**Package leaflet: Information for the user**

**Comtess 200 mg film-coated tablets**
entacapone

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Comtess is and what it is used for
2. What you need to know before you take Comtess
3. How to take Comtess
4. Possible side effects
5. How to store Comtess
6. Contents of the pack and other information


## 1. What Comtess is and what it is used for

Comtess tablets contain entacapone and are used together with levodopa to treat Parkinson's disease. Comtess aids levodopa in relieving the symptoms of Parkinson's disease. Comtess has no effect on relieving the symptoms of Parkinson's disease unless taken with levodopa.

## 2. What you need to know before you take Comtess

**Do not take Comtess**
- if you are allergic to entacapone or to peanut or soya or any of the other ingredients of this medicine (listed in section 6);
- 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 or pharmacist whether your antidepressive medicine can be taken together with Comtess);
- if you have liver disease;
- if you have ever suffered from a rare reaction to antipsychotic medicines called neuroleptic malignant syndrome (NMS). See section 4 Possible side effects for the characteristics of NMS;
- if you have ever suffered from a rare muscle disorder called rhabdomyolysis which was not caused by injury.

**Warnings and precautions**
Talk to your doctor or pharmacist before taking Comtess:
- if you have ever had a heart attack or any other diseases of the heart;
- 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 diarrhoea, monitoring of your weight is recommended in order to avoid potentially excessive weight loss;
- if you experience increasing loss of appetite, weakness, exhaustion and weight loss within a relatively short period of time, a general medical evaluation including liver function should be considered.

Tell your doctor if you or your family/carer 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.

As Comtess tablets will be taken together with other 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 Comtess. 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 Comtess 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 Comtess and other medicines to treat Parkinson's disease.

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

**Other medicines and Comtess**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular please tell your doctor if you are taking any of the following:
- rimiterole, isoprenaline, adrenaline, noradrenaline, dopamine, dobutamine, alpha-methyldopa, apomorphine;
- antidepressants including desipramine, maprotiline, venlafaxine, paroxetine;
- warfarin used to thin the blood;
- iron supplements. Comtess may make it harder for you to digest iron. Therefore, do not take Comtess and iron supplements at the same time. After taking one of them, wait at least 2 to 3 hours before taking the other.

**Pregnancy, breast-feeding and fertility**
Do not use Comtess during pregnancy or if you are breast-feeding.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Driving and using machines**
Comtess 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 use tools or machinery.

In addition, Comtess 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.

**Comtess contains soya lecithin and sodium**
Comtess contains soya lecithin. If you are allergic to peanut or soya, do not use this medicinal

product.

This medicine contains 7.9 mg sodium (main component of cooking/table salt) in each tablet. The maximum recommended daily dose (10 tablets) contains 79 mg of sodium. This is equivalent to 4% of the recommended maximum daily dietary intake of sodium for an adult.

## 3. How to take Comtess

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

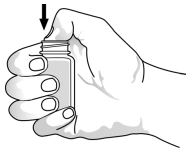
Comtess is taken together with medicines containing levodopa (either levodopa/carbidopa preparations or levodopa/benserazide preparations). You may also use other medicines to treat Parkinson's disease at the same time.

The recommended dose of Comtess is one 200 mg tablet with each levodopa dose. The maximum recommended dose is 10 tablets per day, i.e. 2,000 mg of Comtess.

If you are receiving dialysis for renal insufficiency, your doctor may tell you to increase the time between doses.

To open the bottle for the first time: open the closure, and then press with your thumb on the seal until it breaks. See picture 1.

Picture 1



**Use in children and adolescents**
Experience with Comtess in patients under 18 years is limited. Therefore, the use of Comtess in children or adolescents cannot be recommended.

**If you take more Comtess than you should**
In the event of an overdose, consult your doctor, pharmacist or the nearest hospital immediately.

**If you forget to take Comtess**
If you forget to take the Comtess tablet with your levodopa dose, you should continue the treatment by taking the next Comtess tablet with your next levodopa dose.

Do not take a double dose to make up for a forgotten tablet.

**If you stop taking Comtess**
Do not stop taking Comtess 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 Comtess and other medicines to treat Parkinson´s disease may result in unwanted side effects. See Section 2 Warnings and precautions.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Usually side effects caused by Comtess are mild to moderate.

Some of the side effects are often caused by the increased effects of levodopa therapy and are most

common at the start of treatment. If you experience such effects at the start of treatment with Comtess you should contact your doctor who may decide to adjust your dosage of levodopa.

Very common (may affect more than 1 in 10 people):
- Uncontrollable movements with difficulty in performing voluntary movements (dyskinesias);
- feeling sick (nausea);
- harmless reddish-brown discolouration of urine.

Common (may affect up to 1 in 10 people):
- Excessive movements (hyperkinesias), worsening of symptoms of Parkinson´s disease, prolonged muscle cramps (dystonia);
- being sick (vomiting), diarrhoea, abdominal pain, constipation, dry mouth;
- dizziness, tiredness, increased sweating, fall ;
- hallucinations (seeing/hearing/feeling/smelling things that are not really there), sleeplessness, vivid dreams, and confusion;
- heart or artery disease events (e.g. chest pain).

Uncommon (may affect up to 1 in 100 people):
- Heart attack.

Rare (may affect up to 1 in 1,000 people):
- Rashes;
- abnormal results in liver function test.

Very rare (may affect up to 1 in 10,000 people):
- Agitation;
- decreased appetite, weight loss;
- hives.

Not known (frequency cannot be estimated from the available data):
- Inflammation of the colon (colitis), inflammation of the liver (hepatitis) with yellowing of the skin and whites of the eyes;
- discolouration of skin, hair, beard and nails.

When Comtess 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.

Other important side effects which may occur:
- Comtess 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 and confusion, coma, high body temperature, increased heart rate, and unstable blood pressure;

- a rare severe muscle disorder (rhabdomyolysis) which causes pain, tenderness and weakness of the muscles and may lead to kidney problems.

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 personal or 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 behaviours; they will discuss ways of managing or reducing the symptoms.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Comtess

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the bottle label. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Comtess contains**
- The active substance is entacapone. Each tablet contains 200 mg of entacapone.
- The other ingredients in the tablet core are microcrystalline cellulose, croscarmellose sodium, povidone and magnesium stearate.
- The film-coating contains partly hydrolysed polyvinyl alcohol, talc, macrogol, soya lecithin, yellow iron oxide (E 172), red iron oxide (E 172) and titanium dioxide (E 171).

**What Comtess looks like and contents of the pack**
Comtess 200 mg film-coated tablets are brownish-orange, oval tablets with "COMT" engraved on one side. They are packed in bottles.

There are four different pack sizes (bottles containing 30, 60, 100 or 175 tablets). Not all pack sizes may be marketed.

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Orion Corporation
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**Manufacturer**
Orion Corporation Orion Pharma

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For further information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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**This leaflet was last revised in**

November 2021.