

COMTAN[®] (entacapone)

200 mg film-coated tablets

Basic Succinct Statement

Code: BSS RD 18 JUN 2013; APPR 27 JUN 2014

This material is only meant for Healthcare Professionals

COMTAN® 200 mg film-coated tablets

Catechol-O-methyl transferase inhibitor

Presentation: *Entacapone*. Film-coated tablets containing 200 mg of entacapone.

Indications: Adjunct to levodopa/benserazide or levodopa/carbidopa treatment in patients with Parkinson's disease and end-of-dose motor fluctuations, who cannot be stabilized on those combinations.

Dosage: One tablet with each levodopa/dopa decarboxylase inhibitor dose. Maximum recommended daily dose: 2,000 mg entacapone.

Contraindications: ♦Hypersensitivity to entacapone or to any of the excipients ♦Liver impairment ♦Pheochromocytoma ♦Concomitant use with non-selective monoamine oxidase inhibitors (MAO-A and MAO-B) Concomitant use with a selective MAO-A plus a selective MAO-B inhibitor ♦History of neuroleptic malignant syndrome (NMS) and/or nontraumatic rhabdomyolysis.

Warnings/Precautions: ♦Dosage of levodopa and other antiparkinsonian medications (e.g. dopamine agonists) may need to be adjusted when entacapone treatment is initiated. Levodopa-induced orthostatic hypotension may be aggravated. ♦Effects of medicinal products metabolized by catechol-O-methyl transferase may be potentiated. ♦Caution in patients with ischaemic heart disease ♦Caution when discontinuing entacapone treatment (isolated cases of NMS reported). ♦Caution when driving or operating machines; patients presenting somnolence and/or sudden sleep onset episodes must refrain from driving and operating machinery ♦Follow-up of weight recommended in patients experiencing diarrhoea. General medical evaluation including liver function in case of progressive anorexia, asthenia and weight decrease within a relatively short period of time. Comtan should be discontinued if prolonged/persistent diarrhoea is suspected to be related to the drug. Prolonged/persistent diarrhoea may be a sign of colitis. ♦Development of impulse control disorders (e.g. pathological gambling, increased libido, hypersexuality) should be regularly monitored. ♦Caution in patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency. ♦Do not use during pregnancy or while breast-feeding.

Interactions: Caution when used concomitantly with MAO-A inhibitors, tricyclic antidepressants, noradrenaline reuptake inhibitors, and medicinal products metabolized by COMT. Entacapone can be used with selegiline (a selective MAO-B inhibitor) but the daily dose of selegiline should not exceed 10 mg. Entacapone and iron preparations should be taken at least 2 to 3 hours apart. Control of INR is recommended when treatment is initiated in patient receiving warfarin.

Adverse reactions: ♦Very common ($\geq 10\%$): dyskinesia, urine discolouration, nausea ♦Common (1 to $<10\%$): gastrointestinal symptoms (e.g. vomiting, abdominal pain, constipation, diarrhoea, dry mouth), ischaemic heart disease, insomnia, hallucinations, confusion, nightmares, Parkinsonism aggravated, dizziness, dystonia, hyperkinesia, fatigue, increased sweating, fall. ♦Uncommon (0.1 to $<1\%$) and rare (0.01 to $<0.1\%$) but potentially serious adverse reactions: myocardial infarction, hepatic function test abnormal, erythematous or maculopapular rash. ♦Very rare ($<0.01\%$): colitis, agitation, urticaria, anorexia, weight decrease. ♦Other (frequency unknown): hepatitis with mainly cholestatic features, discolouration of skin, hair, beard and nails, sudden sleep onset episodes, neuroleptic

malignant syndrome (NMS), rhabdomyolysis. Impulse control disorders (e.g. pathological gambling, increased libido, hypersexuality).