Protecting Tomorrow

Syntopar®

Paroxetine

SYNTOPAR®10mg tablets • **SYNTOPAR**®20mg tablets • **SYNTOPAR**®30mg tablets • **SYNTOPAR**®40mg tablets

CODAL-SYNTO

Summary of SPC for Syntopar®

Trade Name of the Medicinal Product:	Syntopar®
Qualitative and Quantitative Composition:	Each 10/20/30/40 mg tablet contains 10/20/30/40 mg paroxetine as paroxetine hydrochloride anhydrate.
Pharmaceutical form	Tablet.
Indications&Posology and Method of Administration:	Major depressive episode: 20 mg daily. In patients with insufficient response to 20 mg, the dose may be increased gradually up to a maximum of 50 mg a day in 10 mg steps according to the patient's response. Obsessive compulsive disorder: 40 mg daily. Patients should start on 20 mg/day and dose may be increased gradually in 10 mg increments to the recommended dose. If after some weeks on the recommended dose insufficient response is seen some patients may benefit from having their dose increased gradually up to a maximum of 60 mg / day. Panic disorder: 40 mg daily. Patients should be started on 10 mg/day and the dose gradually increased in 10 mg steps according to the patient's response up to the recommended dose. If after some weeks on the recommended dose insufficient response is seen some patients may benefit from having their dose increased gradually up to a maximum of 60 mg/day. Social anxiety disorders / Social phobia & Generalized anxiety disorder & Post-traumatic stress disorder: 20 mg daily. If after some weeks on the recommended dose insufficient response is seen some patients may benefit from having their dose increased gradually in 10 mg steps up to a maximum of 50 mg/day. Children aged below 18 years: Should not be used. Elderly: The maximum dose should not exceed 40 mg daily.
Contra-indications:	Hypersensitivity; Concomitant use with MAOIs, Thioridazine and Pimozide.
Special Warnings and Precautions for Use:	Treatment with paroxetine should be initiated cautiously two weeks after terminating with an irreversible MAOI or 24 hours after terminating treatment with a reversible MAO; Paediatric population; Suicide/Suicidal thoughts or clinical worsening; Akathisia/psychomotor restlessness; Serotonin Syndrome/Neuroleptic Malignant Syndrome; History of Mania; Renal/hepatic impairment; Diabetes; Epilepsy; Seizures; ECT; Glaucoma; Cardiac conditions; Hyponatraemia, in elderly; Haemorrhage; Interaction with tamoxifen; Withdrawal symptoms.
Interactions with other Medicaments and other forms of Interaction:	Serotonergic drugs, MAOIs; Drug metabolising enzymes inhibitor; Neuromuscular blockers; Fosamprenavir/ritonavir; Procyclidine; Anticonvulsants; TCAs, phenothiazine neuroleptics, risperidone, atomoxetine, certain type 1c antiarrhythmics, tamoxifen; Alcohol; Oral anticoagulants; NSAIDs and acetylsalicylic acid and other antiplatelet agents; Pravastatin.
Pregnancy and Lactation:	Should only be use during pregnancy when strictly indicated. Abrupt discontinuation should be avoided during pregnancy. Since no effects are anticipated, breast-feeding can be considered.
Undesirable Effects:	Abnormal bleeding, thrombocytopenia; Severe and potentially fatal allergic reactions; Syndrome of inappropriate anti–diuretic hormone secretion; Increases in cholesterol levels, decreased appetite, altered glycaemic control, hyponatremia; Somnolence, insomnia, agitation, abnormal dreams, confusion, hallucinations, manic reactions, anxiety, depersonalisation, panic attacks, akathisia, suicidal ideation and suicidal behaviour, aggression; Dizziness, tremor, headache, concentration impaired, extrapyramidal disorders, convulsions, restless legs syndrome, serotonin syndrome; Blurred vision, mydriasis, acute glaucoma; Tinnitus; Sinus tachycardia, bradycardia; Transient increases or decreases in blood pressure, postural hypotension; Yawning; Nausea, constipation, diarrhoea, vomiting, dry mouth, gastrointestinal bleeding; Elevation of hepatic enzymes, hepatic events; Sweating, skin rashes, pruritus, severe cutaneous adverse reactions, urticaria, photosensitivity reactions; Urinary retention, urinary incontinence; Sexual dysfunction, hyperprolactinaemia/galactorrhoea, menstrual disorders, priapism; Arthralgia, myalgia; Asthenia, body weight gain, peripheral oedema.
Date of revision of the text:	07/2015.
	MAH: Codal-Synto ltd.