Tiogiva (tiotropium bromide) 18 mcg inhalation powder

Please refer to the Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** Delivered dose: 10 mcg of tiotropium per capsule (the dose that leaves the mouthpiece is 12.1 microgram tiotropium bromide). Each capsule contains 21.7 mcg of tiotropium bromide, equivalent to 18 mcg of tiotropium. **Indications:** Maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD). **Dosage and administration:** For inhalation only. Must not be swallowed. Inhalation should be at the same time each day. *Adults:* Inhalation of the contents of one capsule once daily with the dry powder inhaler. To get a full daily dose, the patient must breathe out completely. The patient should also inhale a second time from the same capsule. See SmPC for administration and instructions for use. *Children:* Not to be used in children or adolescents <18 years of age. *Elderly:* No special requirements. *Renal Impairment:* Mild (creatinine clearance >50 ml/min): no special requirements. Moderate to severe (creatinine clearance ≤50 ml/min): Use only if expected benefit outweighs the potential risk. There is no long-term experience in patients with severe renal impairment. *Hepatic Impairment:* No special requirements. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients, or to atropine or its derivatives, e.g. ipratropium or oxitropium. **Precautions:** Not to be used for the initial treatment of acute episodes of bronchospasm, i.e. rescue therapy. Immediate hypersensitivity reactions may occur. Use with caution in patients with narrow-angle glaucoma, prostatic hyperplasia or bladder-neck obstruction. Inhaled medicines may cause inhalation-induced bronchospasm. Use with caution in patients with recent myocardial infarction <6 months; unstable or life-threatening cardiac arrhythmia; cardiac arrhythmia requiring intervention or a change in drug therapy in the past year; hospitalisation for heart failure (NYHA Class III or IV) within past year. Avoid getting the powder into eyes (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 Tiogiva and consult a specialist immediately). Dry mouth, which has been observed with anti-cholinergic treatment, may in the long term be associated with dental caries. Tiogiva should not be used more frequently than once daily. Contains lactose; patients with rare hereditary problems of galactose intolerance, total 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:** No formal drug interaction studies have been performed. Co-administration with other anticholinergic drugs not recommended. **Adverse reactions:** *Common:* dry mouth. *Uncommon:* dizziness, headache, taste disorders, vision blurred, atrial fibrillation, pharyngitis, dysphonia, cough, gastro-oesophageal reflux disease, constipation, oropharyngeal candidiasis, rash, dysuria, urinary retention. *Rare:* 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. *Frequency not known:* dehydration, dental caries, anaphylactic reaction, skin infection, skin ulcer, dry skin, joint swelling. Please consult the summary of product characteristics for further information. **Marketing Authorisation Number:** PL 25258/0370. **Marketing authorization Holder:** Glenmark Pharmaceuticals Europe Limited Laxmi House, 2B Draycott Avenue, Kenton, Harrow, Middlesex, HA3 0BU, UK. **Distributer:** As above. **Legal classification:** POM. **Price:** 30 capsules + inhaler £19.99, 30 capsules £19.20, 60 capsules £38.40. **Job code:** PP-UK-TIO-0055. **Date of preparation:** September 2021

Adverse events should be reported.
Reporting forms and information can be found at https://yellowcard.mhra.gov.uk. Adverse events should also be reported to Glenmark Pharmaceuticals Europe Ltd medical_information@glenmarkpharma.com or call 0800 458 0383

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GLENMARK Respiratory

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