets of Comtan each day. The maximum dose is 10 tablets each day.
- Because Comtan increases the action of levodopa, it can also increase some of its side effects, especially at the start of treatment. To prevent this from happening, your doctor may lower your usual dose of levodopa for a few days or weeks. However, it is still important that you take a tablet of Comtan each time you take a dose of levodopa.

How to take Comtan

- **Take the tablet with a full glass of water at the same time as you take a dose of levodopa.**
- **If your stomach is upset after taking the tablet, take it with a meal or after a snack.**
- It does not matter if you take Comtan with or without food but avoid fatty meals.
- **If you are taking any medicines containing iron, take them at least 2 or 3 hours before or after a dose of Comtan.**
- If you take the two medicines at the same time, your body may absorb less iron than usual.

How long to take Comtan

- **Do not stop taking this medicine without first checking with your doctor.**
- You may need to take Comtan for a long time to control your symptoms. If you stop taking it, the dose of your other medicines for Parkinson's disease may have to be increased to prevent your symptoms from getting worse.

If you forget to use Comtan

Comtan should be used regularly at the same time each day. If you miss your dose at the usual time, wait until the next dose of levodopa is due and start taking Comtan again at that time.

Do not take a double dose to make up for the dose you missed.

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

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you use too much Comtan

If you think that you have used too much Comtan, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Comtan?

Things you should do

If you become pregnant, tell your doctor immediately.

You should not take this medicine while you are pregnant.

Before having any surgery or other hospital treatment, tell the anaesthetist or the doctor in charge that you are taking Comtan.

It may cause unwanted side effects if you take it at the same time as some medicines that are used in hospital.

Remind any doctor, dentist or pharmacist you visit that you are using Comtan.

Things you should not do

- **Do not give this medicine to anyone else, even if their condition seems similar to yours.**
- **Do not use it to treat any other complaints unless your doctor tells you to.**

Things to be careful of

If this medicine makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.

These symptoms may be a sign of low blood pressure. You can usually prevent them by getting up slowly and flexing leg muscles and toes to get the blood flowing. When getting out of bed, dangle your legs over the side for a minute or two before standing up.

Tell your doctor if you experience:

- temporary paralysis or severe weakness of the muscles
- prolonged diarrhoea. Your doctor may follow-up on your weight in order to prevent potential excessive weight loss
- 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 a preoccupation with an increase in sexual thoughts or feelings. Your doctor may need to review your treatments.
- progressive anorexia, asthenia (weakness, exhaustion) and weight decrease within a relatively short period of time. Your doctor may decide to conduct a general medical evaluation including liver function
- symptoms such as sudden increase in body temperature, more rapid heart beat, extremely high blood pressure or severe convulsions.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Comtan affects you.

This medicine may increase the dizziness, light headedness or sleepiness that sometimes happens when you take levodopa. Very rarely it can cause extreme sleepiness and sudden onset of sleep in the middle of daytime activities, sometimes without warning.

If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Looking after your medicine

- Keep your medicine in the original container until it is time to take it.

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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.

Some of the side effects listed below are more common at the beginning of treatment and may disappear as treatment continues.

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

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• nausea (feeling sick) or vomiting• diarrhoea• pain in the stomach• constipation• dry mouth• dizziness or lightheadedness• spinning sensation (vertigo)• tiredness• shakiness• aches and pains• leg cramps• headache• increased sweating• difficulty sleeping or unusual dreams• feeling depressed, confused or agitated• a reddish-brown colour to the urine (this is harmless)• discolouration of hair, beard, skin or nails• inability to resist the impulse to perform an action that could be harmful, which may include:<ul style="list-style-type: none">• strong impulse to gamble excessively despite serious or personal family consequences• altered or increase 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	Speak to your doctor if you have any of these less serious side effects and they worry you.

than normal and more than is needed to satisfy your hunger).

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">rash, itching or hives on the skinunusual and uncontrolled movements of the body such as twisting, jerking or writhing movementssymptoms of neuroleptic malignant syndrome, such as a sudden increase in body temperature, sweating, fast heart beat, muscle stiffness and fluctuating blood pressureextreme sleepiness or sudden onset of sleep in the middle of daytime activitiesworsening of your symptoms of Parkinson's diseaseconfusion or hallucinations (seeing, hearing or feeling things that are not there)difficulty breathing, congestion in the chest, chest painsigns of possible anaemia (low amount of iron in your blood) such as tiredness, headaches, shortness of breath when exercising, dizziness and looking palesigns of possible liver problems such as loss of appetite, feeling generally unwell, fever, itching, yellow colour to the skin and eyesweight loss, often in association with diarrhoea and loss of appetitediarrhoea, usually with blood and mucus, stomach pain, fever	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these 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. 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 Comtan contains

Active ingredient (main ingredient)	entacapone
Other ingredients (inactive ingredients)	microcrystalline cellulose mannitol croscarmellose sodium hydrogenated vegetable oil hypromellose polysorbate 80 glycerol 85% sucrose magnesium stearate iron oxide yellow CI77492 iron oxide red CI77491 titanium dioxide.
Potential allergens	sucrose and sorbates.

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

What Comtan looks like

Comtan – oval, brownish-orange tablets, marked COMTAN on one side; packs of 30, 60 or 100 tablets (AUST R 68463).

Not all pack sizes marketed.

Who distributes Comtan

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

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