

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Comtan.

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

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine. You can also download the most up-to-date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

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

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

Keep this leaflet with the medicine.

You may need to read it again.

What Comtan is used for

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.

This medicine is only available with a doctor's prescription. It is not habit-forming.

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

Before you take Comtan

When you must not take it

Do not take Comtan if you have ever had an allergy to entacapone

(the active ingredient in Comtan) or to any of the other ingredients listed at the end of this leaflet.

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.

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.

Do not take Comtan if 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.

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

Do not take Comtan after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to take it

Tell your doctor if you have or ever had any of the following health problems / medical conditions:

- 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.

Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies.

Tell your doctor if you have an intolerance to sucrose.

This medicine contains sucrose.

Taking other medicines

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.

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

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.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

How to take 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 it

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 it

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 take it

If you forget to take a tablet of Comtan with your dose of levodopa, 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 one that 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 take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Comtan. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

While you are taking Comtan

Things you must 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.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Comtan.

Tell any other doctor, dentist or pharmacist who treats you that you are taking Comtan.

Things you must 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

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

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.

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.

Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

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

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

Tell your doctor if you experience any of these behaviours.

Your doctor will discuss ways of managing or reducing the symptoms.

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

- rash, itching or hives on the skin
- unusual and uncontrolled movements of the body such as twisting, jerking or writhing movements
- symptoms of neuroleptic malignant syndrome, such as a sudden increase in body temperature, sweating, fast heart beat, muscle stiffness and fluctuating blood pressure
- extreme sleepiness or sudden onset of sleep in the middle of daytime activities
- worsening of your symptoms of Parkinson's disease
- confusion or hallucinations (seeing, hearing or feeling things that are not there)
- difficulty breathing, congestion in the chest, chest pain
- signs of possible anaemia (low amount of iron in your blood) such as tiredness, headaches, shortness of breath when exercising, dizziness and looking pale
- signs of possible liver problems such as loss of appetite, feeling generally unwell, fever, itching, yellow colour to the skin and eyes
- weight loss, often in association with diarrhoea and loss of appetite
- diarrhoea, usually with blood and mucus, stomach pain, fever

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet.

After using Comtan

Storage

- Keep your medicine in the original container until it is time to take it.
- Store it in a cool dry place.
- Do not store Comtan or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

Keep this medicine where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking Comtan 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

Comtan tablets are oval, brownish-orange tablets, marked COMTAN on one side; packs of 100 tablets.

Ingredients

Comtan tablets contain 200 mg of entacapone as the active ingredient.

The tablets also contain:

- 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.

Comtan contains sucrose and sorbates.

Comtan does not contain gluten, tartrazine or any other azo dyes.

Sponsor

Comtan is supplied in Australia by:

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Tel: 1800 726 369

® = Registered Trademark

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