

## Prescribing Information (UK) SPIRIVA® (tiotropium)

Inhalation powder, hard capsules containing 18 microgram tiotropium (as bromide monohydrate).

**Indication:** Tiotropium is indicated as a maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD).

**Dose and Administration:** Adults only age 18 years or over: Inhalation of the contents of one capsule once daily from the HandiHaler® device. **Contraindications:** Hypersensitivity to tiotropium bromide or to the excipient lactose monohydrate (which may contain small amounts of milk proteins) or to atropine or its derivatives.

**Warnings and Precautions:** Not for the initial treatment of acute episodes of bronchospasm, i.e. rescue therapy. Immediate hypersensitivity reactions may occur after administration of tiotropium bromide inhalation powder. 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 drug powder 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. Spiriva capsules contain 5.5mg lactose monohydrate. This amount does not normally cause problems in lactose intolerant patients. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. The excipient lactose monohydrate may contain small amounts of milk proteins which may cause allergic reactions. **Interactions:** Although no formal drug interaction studies have been performed, tiotropium bromide inhalation powder has been used concomitantly with other drugs without clinical evidence of drug interactions. These include sympathomimetic bronchodilators, methylxanthines, oral and inhaled steroids, commonly used in the treatment of COPD. 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:** There is a very limited amount of data from the use of tiotropium in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity at clinically relevant doses. As a precaution, avoid the use of Spiriva during pregnancy. It is unknown whether tiotropium bromide is excreted in human breast milk. Use of Spiriva is not recommended during breast feeding. A decision on whether to continue or discontinue breast feeding or therapy with Spiriva should be made taking into account the benefit of breast feeding to the child and the benefit of Spiriva 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, blurred vision, or headache may influence the ability to drive and use machinery. **Undesirable effects:** Common (≥ 1/100 to <1/10): Dry mouth. Uncommon (≥ 1/1000 to <1/100): Dizziness,

headache, taste disorders, vision blurred, atrial fibrillation, pharyngitis, dysphonia, cough, gastroesophageal reflux disease, constipation, oropharyngeal candidiasis, rash, dysuria, urinary retention. Rare (≥1/10,000 to <1/1,000): Insomnia, glaucoma, intraocular pressure increased, supraventricular tachycardia, tachycardia, palpitations, bronchospasm, epistaxis, laryngitis, sinusitis, intestinal obstruction including ileus paralytic, gingivitis, glossitis, dysphagia, stomatitis, nausea, urticaria, pruritus, hypersensitivity (including immediate reactions), angioedema, urinary tract infection. Not known (frequency cannot be estimated from the available data): Dehydration, dental caries, anaphylactic reaction, skin infection, skin ulcer, dry skin, joint swelling. Serious undesirable effects consistent with anticholinergic effects: glaucoma, constipation and intestinal obstruction including ileus paralytic as well as urinary retention. An increase in anticholinergic effects may occur with increasing age. Prescribers should consult the Summary of Product Characteristics for further information on side effects. **Pack sizes and NHS price:** Combopack HandiHaler device and 30 capsules (3 blisters) £34.87 Refill Pack 30 capsules (3 blisters) £33.50; 60 capsules (6 blisters) £67.00. **Legal category:** POM. **MA Number:** PL 14598/0062. **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 March 2018**

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