

Read all of this leaflet carefully before you start taking COMTAN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

PATIENT INFORMATION LEAFLET

S4

COMTAN® 200 mg Tablets

Entacapone

1. WHAT COMTAN 200 mg CONTAINS

The active substance is entacapone. Each tablet contains 200 mg entacapone.

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

2. WHAT COMTAN 200 mg IS USED FOR

COMTAN 200 mg is used together with levodopa to treat Parkinson's disease.

COMTAN 200 mg has no antiparkinsonian activity without levodopa.

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

If you have any questions about how COMTAN 200 mg works or why this medicine has been prescribed for you, ask your doctor.

3. BEFORE YOU TAKE COMTAN 200 mg

Follow all your doctor's instructions carefully, even if they differ from the general information contained in this leaflet.

Do not take COMTAN 200 mg:

- If you are hypersensitive (allergic) to entacapone or any of the other ingredients of COMTAN 200 mg tablets.
- 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 200 mg).
- 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) and/or a rare muscle disorder called non-traumatic rhabdomyolysis.
- If you are pregnant.
- If you are breastfeeding.

If any of these apply to you, tell your doctor without taking COMTAN 200 mg.

Take special care with COMTAN 200 mg:

If you have (or have ever had) a liver or severe kidney disease, or if you have any allergies to other medicines, or to food, dyes, or preservatives.

If you are receiving dialysis for renal insufficiency, it may be necessary for you to leave a longer interval between doses.

If you experience symptoms such as sudden increase in body temperature, more rapid heart beat, extremely high blood pressure or severe convulsions.

If you experience temporary paralysis or severe weakness of the muscles.

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

If you experience prolonged diarrhoea, your doctor may follow-up on your weight in order to prevent potential excessive weight loss.

If you experience progressive anorexia, asthenia (weakness, exhaustion) and weight decrease within a relatively short period of time, contact your doctor. He/she may decide to conduct a general medical evaluation including liver function.

If any of these apply to you, tell your doctor before you take COMTAN 200 mg.

Use in older people:

COMTAN 200 mg can be used by people over 65.

Use in children:

Experience with COMTAN 200 mg in patients aged less than 18 years is limited. Use of COMTAN 200 mg in children therefore cannot be recommended.

Pregnancy and breastfeeding:

Do not use COMTAN 200 mg if you are pregnant. Stop taking COMTAN 200 mg immediately and consult your doctor, pharmacist or other healthcare professional for advice, if you become pregnant during treatment.

Do not use COMTAN 200 mg if you are breastfeeding.

Driving and using machinery:

COMTAN 200 mg 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.

COMTAN 200 mg taken with levodopa may make you feel very drowsy or cause you to sometimes find yourself suddenly falling asleep. If this happens, you must not drive or do anything else that requires you to be alert (e.g. operate tools or machines) until you are clear of such problems. Otherwise you may put yourself and others at risk of serious injury or even death.

Taking other medicines with COMTAN 200 mg:

If you are taking medicines on a regular basis, including complementary or traditional medicines, the use of COMTAN 200 mg with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

COMTAN 200 mg may increase the effects of other medicinal products (e.g. those containing rimiterol, isoprenaline, adrenaline, noradrenaline, dopamine, dobutamine, alpha-methyldopa, apomorphine and paroxetine).

COMTAN 200 mg may make it harder for you to digest iron. Therefore, do not take COMTAN 200 mg and iron supplements at the same time. After taking one of them, wait at least 2 to 3 hours before taking the other.

4. HOW TO TAKE COMTAN 200 mg

Always take COMTAN 200 mg exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

How much to take:

COMTAN 200 mg is taken together with preparations containing levodopa (either levodopa/carbidopa preparations or levodopa/benserazide preparations). You may also be prescribed other antiparkinsonian medicinal products to take at the same time.

The usual dose of COMTAN 200 mg is one 200 mg tablet with each levodopa dose. If you are receiving dialysis for renal insufficiency, your doctor may tell you to extend the interval between doses.

The maximum recommended dose is 200 mg ten times a day, i.e. 2 g of COMTAN.

If you have the impression that the effect of COMTAN 200 mg is too strong or too weak, talk to your doctor or pharmacist.

When and how to take COMTAN 200 mg:

Take COMTAN 200 mg at the same time as you take a dose of your levodopa medication.

Swallow the tablet with a full glass of water. COMTAN 200 mg can be taken with or without food.

How long to take COMTAN 200 mg:

Continue to take COMTAN 200 mg as long as your doctor tells you to.

If you take more COMTAN 200 mg than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre. Take the remaining tablets with you so that the doctor will know what the patient has taken. You may require medical attention.

If you forget to take COMTAN 200 mg:

If you forget to take a COMTAN 200 mg tablet with your levodopa dose, you should continue the treatment by taking the next COMTAN 200 mg tablet with your next levodopa dose.

Do not take a double dose of COMTAN 200 mg to make up for forgotten individual doses.

Effects when treatment with COMTAN 200 mg is stopped:

Do not stop taking COMTAN 200 mg unless your doctor tells you to. Your doctor may need to re-adjust the dosage of your other antiparkinsonian medication if you stop taking COMTAN 200 mg. Abrupt discontinuation of both COMTAN and other antiparkinsonian medication may result in unwanted side effects, such as severe muscular stiffness, high fever and altered consciousness.

5. POSSIBLE SIDE EFFECTS

COMTAN 200 mg can have side effects.

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 200 mg.

Some side effects could be serious:

- Any yellowing of your skin or the whites of your eyes.
- Feeling unwell while taking COMTAN 200 mg.
- Unusual and uncontrolled movements of the body and apparent deterioration of your present condition including a tendency to fall.
- Hallucinations.
- Fever.
- Leg cramps.
- Prolonged muscle contractions.
- Muscle weakness.
- Confusion.
- Excessive daytime somnolence, sudden sleep onset episodes.
- Severe muscular stiffness, high fever and altered consciousness.
- Inflammation of the colon which may lead to diarrhoea and weight loss.

If you experience any of these, tell your doctor immediately.

COMTAN 200 mg may have other side effects: sleeplessness, agitation, worsening of symptoms of Parkinson's disease, dizziness or light headedness, vertigo (sensation of spinning or whirling motion), tremor, low blood pressure, feeling sick (nausea) or vomiting, diarrhoea, constipation, pain in the stomach, dryness of the mouth, decreased appetite, rash, hives, a reddish-brown discolouration of the urine, discolouration of hair, beard, skin or nails, tiredness, increased sweating, weight decrease, excessive daytime somnolence, sudden sleep onset episodes. You may also experience behavioural changes such as urge to gamble (pathological gambling) or increased sexual desire urges (increased libido and hypersexuality) when taking COMTAN in combination with levodopa/carbidopa.

If any of these side effects worry you, tell your doctor as soon as possible.

Some effects, such as uncontrolled movements, feeling sick (nausea) and pain in the stomach may also be more common with higher COMTAN 200 mg doses (1 400 to 2 000 mg per day).

Abnormal results of blood tests have been observed in people taking COMTAN 200 mg.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF COMTAN 200 mg

Keep all medicines out of the reach and sight of children.

Do not store above 25°C.

Do not use after the expiry date stated on the label or carton.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF COMTAN 200 mg

COMTAN® 200 mg tablets are packed in amber glass bottles containing 30, 60, 100 or 500 tablets.

8. IDENTIFICATION OF COMTAN 200 mg

COMTAN® 200 mg tablets are brownish-orange, oval shaped tablets with "COMTAN" printed on it.

9. REGISTRATION NUMBER

32/5.4.1/0684

10. NAME AND ADDRESS OF REGISTRATION HOLDER

NOVARTIS SOUTH AFRICA (Pty) Ltd

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