

## entacapone 200 mg film-coated tablets

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### What Comtan is used for

Comtan tablets contain entacapone and are used together with levodopa to treat Parkinson's disease.

### How Comtan works

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. Levodopa works by increasing the level of dopamine in the brain. Comtan aids levodopa in relieving the symptoms of Parkinson's disease, such as shaking of the limbs, and stiffness and slowness of movement, which make it difficult to perform normal daily activities.

Comtan has no effect on relieving the symptoms of Parkinson's disease unless taken with levodopa.

You may also be given other medicines to help treat this condition.

If you have any questions about how Comtan works or why this medicine has been prescribed for you, ask your doctor.

### Before you use Comtan

Follow all your doctor's instructions carefully, even if they differ from the general

information contained in this leaflet.

#### When you must not use it

- If you are hypersensitive (allergic) to entacapone or any of the other ingredients of Comtan.
  - If you have a liver disease.
  - If you have a tumour of the adrenal gland (known as pheochromocytoma; this may increase the risk of severe high blood pressure).
  - If you are taking certain antidepressants (ask your doctor whether your antidepressive medication can be taken together with Comtan).
  - If you have ever suffered from a rare reaction to antipsychotic medicines called neuroleptic malignant syndrome [NMS] (with symptoms such as rigidity, agitation, extreme increase in body temperature, rapid heart beat, and extreme fluctuations in blood pressure)
  - If you have ever suffered from a rare muscle disorder called rhabdomyolysis which was not caused by injury.
  - If you are pregnant.
  - If you are breast-feeding.
- If you think you may be allergic, ask your doctor for advice. If any of these apply to you, tell your doctor without taking Comtan.

#### ***Pregnancy and breast-feeding***

You should not use Comtan if you are pregnant or if you are breast-feeding.

Stop taking Comtan immediately and consult your doctor if you become pregnant during treatment. Ask your doctor or pharmacist for advice before taking any medicine.

#### Before you start to use it

- Talk to your doctor if any of these apply to you:
- If you have ever had a heart attack or any other diseases of the heart

- If you are receiving dialysis for renal insufficiency. It may be necessary for you to leave a longer interval between doses.
- Comtan tablets contain a sugar called sucrose. Therefore, if you have been told by your doctor that you have an inherited intolerance to sucrose, contact your doctor before taking Comtan.

#### ***Older people (aged 65 years and over)***

Comtan can be used by people over 65.

#### ***Children and adolescents***

Experience with Comtan in patients aged under 18 years is limited. Use of Comtan in children therefore cannot be recommended.

#### Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or herbal medicines. Comtan may increase the effects of other medicinal products.

In particular, tell your doctor if you are taking any of the following

- antidepressants such as desipramine, maprotiline, venlafaxine, paroxetine;
- warfarin used to thin the blood;
- iron supplements. Comtan may make it harder for you to digest iron. Therefore, do not take Comtan and iron supplements at the same time. After taking one of them, wait at least 2 to 3 hours before taking the other;
- as well as any of the following: rimiterol, isoprenaline, adrenaline, noradrenaline, dopamine, dobutamine, alpha-methyldopa, and apomorphine.

**How to use Comtan**

Follow your doctor's instructions carefully. Do not exceed the recommended dosage. You should check with your doctor or pharmacist if you are unsure.

How much to use

Comtan is taken together with medicines containing levodopa (either levodopa/carbidopa preparations or levodopa/benserazide preparations). You may also be prescribed other medicines to treat Parkinson's disease at the same time.

The usual dose of Comtan is one 200 mg tablet with each levodopa dose. The maximum recommended dose is 10 tablets per day, i.e. 2,000 mg of Comtan. If you are receiving dialysis for renal insufficiency, your doctor may tell you to increase the time between doses.

Your doctor will tell you exactly how many tablet of Comtan to take.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose. If you have the impression that the effect of Comtan is too strong or too weak, talk to your doctor or pharmacist.

When to use Comtan

Take Comtan at the same time as you take a dose of your levodopa medication.

Swallow the tablet with a full glass of water. Comtan can be taken with or without food.

How long to use Comtan

Continue to take Comtan as long as your doctor tells you to do.

If you forget to use Comtan

If you forget to take a Comtan tablet with your levodopa dose, you should continue the treatment by taking the next Comtan tablet with your next levodopa dose. Do not take a double dose of Comtan to make up for the one that you missed.

If you take more Comtan than you should (overdose)

If you have accidentally taken too many tablets, talk to your doctor or pharmacist straight away. You may require medical attention.

**While you are using Comtan**Things you must do

- If you experience symptoms such as sudden increase in body temperature, more rapid heartbeat, extremely high blood pressure or severe convulsions.
- If you experience temporary paralysis or severe weakness of the muscles.
- If you are taking a medicine which may cause dizziness or light-headedness (low blood pressure) when rising from a chair or bed.
- If you experience prolonged diarrhoea consult your doctor as it may be a sign of inflammation of the colon,
- If you experience prolonged diarrhoea, your doctor may follow-up on your weight in order to prevent potential excessive weight loss.
- Tell your doctor if you or your family/caregiver notices you are developing 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.
- If you experience increasing loss of appetite, weakness, exhaustion and weight loss within a relatively short period of time, contact your doctor. He/she may decide to conduct a general medical evaluation including liver function.

As Comtan tablets will be taken together with levodopa medicines, please also read the package leaflets of these medicines carefully.

The dose of other medicines to treat Parkinson's disease may need to be adjusted when you start taking Comtan. Follow the instructions that your doctor has given you.

Neuroleptic Malignant Syndrome (NMS) is a serious but rare reaction to certain medicines, and may occur especially when Comtan and other medicines to treat Parkinson's disease are suddenly stopped or the dose is suddenly reduced. For the characteristics of NMS see section 4 Possible side effects.

Your doctor may advise you to slowly discontinue the treatment with Comtan and other medicines to treat Parkinson's disease.

Comtan taken with levodopa may cause drowsiness and may cause you to sometimes suddenly fall asleep. If this happens, you should not drive or use tools or machines (see Driving and using machines).

Things you must not do

Do not stop taking Comtan unless your doctor tells you to.

When stopping, your doctor may need to re-adjust the dosage of your other medicines to treat Parkinson's disease. Suddenly stopping Comtan and other medicines to treat Parkinson's disease may result in unwanted side effects, such as severe muscular stiffness, high fever and altered consciousness.

Things to be careful of  
**Driving and using machines**

Comtan taken together with levodopa may lower your blood pressure, which may make you feel light-headed or dizzy. Be particularly careful when you drive or when you operate any tools or machinery.

In addition, Comtan taken with levodopa may make you feel very drowsy or cause you to sometimes suddenly fall asleep. Do not drive or operate machinery if you experience these side effects.

**Side effects**

As with all medicines, patients treated with Comtan may experience side effects, although not everybody gets them. Usually, these side effects are mild to moderate.

Within the first few days or weeks of therapy, you may experience nausea, vomiting, hallucinations (seeing, hearing, smelling or feeling things that are not really there), and unusual or uncontrolled movements of the body. To reduce these effects, your doctor may need to adjust your levodopa dosage in the first few days or weeks after starting treatment with Comtan.

The frequencies are defined as:  
Very common (*affects more than 1 patient in 10*)

Common (*affects 1 to 10 patients in 100*)

Uncommon (*affects 1 to 10 patients in 1,000*)

Rare (*affects 1 to 10 patients in 10,000*)

Very rare (*affects less than 1 patient in 10,000*)

Not known (*can't be estimated from the available data*)

If you experience any of the below side effects, tell your doctor immediately.

**Some side effects are very common:**

- Uncontrollable movements with difficulty in performing voluntary movements (dyskinesias);
- feeling sick (nausea);
- harmless reddish-brown discoloration of urine

**Some side effects are common:**

- Excessive movements of the body (hyperkinesias),
- prolonged muscle cramps (dystonia),
- hallucinations (seeing/hearing/feeling/smelling things that are not really there), confusion,
- heart or artery disease events (e.g. chest pain);
- worsening of symptoms of Parkinson's disease;

- being sick (vomiting), diarrhoea, abdominal pain, constipation, dry mouth;
- dizziness or light headedness, tiredness, increased sweating; falling
- sleeplessness, nightmares.

**Some side effects are uncommon:**

- Heart attack.

**Some side effects are rare:**

- Rashes;
- abnormal results in liver function test.

**Some side effects are very rare:**

- Inflammation of the colon (colitis) which may lead to diarrhoea and weight loss;
- Agitation;
- decreased appetite, weight loss;
- hives.

**Some side effects have an unknown frequency:**

- Inflammation of the liver (hepatitis) with any yellowing of your skin or the whites of your eyes;
- discolouration of the skin, hair, beard and nails.

**Comtan may have other important side effects**

- A rare severe muscle disorder (rhabdomyolysis) which causes pain, tenderness and weakness of the muscles and may lead to kidney problems;
- Comtan taken with levodopa may rarely make you feel very drowsy during the day, and cause you to suddenly fall asleep;
- Neuroleptic malignant syndrome (NMS) is a rare severe reaction to medicines used to treat disorders of the nervous system. It is characterised by stiffness, muscle twitching, shaking, agitation, confusion, coma, high body temperature, increased heart rate, and unstable blood pressure;
- headache, fever, leg cramps, vertigo (sensation of spinning or whirling

motion), tremor, low blood pressure,

You may experience the following side effects:

- 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 increased 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 behaviors; your doctor will discuss ways

**When Comtan is given at higher doses:**

In doses of 1,400 to 2,000 mg per day, the following side effects are more common:

- Uncontrollable movements;
- nausea;
- abdominal pain.

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

**Storage and Disposal of Comtan****- Storage**

Do not use after the expiry date printed on the pack.

Do not use if the pack is damaged or shows signs of tampering.

Store below 30°C

Store in the original package.  
There are no special storage instructions.  
Keep out of the sight and reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product Description**

What it looks like

Comtan 200 mg film-coated tablets are brownish-orange oval tablets with Comtan engraved on one side. They are packed in bottles.

Ingredients

- Active ingredients

The active substance of Comtan is *entacapone*.

- Inactive ingredients

The other ingredients are microcrystalline cellulose, mannitol, croscarmellose sodium, hydrogenated vegetable oil, hypromellose, polysorbate 80, glycerol 85%, sucrose, magnesium stearate, yellow iron oxide (E 172), red iron oxide (E 172), titanium dioxide (E 171).

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**Manufacturer**

Orion Corporation, Orionintie 1,  
Fin-02200 Espoo, Finland

**Product Registration Holder**

Novartis Corporation (Malaysia)  
Sdn. Bhd.  
Level 22, Tower B, Plaza 33,  
No. 1, Jalan Kemajuan, Seksyen  
13,  
46200 Petaling Jaya

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