Prescribing Information (UK)

SPIRIVA® RESPIMAT® (tiotropium)
Inhalation solution containing 2.5 microgram tiotropium (as bromide monohydrate) per puff.
Indication: COPD: Spiriva Respimat is indicated as a maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD). Asthma: Spiriva Respimat is indicated as add-on maintenance bronchodilator treatment in patients aged 6 years and older with severe asthma who experienced one or more severe asthma exacerbations in the preceding year.
Dose and Administration: COPD Adults only age 18 years or over: 5 microgram tiotropium given as two puffs from the Respimat inhaler once daily, at the same time of the day. Asthma Adults and patients 6 to 17 years of age: 5 microgram tiotropium given as two puffs from the Respimat inhaler once daily, at the same time of the day. In adult patients with severe asthma, tiotropium should be used in addition to inhaled corticosteroids (≥ 800 µg budesonide/day or equivalent) and at least one controller. In adolescents (12 - 17 years) with severe asthma, tiotropium should be used in addition to inhaled corticosteroids (> 800 - 1600 µg budesonide/day or equivalent) and one controller or in addition to inhaled corticosteroids (400 - 800 µg budesonide/day or equivalent) with two controllers. For children (6 - 11 years) with severe asthma, tiotropium should be used in addition to inhaled corticosteroids (> 400 µg budesonide/day or equivalent) and one controller or in addition to inhaled corticosteroids (200 - 400 µg budesonide/day or equivalent) with two controllers. **Contraindications:** Hypersensitivity to tiotropium bromide, atropine or its derivatives, e.g. ipratropium or oxitropium or to any of the excipients; benzalkonium chloride, disodium edetate, purified water, hydrochloric acid 3.6 % (for pH adjustment). **Warnings and Precautions:** Benzalkonium chloride may cause wheezing and breathing difficulties; patients with asthma are at an increased risk for these adverse events. Not for the initial treatment of acute episodes of bronchospasm or for the relief of acute symptoms. Spiriva Respimat should not be used as monotherapy for asthma. Asthma patients must be advised to continue taking anti-inflammatory therapy, i.e. inhaled corticosteroids, unchanged after the introduction of Spiriva Respimat, even when their symptoms improve. Immediate hypersensitivity reactions may occur after administration of tiotropium bromide inhalation solution. Caution in patients with narrow-angle glaucoma, prostatic hyperplasia or bladder-neck obstruction. Inhaled medicines may cause inhalation-induced bronchospasm. Tiotropium should be used with caution in patients with recent myocardial infarction < 6 months; any unstable or life threatening cardiac arrhythmia or cardiac arrhythmia requiring intervention or a change in drug therapy in the past year; hospitalisation of heart failure (NYHA Class III or IV) within the past year. These patients were excluded from the clinical trials and these conditions may be affected by the anticholinergic mechanism of action. In patients with moderate to severe renal impairment (creatinine clearance ≤ 50 ml/min) tiotropium bromide should be used only if the expected benefit outweighs the potential risk. Patients should be cautioned to avoid getting the spray into their eyes. They should be advised that this may result in precipitation or worsening of narrow-angle glaucoma, eye pain or discomfort, temporary blurring of vision, visual halos or coloured images in association with red eyes from conjunctival congestion and corneal oedema. Should any combination of these eye symptoms develop, patients should stop using tiotropium bromide and consult a specialist immediately. Tiotropium bromide should not be used more frequently than once a day. **Interactions:** Although no formal drug interaction studies have been performed, tiotropium bromide has been used concomitantly with other drugs commonly used in the treatment of COPD and asthma, including sympathomimetic bronchodilators, methylxanthines, oral and inhaled steroids, antihistamines, mucolytics, leukotriene modifiers, cromones, anti-IgE treatment without clinical evidence of drug interactions. Use of LABA or ICS was not found to alter the exposure to tiotropium. The co-administration of tiotropium bromide with other anticholinergic-containing drugs has not been studied and is therefore not recommended. **Fertility, Pregnancy and Lactation:** Very limited amount of data in pregnant women. Avoid the use of Spiriva Respimat during pregnancy. It is unknown whether tiotropium bromide is excreted in human breast milk. Use of Spiriva Respimat during breast feeding is not recommended. A decision on whether to continue/discontinue breast feeding or therapy with Spiriva Respimat should be made taking into account the benefit of breast feeding to the child and the benefit of Spiriva Respimat therapy to the woman. Clinical data on fertility are not available for tiotropium. **Effects on ability to drive and use machines:** No studies have been performed. The occurrence of dizziness or blurred vision may influence the ability to drive and use machinery.
Undesirable effects: COPD: Common (≥ 1/100 to < 1/10) Dry mouth. Uncommon (≥ 1/1,000 to < 1/100) Dizziness, headache, cough, pharyngitis, dysphonia, constipation, oropharyngeal candidiasis, rash, pruritus, urinary retention, dysuria. Rare (≥1/10,000 to <1/1,000): Insomnia, glaucoma, intraocular pressure increased, vision blurred, atrial fibrillation, palpitations, supraventricular

tachycardia, tachycardia, epistaxis, bronchospasm, laryngitis, dysphagia, gastrooesophageal reflux disease, dental caries, gingivitis, glossitis, angioneurotic oedema, urticaria, skin infection/skin ulcer, dry skin, urinary tract infection. Not known (cannot be estimated from the available data): Dehydration, sinusitis, stomatitis, intestinal obstruction including ileus paralytic, nausea, hypersensitivity (including immediate reactions), anaphylactic reaction, joint swelling. Asthma: Uncommon (≥ 1/1,000 to < 1/100) Dizziness, headache, insomnia, palpitations, cough, pharyngitis, dysphonia, bronchospasm, dry mouth, oropharyngeal candidiasis, rash. Rare (≥1/10,000 to <1/1,000): Epistaxis, constipation, gingivitis, stomatitis, pruritus, angioneurotic oedema, urticaria, hypersensitivity (including immediate reactions), urinary tract infection. Not known (cannot be estimated from the available data): Dehydration, glaucoma, intraocular pressure increased, vision blurred, atrial fibrillation, supraventricular tachycardia, tachycardia, laryngitis, sinusitis, dysphagia, gastrooesophageal reflux disease, dental caries, glossitis, intestinal obstruction including ileus paralytic, nausea, skin infection/skin ulcer, dry skin, anaphylactic reaction, joint swelling, urinary retention, dysuria. Serious undesirable effects consistent with anticholinergic effects: glaucoma, constipation, intestinal obstruction including ileus paralytic and urinary retention. An increase in anticholinergic effects may occur with increasing age. Prescribers should consult the Summary of Product Characteristics for further information on undesirable effects. **Pack sizes and NHS price:** Single pack: 1 Respimat re-usable inhaler and 1 cartridge providing 60 puffs (30 medicinal doses) £23.00; Single refill pack: 1 cartridge providing 60 puffs (30 medicinal doses) £23.00. **Legal category:** POM. **MA number:** PL 14598/0084. **Marketing Authorisation Holder:** Boehringer Ingelheim International GmbH, 55216 Ingelheim am Rhein, Germany. Prescribers should consult the Summary of Product Characteristics for full prescribing information. **Prepared in** December 2022.

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).

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