

Slogan.....

**Syntopine<sup>®</sup>**

Carbamazepine

**SYNTOPINE<sup>®</sup>** 200mg tablets



**CODAL-SYNTO**

## Summary of SPC for Syntopine®

<b>Trade Name of the Medicinal Product:</b>	Syntopine®
<b>Qualitative and Quantitative Composition:</b>	Carbamazepine 200mg.
<b>Indications &amp; Posology and Method of Administration:</b>	<u>Epilepsy</u> : Adults: The initial dose is 100 - 200 mg once or twice daily. The dose may be increased gradually until the best response is obtained up to 800-1200 mg daily. In some cases 1600 mg or 2000 mg daily are necessary. Children 5-10 years old: 400-600mg daily, in 2-3 divided doses. Children 10-15 years old: 200mg 3-5 times daily. When Taver is added to existing antiepileptic therapy, this should be done gradually while maintaining or, if necessary, adapting the dosage of the other antiepileptics. <u>Trigeminal neuralgia</u> : In the majority of the patients 200-400 mg daily are adequate to maintain a pain-free state. Doses up to 1600 mg have been used. For elderly patients the initial dose should be 100 mg twice daily. <u>Prophylaxis of manic-depressive psychosis in patients unresponsive to lithium treatment</u> : The initial dose is 400 mg in daily divided doses. Dosage may be gradually increased up to 1600 mg daily until symptoms are controlled. The usual dosage range is 400 mg to 600 mg daily, given in divided doses.
<b>Contra-indications:</b>	Hypersensitivity. Atrioventricular block. History of previous bone marrow depression or acute intermittent porphyria. Concomitantly use with MAOIs.
<b>Special Warnings and Precautions for Use:</b>	Blood counts, eye examinations, renal and liver function should be checked (baseline and periodic). Suicidal ideation and behaviours. Dermatologic reactions. HLA-B*1502 in individuals of Han Chinese and Thai origin. Activation of a latent psychosis. Mixed seizure disorder. History of cardiac, hematologic reactions, hepatic, or renal damage. Thyroid function. Hyponatraemia. Interference with some pregnancy tests. Neonatal withdrawal syndrome.
<b>Interactions with other Medicaments and other forms of Interaction:</b>	CYP 3A4 inhibitors and inducers, grapefruit juice, mefloquine, valproic acid, primidone, isotretinoin, clomipramine, phenytoin, lithium, metoclopramide, paracetamol, isoniazid, diuretics, MAOIs, muscle relaxants, alcohol, St. John's wort.
<b>Pregnancy and Lactation:</b>	Pregnancy: Should not be used during pregnancy unless clearly necessary. Lactation: Should not be used during lactation unless the expected benefits to the mother justify the potential risks for the infant.
<b>Undesirable Effects:</b>	Particularly at the start of treatment or if the initial dosage is too high or when treating elderly patients, certain types of adverse reactions occur very commonly or commonly e.g. CNS adverse reactions (dizziness, headache, ataxia, drowsiness, fatigue, diplopia); gastrointestinal disturbances (nausea, vomiting), as well as allergic skin reactions. The dose related adverse reactions usually abate within a few days either spontaneously or after a transient dosage reduction. Other reported adverse reactions are from the following systems: Blood, Liver, Cardiovascular, Endocrine and metabolism, Urogenital system, Sense organs, Musculoskeletal, Respiratory tract and Hypersensitivity reactions.

MAH: Codal Synto Ltd.

