

COMPOSITION*: Vastarel 35mg, modified-release film-coated tablet containing 35mg trimetazidine. **INDICATIONS***: Indicated in adults as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled by or intolerant to first-line antianginal therapies. **DOSAGE and ADMINISTRATION***: The dose is one tablet of 35mg of trimetazidine twice daily during meals. Benefit of the treatment should be assessed after three months and trimetazidine should be discontinued if there is no treatment response. Patients with renal impairment/elderly: In patients with moderate renal impairment (creatinine clearance [30-60] ml/mn), 1 tablet of 35mg in the morning during breakfast. **CONTRAINDICATIONS***: Hypersensitivity to the active substance or to any of the excipients. Parkinson disease, parkinsonian symptoms, tremors, restless leg syndrome, and other related movement disorders, Severe renal impairment (creatinine clearance < 30ml/min). **WARNINGS***: This medicine is not a curative treatment for angina attacks, nor is it indicated as an initial treatment for unstable angina or myocardial infarction, nor in the pre-hospital phase or during the first days of hospitalization. In the event of an angina attack, the coronaropathy should be reevaluated and an adaptation of the treatment considered. Trimetazidine can cause or worsen parkinsonian symptoms (tremor, akinesia, hypertonia), which should be regularly investigated, especially in elderly patients. Falls, may occur, related to gait instability or hypotension, in particular in patients taking antihypertensive treatment. **INTERACTIONS***: **FERTILITY***: **PREGNANCY***: Avoid prescription. **BREASTFEEDING***: Should not be used. **DRIVE & USE MACHINES***: Caution because cases of dizziness and drowsiness have been observed. **UNDESIRABLE EFFECTS***: Common: dizziness, headache, abdominal pain, diarrhoea, dyspepsia, nausea, vomiting, rash, pruritus, urticaria, asthenia. Rare: palpitations, extrasystoles, tachycardia, arterial hypotension, orthostatic hypotension that may be associated with malaise, dizziness or fall, in particular in patients taking nihypertensive treatment, flushing. Not known: parkinsonian symptoms (tremor, akinesia, hypertonia), gait instability, restless leg syndrome, other related movement disorders, usually reversible after treatment discontinuation, sleep disorders (insomnia, drowsiness), vertigo, constipation, AGEP (acute generalised exanthematous pustulosis), angioedema, agranulocytosis, thrombocytopenia, thrombocytopenic purpura, hepatitis. **OVERDOSE***: **PROPERTIES***: Trimetazidine acts as a metabolic agent, preserving the myocardial high-energy phosphate intracellular levels. Anti-ischemic effects are achieved without concomitant haemodynamic effects. **PRESENTATION***: Pack of 60 modified-release film-coated tablets of Vastarel 35mg. **SERVIER HONG KONG LIMITED**, Flat 08-09, 43/F, Times Square Tower One, 1 Matheson Street, Causeway Bay, Hong Kong. www.servier.hk *For complete information, please refer to the complete Summary of Product Characteristics.