Please refer to the Summary of Product Characteristics (SmPC) for full details of Prescribing Information

Braltus® (tiotropium bromide) Inhalation Powder Abbreviated Prescribing Information

Presentation: Delivered dose: 10 mcg of tiotropium per capsule. Each capsule contains 16 mcg of tiotropium bromide, equivalent to 13 mcg of tiotropium. **Indications**: Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). **Dosage and administration**:Inhalation use 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 Zonda® inhaler. 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: Use only if expected benefit outweighs the potential risk. *Hepatic Impairment*: No special requirements. **Contraindications**: Hypersensitivity to the active ingredient or any excipients. **Precautions and warnings**: Not to be used for the initial treatment of acute episodes of bronchospasm, i.e. rescue therapy. Immediate hypersensitivity reactions may occur. As with other inhalation therapy, paradoxical bronchospasm may occur and treatment should be immediately discontinued. Use with caution in patients with narrow-angle glaucoma, prostatic hyperplasia or bladder-neck obstruction; 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. The excipient lactose may contain trace amounts of milk proteins which may cause allergic reactions in patients with severe hypersensitivity or allergy to milk protein. **Interactions**: No formal drug interaction studies have been performed. Co-administration with other anticholinergic drugs not recommended. **Pregnancy and lactation**: Not recommended. **Effects on ability to drive and use machines**: No studies on the effects on the ability to drive and use machines have been performed. The occurrence of dizziness, blurred vision, or headache may influence the ability to drive and use machinery. **Adverse reactions**: *Serious*: Hypersensitivity reactions, anaphylactic reaction, bronchospasm, anticholinergic effects (glaucoma, constipation, intestinal obstruction including ileus paralytic as well as urinary retention), atrial fibrillation, supraventricular tachycardia, tachycardia. *Common*: Dry mouth. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose**: May lead to anticholinergic signs and symptoms. Price: £25.80 **Legal category**: POM. **Marketing Authorisation Number**: PL 00289/1870 **Marketing Authorisation Holder**: Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, BN22 9AG, United Kingdom. **Job Code**: UK/MED/18/0138. **Date of Preparation**: April 2018.

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 Teva UK Limited on 0207 540 7117 or medinfo@tevauk.com