NOVARTIS

# RITALIN® / RITALIN® LA
(methylphenidate hydrochloride)

Tablets: Ritalin 10 mg

Capsules: Ritalin LA 10mg, 20 mg, 30 mg, 40 mg

## Basic Succinct Statement
## Version 3.0

## New indication: Adult ADHD (Aligned to AUS PI)

## Code: BSS RD 17 JUL 2017; APPR 3 MAY 2018

## This material is only meant for Healthcare Professionals

# RITALIN® / RITALIN® LA

**Important note:** Before prescribing, consult full prescribing information.

**Presentation:** ♦Immediate-release (Ritalin®) tablets containing 10 mg methylphenidate hydrochloride. ♦Modified-release capsules (Ritalin® LA) containing 20 mg, 30 mg, or 40 mg methylphenidate hydrochloride.

**Indications:** Attention-deficit/hyperactivity disorder (ADHD) in children aged 6 years and older; ADHD in adults (Ritalin LA only); narcolepsy (Ritalin tablets only).

**Dosage and administration:** ♦Maximum daily dose is 60 mg for narcolepsy and for the treatment of ADHD in children. ♦Maximum daily dose is 80 mg for the treatment of ADHD in adults. ♦For children, start with 5 mg once or twice daily and increase in increments of 5 to 10 mg weekly. ♦For Ritalin LA, starting dose is 20 mg. ♦Ritalin LA dosage may be adjusted in 20 mg increments for the treatment of ADHD in adults. ♦For adults treated for narcolepsy, the usual daily dose is 20 to 30 mg. ♦Ritalin LA is for once daily administration.

**Contraindications:** ♦Hypersensitivity to methylphenidate or to any of the excipients, anxiety, tension, agitation, hyperthyroidism, pre-existing cardiovascular disorders including severe hypertension, angina, arterial occlusive disease, heart failure, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias and channelopathies, during treatment with monoamine oxidase (MAO) inhibitors, or within a minimum of 2 weeks of discontinuing those drugs, glaucoma, pheochromocytoma, diagnosis or family history of Tourette's syndrome.

**Warnings andprecautions:** ♦Generally should not be used in patients with structural cardiac abnormalities or other serious cardiac disorders that may increase the risk of sudden death. ♦Pre-existing cardiovascular disorders, a family history of sudden death and ventricular arrhythmia should be assessed before initiating treatment. ♦Caution in patients with pre-existing hypertension. Blood pressure should be monitored during treatment. ♦Patients who develop symptoms suggestive of cardiac disease should undergo prompt cardiac evaluation. Misuse may be associated with sudden death and other serious cardiovascular adverse events. ♦Patients with pre-existing cerebrovascular abnormalities should not be treated. ♦Patients with additional risk factors (history of cardiovascular disease, concomitant medications that elevate blood pressure) should be assessed regularly for neurological/psychiatric signs and symptoms. ♦Pre-existing psychiatric disorders and a family history of psychiatric disorders should be assessed before initiating treatment. ♦Should not be initiated in patients with acute psychosis, acute mania or acute suicidality. ♦In case of emergent psychiatric symptoms (e.g. hallucinations or mania, aggressive behaviour and suicidal tendency) or exacerbation of pre-existing psychiatric symptoms, Ritalin should not be given to patients unless the benefit outweighs the potential risk. ♦Family history should be assessed and clinical evaluation for tics or Tourette’s syndrome in children should precede ADHD treatment. ♦Patients should be regularly monitored for the emergence or worsening of tics during initiating treatment. ♦Growth should be monitored during treatment as clinically necessary, treatment interruption may be considered. ♦Caution in patients with epilepsy. ♦Patients who develop priapism should seek immediate medical attention. ♦Not recommended together with serotonergic drugs due to

risk of serotonin syndrome. ♦Chronic abuse can lead to marked tolerance and psychological dependence. ♦Caution in emotionally unstable patients. ♦Careful supervision during withdrawal. ♦Blood count monitoring during long-term treatment. Consider appropriate medical intervention in the event of haematological disorders. ♦Not recommended for children under 6 years of age. ♦Patients should refrain from driving and using machinery if dizziness, drowsiness, blurred vision, hallucination or other CNS side effects occur. ♦Not recommended during pregnancy unless benefits outweigh risks. ♦Patients should avoid breast-feeding during treatment with Ritalin.

**Pregnancy, lactation, females and males of reproductive potential**: Pregnancy: ♦Ritalin should not be given to pregnant women unless the potential benefit outweighs the risk to the fetus. Lactation: ♦Methylphenidate was distributed into breast milk. A decision should be made whether to abstain from breast-feeding or to abstain from Ritalin therapy, taking into account the benefit of breast-feeding to the child and the benefit of therapy to the woman.

**Adverse drug reactions:** ***Very common:*** nasopharyngitis, decreased appetite, nervousness, insomnia, nausea, dry mouth. ***Common:*** anxiety, restlessness, sleep disorder, agitation, tremor, dyskinesia, headache, drowsiness, dizziness, dyskinesia, tachycardia, palpitation, arrhythmias, changes in blood pressure and heart rate (usually an increase), cough, abdominal pain, vomiting, dyspepsia, toothache, rash, pruritus, urticaria, fever, scalp hair loss, hyperhidrosis, arthralgia. ***Rare:*** difficulties in visual accommodation, blurred vision, angina pectoris, moderately reduced weight gain and slight growth retardation during prolonged use in children, weight decreased, feeling jittery. ***Very rare:*** leucopoenia, thrombocytopenia, anaemia, hypersensitivity reactions, including angioedema and anaphylaxis, hyperactivity, psychosis (sometimes with visual and tactile hallucinations), transient depressed mood, convulsions, choreoathetoid movements, tics or exacerbation of existing tics and Tourette's syndrome, cerebrovascular disorders including vasculitis, cerebral haemorrhages and cerebrovascular accidents, neuroleptic malignant syndrome, abnormal liver function, thrombocytopenic purpura, exfoliative dermatitis, erythema multiforme, muscle cramps. Frequency ***not known***: priapism.

***Reported with other methylphenidate-containing products*****:** pancytopenia, auricular swelling, irritability, aggression, affect lability, abnormal behaviour or thinking, anger, suicidal ideation or attempt (including completed suicide), mood altered, mood swings, hypervigilance, mania, disorientation, libido disorder, apathy, repetitive behaviours, over-focusing, confusional state, dependence, cases of abuse and dependence have been described, more often with immediate release formulations, reversible ischaemic neurological deficit, migraine, mydriasis, visual disturbance, cardiac arrest, myocardial infarction, peripheral coldness, Raynaud's phenomenon, pharyngolaryngeal pain, dyspnoea, diarrhoea, constipation, angioneurotic oedema, erythema, fixed drug eruption, myalgia, muscle twitching, haematuria, gynaecomastia, chest pain, fatigue, sudden cardiac death, cardiac murmur.

**Interactions:** ♦**Concomitant use contraindicated**: MAO inhibitors (currently or within the preceding 2 weeks). ♦Caution when used concomitantly with drugs that elevate blood pressure, coumarin anticoagulants, anticonvulsants, centrally acting alpha-2 agonists (e.g. clonidine), direct and indirect dopaminergic drugs (e.g. tricyclic antidepressants, DOPA, antipsychotics), phenylbutazone. ♦**Alcohol**: patients should abstain from alcohol during

treatment. ♦Ritalin should not be taken on the day of a planned surgery due to risk of sudden blood pressure increase during surgery. ♦May induce false positive laboratory tests for amphetamines. ♦Risk of serotonin syndrome with concomitant use of methylphenidate and serotonergic drugs.