

Prescribing Information (UK) ▼ STRIVERDI® RESPIMAT® (olodaterol)

Inhalation solution containing 2.5 microgram olodaterol (as hydrochloride) per actuation. **Indication:** Maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease (COPD). **Dose and Administration:** Adults only age 18 years or over: 5 microgram olodaterol given as two actuations (puffs) from the Respimat inhaler once daily, at the same time of the day. **Contraindications:** Hypersensitivity to olodaterol or to any of the excipients; benzalkonium chloride, disodium edetate, purified water or citric acid (anhydrous). **Warnings and Precautions:** Not for use in asthma or the treatment of acute episodes of bronchospasm, i.e. as rescue therapy. Immediate hypersensitivity reactions may occur after administration. Inhaled medicines may cause inhalation-induced paradoxical bronchospasm. Caution in patients with: cardiovascular disorders, especially ischaemic heart disease, severe cardiac decompensation, cardiac arrhythmias, hypertrophic obstructive cardiomyopathy, hypertension and aneurysm; convulsive disorders or thyrotoxicosis; known or suspected prolongation of the QT interval (e.g. QT>0.44 s); patients unusually responsive to sympathomimetic amines. Experience in the following patient groups is limited therefore use with caution in patients: with a history of myocardial infarction during the previous year or unstable or life-threatening cardiac arrhythmia; hospitalised for heart failure during the previous year or with a diagnosis of paroxysmal tachycardia (>100 beats per minute). In some patients, like other beta-adrenergic agonists, olodaterol may produce: clinically significant cardiovascular effects; significant hypokalaemia; increases in plasma glucose after inhalation of high doses.

Caution in planned operations with halogenated hydrocarbon anaesthetics due to increased susceptibility of adverse cardiac effects. Benzalkonium chloride may cause wheezing and breathing difficulties; patients with asthma are at an increased risk for these adverse events. Should not be used in conjunction with any other long-acting beta₂-adrenergic agonists. **Interactions:** Concomitant administration with other adrenergic agents (alone or in combination therapy) may potentiate the undesirable effects of Striverdi Respimat. Concomitant treatment with xanthine derivatives, steroids, or non-potassium sparing diuretics may potentiate any hypokalemic effect of adrenergic agonists. Beta-adrenergic blockers may weaken or antagonise the effect of Striverdi Respimat which should only be given together if there are compelling reasons for their use. MAO inhibitors, tricyclic antidepressants, or QTc prolonging drugs may potentiate the action of Striverdi Respimat on the cardiovascular system. **Fertility, Pregnancy and Lactation:** No data on the use of Striverdi Respimat in pregnant women are available. As a precautionary measure, it is preferable to avoid use during pregnancy. Like other beta₂-adrenergic agonists, olodaterol may inhibit labour due to a relaxant effect on uterine smooth muscle. It is unknown whether olodaterol/metabolites are excreted in human milk. A decision on whether or not to discontinue/abstain from Striverdi Respimat should be made taking into account the benefit of breast feeding to the child or benefit of therapy for the woman. Clinical data on fertility are not available for Striverdi Respimat. **Effects on ability to drive and use machines:** No studies have been performed. The occurrence of dizziness may affect

the ability to drive or operate machinery. **Undesirable effects:** Uncommon (≥1/1,000 to <1/100) Nasopharyngitis, dizziness, rash. Rare (≥1/10,000 to <1/1,000) Hypertension, arthralgia. Occurrence of undesirable effects related to the beta-adrenergic agonist class should be taken into account such as tachycardia, arrhythmia, palpitations, myocardial ischaemia, angina pectoris, hypertension or hypotension, hypokalemia, hyperglycemia, tremor, headache, nervousness, insomnia, dizziness, dry mouth, nausea, muscle spasms, fatigue, malaise, and metabolic acidosis. Prescribers should consult the Summary of Product Characteristics for further information on side effects. **Pack sizes and NHS price:** Single pack: 1 Respimat re-usable inhaler and 1 cartridge providing 60 actuations (puffs) (30 medicinal doses) £26.35; Single refill pack: 1 cartridge providing 60 actuations (puffs) (30 medicinal doses) £26.35 **Legal category:** POM **MA numbers:** PL 14598/0093 **Marketing Authorisation Holder:** Boehringer Ingelheim International GmbH, D-55216 Ingelheim am Rhein, Germany. Prescribers should consult the Summary of Product Characteristics for full prescribing information. **Prepared in** September 2019

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard Adverse events should also be reported to Boehringer Ingelheim Drug Safety on 0800 328 1627 (freephone).