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

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

DuoResp® Spiromax® (budesonide/formoterol) 160mcg/4.5mcg inhalation powder and DuoResp® Spiromax® (budesonide/formoterol) 320mcg/9mcg inhalation powder Abbreviated Prescribing Information. **Presentation:** *DuoResp® Spiromax® 160/4.5*: Each delivered dose contains 160mcg of budesonide and 4.5mcg of formoterol fumarate dihydrate. This is equivalent to a metered dose of 200mcg budesonide and 6mcg of formoterol fumarate dihydrate. *DuoResp® Spiromax® 320/9*: Each delivered dose contains 320mcg of budesonide and 9mcg of formoterol fumarate dihydrate. This is equivalent to a metered dose of 400mcg budesonide and 12mcg of formoterol fumarate dihydrate. Inhalation powder. **Indications:** Asthma: Treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting β_2-adrenoceptor agonist) is appropriate. COPD: Symptomatic treatment of patients with COPD with forced expiratory volume in 1 second (FEV_1) < 70% predicted normal (post bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators. **Dosage and administration:** For use in adults and adolescents 12 years and older for Asthma, and adults aged 18 years and older for COPD. Not for use in children < 12 years of age. ***Asthma*:** Not intended for the initial management. If an individual patient should require a combination of doses other than those available in the combination inhaler, appropriate doses of β_2-adrenoceptor agonists and/or corticosteroids by individual inhalers should be prescribed. The dose should be titrated to the lowest dose at which effective control of symptoms is maintained. When control of symptoms is achieved titrate to the lowest effective dose, which could include once daily dosing. *DuoResp® Spiromax® 160/4.5*: maintenance therapy - regular maintenance treatment with a separate reliever inhaler: *Adults (18 years and older)*: 1-2 inhalations twice daily (maximum of 4 inhalations twice daily). *Adolescents (12 years and older):* 1-2 inhalations twice daily. *DuoResp® Spiromax®* maintenance and reliever therapy: For patients taking DuoResp as reliever, preventative use of DuoResp Spiromax for allergen or exercise-induced bronchoconstriction should take into consideration the frequency of need. In case of frequent need of bronchodilation without corresponding need for an increased dose of inhaled corticosteroids, an alternative reliever should be used. Regular maintenance treatment and as needed in response to symptoms: should be considered for patients with: (i) inadequate asthma control and in frequent need of reliever medication (ii) previous asthma exacerbations requiring medical intervention. *Adults and adolescents*: The recommended maintenance dose is 2 inhalations per day, given either as one inhalation morning and evening or as 2 inhalations in either the morning or evening. For some patients a maintenance dose of 2 inhalations twice daily may be appropriate. Patients should take 1 additional inhalation as needed in response to symptoms. If symptoms persist after a few minutes, an additional inhalation should be taken. Not more than 6 inhalations should be taken on any single occasion. A total daily dose of up to 12 inhalations could be used for a limited period. Patients using more than 8 inhalations daily should be strongly recommended to seek medical advice. *DuoResp® Spiromax® 320/9*: Only to be used as maintenance therapy. *Adults (18 years and older)*: 1 inhalation twice daily (maximum of 2 inhalations twice daily). *Adolescents (12 years and older):* 1 inhalation twice daily. ***COPD*:** *Adults*: 1 inhalation twice daily. *Elderly patients (≥65 years old)*: No special requirements. *Patients with renal or hepatic impairment*: No data available. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Precautions and warnings:** If treatment is ineffective, or exceeds the highest recommended dose, medical attention must be sought. Patients with sudden and progressive deterioration in control of asthma or COPD should undergo urgent medical assessment. Patients should have their rescue inhaler available at all times. The reliever inhalations should be taken in response to symptoms and are not intended for regular prophylactic use e.g. before exercise. In case of frequent need of bronchodilation without corresponding need for an increased dose of inhaled corticosteroids, an alternative reliever should be used. Patients should not be initiated during an exacerbation. Serious asthma-related adverse events and exacerbations may occur. If asthma symptoms remain uncontrolled or worsen, patients should continue treatment and seek medical advice. If paradoxical bronchospasm occurs, treatment should be discontinued immediately. Paradoxical bronchospasm responds to a rapid-acting inhaled bronchodilator and should be treated straightaway. Visual disturbance may be reported with systemic and topical corticosteroid use. Such patients should be considered for referral to an ophthalmologist for evaluation of possible causes. Systemic effects may occur, particularly at high doses prescribed for long periods. Potential effects on bone density should be

considered, particularly in patients on high doses for prolonged periods that have co-existing risk factors for osteoporosis. Prolonged treatment with high doses of inhaled corticosteroids may result in clinically significant adrenal suppression. Additional systemic corticosteroid cover should be considered during periods of stress. Treatment should not be stopped abruptly – tapering of dose is recommended. Transfer from oral steroid therapy to a budesonide/formoterol fumarate fixed-dose combination may result in the appearance of allergic or arthritic symptoms which will require treatment. In rare cases, tiredness, headache, nausea and vomiting can occur due to insufficient glucocorticosteroid effect and temporary increase in the dose of oral glucocorticosteroids may be necessary. To minimise risk of oropharyngeal Candida infection patients should rinse mouth with water after inhaling the dose. Administer with caution in patients with thyrotoxicosis, phaeochromocytoma, diabetes mellitus, untreated hypokalaemia, or severe cardiovascular disorders. The need for, and dose of inhaled corticosteroids should be re-evaluated in patients with active or quiescent pulmonary tuberculosis, fungal and viral infections in the airways. Additional blood glucose controls should be considered in diabetic patients. Hypokalaemia may occur at high doses. Particular caution is recommended in unstable or acute severe asthma. Serum potassium levels should be monitored in these patients. As with other lactose containing products the small amounts of milk proteins present may cause allergic reactions. There is some evidence of an increased risk of pneumonia with increasing steroid dose but this has not been demonstrated conclusively across all studies. Physicians should remain vigilant for the possible development of pneumonia in patients with COPD as the clinical features of such infections overlap with the symptoms of COPD exacerbations. **Interactions:** Concomitant treatment with potent CYP3A4 inhibitors should be avoided. If this is not possible the time interval between administration should be as long as possible. Co-treatment with CYP3A inhibitors, including cobicistat-containing products is expected to increase risk of systemic side effects and the use in combination should be avoided. Not recommended with β-adrenergic blockers (including eye drops) unless compelling reasons. Concomitant treatment with quinidine, disopyramide, procainamide, phenothiazines, antihistamines (terfenadine), and Tricyclic Antidepressants (TCAs) can prolong the QTc-interval and increase the risk of ventricular arrhythmias. L-Dopa, L-thyroxine, oxytocin and alcohol can impair cardiac tolerance. Concomitant treatment with MAOIs, including agents with similar properties, may precipitate hypertensive reactions. Patients receiving anaesthesia with halogenated hydrocarbons have an elevated risk of arrhythmias. Hypokalaemia may increase the disposition towards arrhythmias in patients taking digitalis glycosides. **Pregnancy and lactation:** Use only when benefits outweigh potential risks. Budesonide is excreted in breast milk; at therapeutic doses no effects on infants are anticipated. **Effects on ability to drive and use machines:** No or negligible influence. **Adverse reactions:** Since *DuoResp® Spiromax®* contains both budesonide and formoterol, the same pattern of adverse reactions as reported for these substances may occur. No increased incidence of adverse reactions has been seen following concurrent administration of the two compounds. *Serious*: Immediate and delayed hypersensitivity reactions, e.g. exanthema, urticaria, pruritus, dermatitis, angioedema and anaphylactic reaction, Cushing´s syndrome, adrenal suppression, growth retardation, decrease in bone mineral density, hypokalaemia, hyperglycaemia, aggression, psychomotor hyperactivity, anxiety, sleep disorders, depression, behavioural changes, cataract and glaucoma, tachycardia, cardiac arrhythmias, e.g. atrial fibrillation, supraventricular tachycardia and extrasystoles, angina pectoris, prolongation of QTc-interval, variations in blood pressure, bronchospasm, pneumonia in COPD patients and paradoxical bronchospasm. *Common:* Candida infections in the oropharynx, headache, tremor, palpitations, mild irritation in the throat, coughing, pneumonia in COPD patients, dysphonia including hoarseness. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** An overdose of formoterol may lead to: tremor, headache, palpitations. Symptoms reported from isolated cases are tachycardia, hyperglycaemia, hypokalaemia, prolonged QTc-interval, arrhythmia, nausea and vomiting. Supportive and symptomatic treatment may be indicated. **Price per pack:** *DuoResp® Spiromax® 160/4.5* and *DuoResp® Spiromax® 320/9*: £27.97. **Legal Category:** POM. **Marketing Authorisation Numbers:** *DuoResp® Spiromax® 160/4.5*: EU/1/14/920/001, PLGB 00289/2438. *DuoResp® Spiromax® 320/9*: EU/1/14/920/004, PLGB 00289/2439. **Marketing Authorisation Holder/Business Responsible for Sale or Supply:** Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX. **Job Code:** MED-GB-00056. **Date of Preparation:** October 2021.

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

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

Qvar® (beclometasone dipropionate) Aerosol, Autohaler® and Easi-Breathe® Abbreviated Prescribing Information. **Presentation:** Qvar 50 mcg and 100 mcg Autohaler. Qvar 50 mcg and 100 mcg Easi-Breathe Inhaler. Qvar 50 mcg and 100 mcg Aerosol Inhaler. Qvar contains beclometasone dipropionate in solution in propellant HFA-134a resulting in an extrafine aerosol. **Indications**: Prophylactic management of mild, moderate or severe asthma in adults and adolescents with Qvar 50 mcg and 100 mcg Autohaler and Qvar 50 mcg and 100 mcg Aerosol Inhaler also indicated in children aged 5 and over. **Dosage and administration:** The dose should be adjusted to individual patient needs. Patients and carers should be instructed in the proper use of their inhaler, including rinsing out their mouth with water after use. *Adults, elderly, and children over 12 years: Starting and maintenance dose:* Mild asthma: 100 to 200 mcg daily in two divided doses. Moderate asthma: 200 to 400 mcg daily in two divided doses. Severe asthma: 400 to 800 mcg daily in two divided doses. *Qvar 50 mcg and 100 mcg Easi-Breathe Inhaler: Children under 12 years:* No data in children under 12 years of age, hence no dosage recommendation can be made. *Qvar 50 mcg and 100 mcg Autohaler and Qvar 50 mcg and 100 mcg Aerosol Inhaler: Children aged 5 years and over: Starting and maintenance dose:* Mild asthma: 100 mcg daily in two divided doses. Moderate asthma: 100 to 200 mcg daily in two divided doses. Severe asthma: 200 mcg daily in two divided doses. **Contraindications**: Hypersensitivity to the active substance or any other ingredients. **Precautions and warnings:** Patients should be properly instructed on the use of the inhaler to ensure that the drug reaches the target areas within the lungs. Use regularly. When symptoms are controlled, maintenance therapy should be reduced to the minimum effective dose. Not indicated for the immediate relief of asthma attacks or management of status asthmaticus. Advise patients to seek medical attention for review of their maintenance therapy if their asthma seems to be worsening. Patients receiving systemic steroids for long periods and/or at high doses should have stable asthma before transfer to inhaled steroids. Withdrawal of systemic steroids should be gradual. Severe asthma requires regular medical assessment, including lung-function testing, as there is a risk of severe attacks and even death. Patients should be instructed to seek medical attention if their peak flow falls, if symptoms persist or worsen or if their short-acting relief bronchodilator treatment becomes less effective, or more inhalations than usual are required as this may indicate deterioration of asthma control. If this occurs, patients should be assessed and the need for increased anti-inflammatory therapy considered (e.g. higher doses of inhaled corticosteroid or a course of oral corticosteroid). Patients who have received systemic steroids for long periods of time or at high doses, or both, need special care and subsequent management when being transferred to inhaled steroid therapy. Patients should carry a steroid warning card and have adrenocortical function monitored regularly. Patients should be advised that they may feel unwell in a non-specific way during systemic steroid withdrawal despite maintenance of, or even improved respiratory. Discontinuation of systemic steroids may cause exacerbation of allergic diseases such as atopic eczema and rhinitis. Monitor height of children regularly. Prolonged treatment with high doses of inhaled corticosteroids, particularly higher than recommended doses, may result in clinically significant adrenal suppression and acute adrenal crisis. Situations that could potentially trigger acute adrenal crisis include trauma, surgery, infection or any rapid reduction in dose. Additional systemic corticosteroid cover should be considered during periods of stress or elective surgery. Caution in patients with active or latent pulmonary tuberculosis. Paradoxical bronchospasm may occur with an immediate

increase in wheezing and shortness of breath after dosing. Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids. **Interactions:** Qvar contains a small amount of ethanol. There is a theoretical potential for interaction in particularly sensitive patients taking disulfiram or metronidazole. Beclometasone is less dependent on CYP3A metabolism than some other corticosteroids, and in general interactions are unlikely; however the possibility of systemic effects with concomitant use of strong CYP3A inhibitors (e.g. ritonavir, cobicistat) cannot be excluded, and therefore caution and appropriate monitoring is advised with the use of such agents. **Pregnancy and lactation:** There is inadequate evidence of safety in human pregnancy. Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore, be a risk of such effects in the human foetus. It should be noted, however, that the foetal changes in animals occur after relatively high systemic exposure. Beclometasone dipropionate is delivered directly to the lungs by the inhaled route and so avoids the high level of exposure that occurs when corticosteroids are given by systemic routes. There is no experience with or evidence of safety of propellant HFA 134a in human pregnancy or lactation. However, studies on the effect of HFA 134a on reproductive function and embryofoetal development in animals have revealed no clinically relevant adverse effects. **Effects on ability to drive and use machines:** Not relevant. **Adverse reactions:** A serious hypersensitivity reaction including oedema of the eyes, face, lips and throat (angioedema) has been reported rarely. Paradoxical bronchospasm. Systemic effects may occur with inhaled steroids, particularly at high doses prescribed for prolonged periods. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract, glaucoma, and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). *Common:* Hoarseness and candidiasis of the mouth and throat may occur. Taste disturbances. Pharyngitis. Consult the Summary of Product Characteristics (SmPC) in relation to other side-effects. **Overdose:** Acute overdose is unlikely to cause problems. Suppression of HPA axis function following inhalation of large amounts of the drug over a short period. Excessive doses taken over a prolonged period can produce a degree of atrophy of the adrenal cortex in addition to HPA axis suppression. In this event treat patient as steroid-dependent and transfer to a suitable maintenance dose of a systemic steroid such as prednisolone. Once the condition is stabilised, the patient should restart Qvar as described in the SmPC. **Further information:** The AeroChamber Plus® device is compatible with Qvar Aerosol Inhalers. **Price:** Per 200 dose unit: Qvar 50 mcg Aerosol: £7.87, Qvar 100 mcg Aerosol: £17.21 Qvar 50 mcg Autohaler: £7.87, Qvar 100 mcg Autohaler: £17.21, Qvar 50 mcg Easi-Breathe: £7.74, Qvar 100 mcg Easi-Breathe: £16.95. **Legal category:** POM. **Marketing Authorisation Number:** Qvar 50 mcg Aerosol: PL 00289/1371. Qvar 100 mcg Aerosol: PL 00289/1372. Qvar 50 mcg Autohaler: PL 00289/1373. Qvar 100 mcg Autohaler: PL 00289/1374. Qvar 50 mcg Easi-Breathe: PL 00289/1375. Qvar 100 mcg Easi-Breathe: PL 00289/1376. **Marketing Authorisation Holder:** Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX. **Job Code:** MED-GB-00059. **Date of Preparation:** November 2021.

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

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

Seffalair® Spiromax® (salmeterol/fluticasone) 12.75mcg/100mcg and 12.75mcg/202mcg inhalation powder Abbreviated Prescribing Information. **Presentation:** Each delivered dose (dose from the mouthpiece) contains 12.75mcg salmeterol xinafoate and either 100mcg or 202mcg of fluticasone propionate. Each metered dose contains 14mcg of salmeterol xinafoate and either 113mcg or 232mcg of fluticasone propionate. **Indications:** For the regular treatment of asthma in adults and adolescents aged 12 years and older not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting β_2 agonists. **Dosage and administration:** Inhalation use. Device is breath actuated. All patients should be trained on how to use the inhaler by their Health Care Professional. It is important to inhale forcefully to ensure optimal dosing. To be taken every day, even when asymptomatic. If symptoms arise between doses, an inhaled, short-acting beta$_2$ agonist should be used for immediate relief. When choosing the starting dose strength of Seffalair Spiromax, the patients' disease severity, previous asthma therapy including ICS dose and current control of asthma symptoms should be considered. Reassess patient regularly so that the Seffalair dose remains optimal. Dose should be titrated to lowest dose at which effective control of symptoms is maintained. The delivered doses for Seffalair are different from other salmeterol/fluticasone containing products and therefore the products are not interchangeable based on the corresponding dose strengths. Patients should rinse mouth out with water, or brush their teeth after inhaling. Keep inhaler dry and clean at all times by gently wiping the mouthpiece with a dry cloth or tissue. *Adults and adolescents 12 years and older:* one inhalation twice daily of prescribed dose. Once control of asthma is attained, treatment should be reviewed and consideration given as to whether patients should be stepped down to salmeterol/fluticasone propionate containing a lower dose of the inhaled corticosteroid, and then, ultimately, to an inhaled corticosteroid alone. Review patient regularly. If patient requires dosages outside the recommended regimen, appropriate doses of β_2 agonist and/or inhaled corticosteroid should be prescribed. *Children below 12 years of age*: safety and efficacy not established. No data available. *Elderly:* no dose adjustment required. *Renal impairment:* no dose adjustment required. *Hepatic impairment:* no data available. No dosage recommendation can be made. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients. **Precautions and warnings:** Seffalair should not be used to treat acute asthma symptoms for which a fast-and short-acting bronchodilator is required. Patients should have their rescue inhaler available for relief in an acute asthma attack at all times. Do not initiate patient with Seffalair during an exacerbation of if they have significantly worsening or acutely deteriorating asthma. Serious asthma-related adverse events and exacerbations may occur during treatment. In such event, patient should continue Seffalair treatment, and seek medical advice. Increased requirements for use of reliever medication or decreased response to reliever medication indicate deterioration of asthma control. Sudden and progressive deterioration in control of asthma is potentially life threatening and patient should undergo urgent medical assessment and consideration given to increasing inhaled corticosteroid therapy. Treatment with Seffalair should not be stopped abruptly due to risk of exacerbation. Therapy should be down-titrated under medical supervision. Administer with caution in patients with active or quiescent pulmonary tuberculosis and fungal, viral or other infections of the airway. Appropriate treatment should be promptly instituted, if indicated. Rarely, salmeterol/fluticasone propionate may cause cardiac arrhythmias e.g. supraventricular tachycardia, extrasystoles and atrial fibrillation, and a mild transient reduction in serum potassium at high therapeutics doses. Use with caution in patients with severe cardiovascular disorders or heart rhythm abnormalities and in patients with thyrotoxicosis. Beta-adrenergic agonist medicines may produce significant hypokalaemia in some patients. Increase in blood glucose levels have also been reported. Use with caution in patients with diabetes mellitus, uncorrected hypokalaemia, or patients predisposed to low levels of serum potassium. Paradoxical bronchospasm may occur and may be life-threatening. In such event, treat immediately with a short-acting inhaled bronchodilator. Seffalair should be discontinued immediately, the patient assessed, and alternative therapy instituted if necessary. Pharmacological effects of β_2 agonist treatment, such as tremor, palpitations and headache have been reported but tend to be transient and reduce with regular therapy. Possible systemic effects may occur with any inhaled corticosteroid, particularly at high doses prescribed for long periods. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, decrease in bone mineral density, cataract and glaucoma, and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression, or aggression (particularly in children). Review patient regularly and the dose of inhaled corticosteroid should be the lowest dose at which effective control of asthma is maintained. Visual disturbance may be reported and in such cases, the patient should be referred to an ophthalmologist for evaluation of possible causes. Prolonged treatment of patients with high doses of inhaled corticosteroids may result in adrenal suppression and acute adrenal crisis and therefore additional systemic corticosteroid treatment should be considered during periods of stress or elective

surgery. Patients transferring from oral steroids may remain at risk of impaired adrenal reserve for a considerable time. These patients should be treated with special care and adrenocortical function regularly monitored. Patients who have required high dose emergency corticosteroid therapy in the past may also be at risk. This possibility of residual impairment should always be borne in mind in emergency and elective situations likely to produce stress, and appropriate corticosteroid treatment must be considered. The extent of the adrenal impairment may require specialist advice before elective procedures. Ritonavir can greatly increase the concentration of fluticasone propionate in plasma. There is also an increased risk of systemic undesirable effects when combining fluticasone propionate with other potent CYP3A inhibitors. Concomitant use of systemic ketoconazole significantly increases systemic exposure to salmeterol which may lead to an increase in the incidence of systemic effects. Concomitant treatment with ritonavir, ketoconazole or other potent CYP3A4 inhibitors should therefore be avoided unless the benefits outweigh the potentially increased risk of systemic undesirable effects of salmeterol/fluticasone treatment. Children and adolescents less than 16 years taking high doses of fluticasone propionate may be at particular risk of systemic effects, particularly when prescribed for long periods. Consider referring the child or adolescent to a paediatric respiratory specialist. It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroids is regularly monitored. Hoarseness and candidiasis (thrush) of the mouth and throat and, rarely of the oesophagus, can occur in some patients which may be relieved by rinsing the mouth with water and spitting out and/or brushing the teeth after using Seffalair. Symptomatic candidiasis can be treated with topical anti-fungal therapy whilst continuing treatment. Contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. The excipient lactose may contain small amounts of milk proteins which may cause allergic reactions in those with severe hypersensitivity or allergy to milk protein. **Interactions:** Beta adrenergic blockers may weaken or antagonise the effect of salmeterol. Both non-selective and selective β blockers should be avoided unless there are compelling reasons for their use. Potentially serious hypokalaemia may result from β_2 agonist therapy. Particular caution is advised in acute severe asthma as this effect may be potentiated by concomitant treatment with xanthine derivatives, steroids, and diuretics. Concomitant administration with ritonavir, ketoconazole, itraconazole, telithromycin and other potent CYP3A4 inhibitors should be avoided unless the benefits outweigh the potentially increased risk of systemic effects of salmeterol/fluticasone treatment. Co-treatment with other CYP3A inhibitors, including cobicistat-containing products should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid effects. Concomitant administration of other sympathomimetic medicinal products (alone or as part of combination therapy) can have a potentially additive effect. **Pregnancy and lactation:** Should only be used during pregnancy if the expected benefit to the patient justifies the potential risk to the foetus. A decision must be made whether to discontinue breast-feeding or to discontinue salmeterol /fluticasone taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. **Effects on ability to drive and use machines:** No or negligible influence. **Adverse reactions:** Cushing's syndrome, Cushingoid features, adrenal suppression and growth retardation in children and adolescents, hypokalaemia, cataract, glaucoma, atrial fibrillation, cardiac arrhythmias (including supraventricular tachycardia and extrasystoles), paradoxical bronchospasm. *Very Common***:** none. *Common:* oral candidiasis, influenza, nasopharyngitis, rhinitis, sinusitis, headache, dizziness, cough, throat irritation, hoarseness/dysphonia, oropharyngeal pain, back pain, myalgia. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** No data with Seffalair Spiromax. *Salmeterol:* signs and symptoms of salmeterol overdose are dizziness, increases in systolic blood pressure, tremor, headache and tachycardia. If salmeterol/fluticasone propionate therapy has to be withdrawn due to overdose of the β_2 agonist component of the medicinal product, provision of appropriate replacement steroid therapy should be considered. Additionally, hypokalaemia can occur and therefore serum potassium levels should be monitored. Potassium replacement should be considered. *Fluticasone propionate:* acute inhalation of fluticasone propionate doses in excess of those recommended may lead to temporary suppression of adrenal function. This does not need emergency action as adrenal function is recovered in a few days, as verified by plasma cortisol measurements. In case of chronic overdose, adrenal reserve should be monitored and treatment with a systemic corticosteroid may be necessary. When stabilised, treatment should be continued with an inhaled corticosteroid at the recommended dose. In cases of both acute and chronic fluticasone propionate overdose, salmeterol/fluticasone propionate therapy should be continued at a suitable dose for symptom control. **Price:** £23.97 (single pack). **Legal category:** POM. **Marketing Authorisation Number:** PLGB 00289/2515, PLGB 00289/2516. **Marketing Authorisation Holder:** Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX. **Job Code:** MED-GB-00047. **Date of Preparation:** September 2021.

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

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

Montelukast Film-Coated Tablets Abbreviated Prescribing Information. **Presentation:** Each film-coated tablet contains 10.40mg montelukast sodium, which is equivalent to 10mg of montelukast. **Indications:** For the treatment of asthma as add-on therapy in patients 15 years of age and older with mild to moderate persistent asthma who are inadequately controlled on inhaled corticosteroids and in whom "as- needed" short-acting β-agonists provide inadequate clinical control of asthma. In those asthmatic patients in whom montelukast is indicated in asthma, montelukast can also provide symptomatic relief of seasonal allergic rhinitis. Montelukast is also indicated in the prophylaxis of asthma, in patients 15 years of age and older, in which the predominant component is exercise-induced bronchoconstriction. **Dosage and administration:** For oral use. Patients should continue taking montelukast even if their asthma is under control, as well as during periods of worsening asthma. Should not be taken concomitantly with other products containing the same active ingredient (montelukast). *Adults and Adolescents (15 years and older)*: One 10mg tablet daily to be taken in the evening. *Children and Adolescents below 15 years of age*: Not recommended for use. *Elderly:* No dose adjustment required. *Renal impairment:* No dose adjustment required. *Hepatic impairment:* No dose adjustment required for patients with mild to moderate hepatic impairment. No data regarding the use of Montelukast in patients with severe hepatic impairment. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Precautions and warnings:** Patients should be advised never to use oral montelukast to treat acute asthma attacks. If an acute attack occurs, a short-acting inhaled β-agonist should be used. Patients should seek their doctor's advice as soon as possible if they need more inhalations of short-acting β-agonists than usual. Montelukast should not be substituted abruptly for inhaled or oral corticosteroids. In rare cases, patients on montelukast may present with systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome. These cases have been sometimes associated with the reduction or withdrawal of oral corticosteroid therapy. Although a causal relationship with leukotriene receptor antagonism has not been established, physicians should be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. Patients who develop these symptoms should be reassessed and their treatment regimens evaluated. Neuropsychiatric events have been reported in adults, adolescents, and children taking montelukast. Prescribers should carefully evaluate the risks and benefits of continuing treatment with Montelukast 10mg Film-coated Tablets if such events occur. This product contains lactose monohydrate. **Interactions:** Montelukast may be administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma. Caution should be exercised, particularly in children, when montelukast is co-administered with inducers of CYP3A4, CYP2C8, and CYP2C9, such as phenytoin, phenobarbital and rifampicin, as they can reduce the plasma concentration of montelukast. Montelukast is not anticipated to markedly alter the metabolism of medicinal products metabolised by CYP2C8 (e.g., paclitaxel, rosiglitazone, and repaglinide). Co-administration with gemfibrozil (an inhibitor of CYP2C8 and CYP2C9) may increase the systemic exposure of montelukast. Co-administration of montelukast with itraconazole (a strong CYP3A4 inhibitor) does not result in a significant increase in the systemic exposure of montelukast. **Pregnancy and lactation:** Montelukast may be used during pregnancy and in breast-feeding women only if it is considered to be clearly essential. **Effects on ability to drive and use machines:** No known effect, but may cause drowsiness or dizziness. **Adverse reactions:** Thrombocytopenia, hypersensitivity reactions, hallucinations, suicidal thinking and behaviour, seizure, hepatitis (including cholestatic, hepatocellular and mixed-pattern liver injury), angioedema and erythema multiforme. *Very Common***:** Upper respiratory tract infection. *Common:* Diarrhoea, nausea, vomiting, elevated levels of serum transaminases, rash and pyrexia. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** No specific information is available on the treatment of overdose with montelukast. The most frequently occurring adverse experiences were consistent with the safety profile of montelukast and included abdominal pain, somnolence, thirst, headache, vomiting, and psychomotor hyperactivity. **Price:** Montelukast 10mg Film-Coated Tablets, Pack of 28: £1.03. **Legal category:** POM. **Marketing Authorisation Number:** PL 00289/1119. **Marketing Authorisation Holder:** Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX. **Job Code:** MED-GB-00147. **Date of Preparation:** July 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 Teva UK Limited on 0207 540 7117 or medinfo@tevauk.com

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

Montelukast Granules Abbreviated Prescribing Information. **Presentation:** Each sachet of granules contains montelukast sodium, which is equivalent to 4 mg montelukast. **Indications:** For the treatment of asthma as add-on therapy in patients aged 6 months to 5 year with mild to moderate persistent asthma who are inadequately controlled on inhaled corticosteroids and in whom "as-needed" short acting beta agonists provide inadequate clinical control of asthma. Montelukast granules may also be an alternative treatment option to low-dose inhaled corticosteroids for 2 to 5 year old patients with mild persistent asthma who do not have a recent history of serious asthma attacks that required oral corticosteroid use, and who have demonstrated that they are not capable of using inhaled corticosteroids. Montelukast granules are also indicated in the prophylaxis of asthma from 2 years of age and older in which the predominant component is exercise-induced bronchoconstriction. **Dosage and administration:** For oral use. Must be given to a child under adult supervision. Patients should be evaluated after 2 to 4 weeks for response to montelukast treatment. Treatment should be discontinued if a lack of response is observed. Patients should be advised to continue taking Montelukast granules even if their asthma is under control, as well as during periods of worsening asthma. Montelukast is not recommended as monotherapy in patients with moderate persistent asthma. In 2 to 5 year old patients, exercise-induced bronchoconstriction may be the predominant manifestation of persistent asthma that requires treatment with inhaled corticosteroids. *Infants and Children aged 6 months to 5 years:* One sachet of 4mg granules daily to be taken in the evening. *Infants under 6 months of age:* Not recommended for use. *Renal impairment:* No dose adjustment required. *Hepatic impairment:* No dose adjustment required for patients with mild to moderate hepatic impairment. No data regarding the use of Montelukast in patients with severe hepatic impairment. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Precautions and warnings:** The diagnosis of persistent asthma in patients aged 6 months to 2 years should be established by a paediatrician or pulmonologist. Patients should be advised never to use oral montelukast to treat acute asthma attacks. If an acute attack occurs, a short-acting inhaled β-agonist should be used. Patients should seek their doctor's advice as soon as possible if they need more inhalations of short-acting β-agonists than usual. Montelukast should not be substituted abruptly for inhaled or oral corticosteroids. In rare cases, patients on montelukast may present with systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome. These cases have been sometimes associated with the reduction or withdrawal of oral corticosteroid therapy. Although a causal relationship with leukotriene receptor antagonism has not been established, physicians should be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. Patients who develop these symptoms should be reassessed and their treatment regimens evaluated. Neuropsychiatric events have been reported in adults, adolescents, and children taking montelukast. Prescribers should carefully evaluate the risks and benefits of continuing treatment with Montelukast Granules if such events occur. **Interactions:** Montelukast may be administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma. Caution should be exercised, particularly in children, when montelukast is co-administered with inducers of CYP3A4, CYP2C8, and CYP2C9, such as phenytoin, phenobarbital and rifampicin, as they can reduce the plasma concentration of montelukast. Montelukast is not anticipated to markedly alter the metabolism of medicinal products metabolised by CYP2C8 (e.g., paclitaxel, rosiglitazone, and repaglinide). Co-administration with gemfibrozil (an inhibitor of CYP2C8 and CYP2C9) may increase the systemic exposure of montelukast. Co-administration of montelukast with itraconazole (a strong CYP3A4 inhibitor) does not result in a significant increase in the systemic exposure of montelukast. **Pregnancy and lactation:** Montelukast may be used during pregnancy and in breast-feeding women only if it is considered to be clearly essential. **Effects on ability to drive and use machines:** No known effect, but may cause drowsiness or dizziness. **Adverse reactions:** Thrombocytopenia, hypersensitivity reactions, hallucinations, suicidal thinking and behaviour, seizure, hepatitis (including cholestatic, hepatocellular and mixed-pattern liver injury), angioedema and erythema multiforme. *Very Common*: Upper respiratory tract infection. *Common:* Diarrhoea, nausea, vomiting, elevated levels of serum transaminases, rash and pyrexia. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** No specific information is available on the treatment of overdose with montelukast. The most frequently occurring adverse experiences were consistent with the safety profile of montelukast and included abdominal pain, somnolence, thirst, headache, vomiting, and psychomotor hyperactivity. **Price:** Montelukast **4**mg Granules, Pack of 28 Sachets: £19.99. **Legal category:** POM. **Marketing Authorisation Number:** PL 00289/1702. **Marketing Authorisation Holder:** Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX. **Job Code:** MED-GB-00088. **Date of Preparation:** February 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 Teva UK Limited on 0207 540 7117 or medinfo@tevauk.com

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

Montelukast Chewable Tablets Abbreviated Prescribing Information. **Presentation:** Each chewable tablet contains 5.20mg montelukast sodium, which is equivalent to 5mg montelukast. **Indications:** For the treatment of asthma as add-on therapy in those patients 6 to 14 years of age with mild to moderate persistent asthma who are inadequately controlled on inhaled corticosteroids and in whom 'as-needed' short-acting β-agonists provide inadequate clinical control of asthma. Montelukast may also be an alternative treatment option to low-dose inhaled corticosteroids for patients with mild persistent asthma who do not have a recent history of serious asthma attacks that required oral corticosteroid use, and who have demonstrated that they are not capable of using inhaled corticosteroids. Montelukast is also indicated in the prophylaxis of asthma, in patients 6 to 14 years of age, in which the predominant component is exercise-induced bronchoconstriction. **Dosage and administration:** Must be given to a child under adult supervision. If taken in connection with food, montelukast should be taken 1 hour before or 2 hours after food. Patients should continue taking montelukast even if their asthma is under control, as well as during periods of worsening asthma. Montelukast is not recommended as monotherapy in patients with moderate persistent asthma. *Children aged 6 to 14 years:* One 5mg chewable tablet daily to be taken in the evening. *Children under 2 years of age:* Not recommended for use. *Renal impairment:* No dose adjustment required. *Hepatic impairment:* No dose adjustment required for patients with mild to moderate hepatic impairment. No data regarding the use of Montelukast in patients with severe hepatic impairment. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Precautions and warnings:** Patients should be advised never to use oral montelukast to treat acute asthma attacks. If an acute attack occurs, a short-acting inhaled β-agonist should be used. Patients should seek their doctor's advice as soon as possible if they need more inhalations of short-acting β-agonists than usual. Montelukast should not be substituted abruptly for inhaled or oral corticosteroids. In rare cases, patients on montelukast may present with systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome. These cases have been sometimes associated with the reduction or withdrawal of oral corticosteroid therapy. Although a causal relationship with leukotriene receptor antagonism has not been established, physicians should be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. Patients who develop these symptoms should be reassessed and their treatment regimens evaluated. Neuropsychiatric events have been reported in adults, adolescents, and children taking montelukast. Prescribers should carefully evaluate the risks and benefits of continuing treatment with Montelukast Chewable Tablets if such events occur. This product contains aspartame which is hydrolysed to phenylalanine in the gastrointestinal tract when orally ingested. This may be harmful for patients with phenylketonuria (PKU). **Interactions:** Montelukast may be administered with other therapies routinely used in the prophylaxis and chronic treatment of asthma. Caution should be exercised, particularly in children, when montelukast is co-administered with inducers of CYP3A4, CYP2C8, and CYP2C9, such as phenytoin, phenobarbital and rifampicin, as they can reduce the plasma concentration of montelukast. Montelukast is not anticipated to markedly alter the metabolism of medicinal products metabolised by CYP2C8 (e.g., paclitaxel, rosiglitazone, and repaglinide). Co-administration with gemfibrozil (an inhibitor of CYP2C8 and CYP2C9) may increase the systemic exposure of montelukast. Co-administration of montelukast with itraconazole (a strong CYP3A4 inhibitor) does not result in a significant increase in the systemic exposure of montelukast. **Pregnancy and lactation:** Montelukast may be used during pregnancy and in breast-feeding women only if it is considered to be clearly essential. **Effects on ability to drive and use machines:** No known effect, but may cause drowsiness or dizziness. **Adverse reactions:** **H**ypersensitivity reactions, hallucinations, suicidal thinking and behaviour, seizure, hepatitis (including cholestatic, hepatocellular and mixed-pattern liver injury), angioedema and erythema multiforme. *Very Common***:** Upper respiratory tract infection. *Common:* Diarrhoea, nausea, vomiting, elevated levels of serum transaminases, rash and pyrexia. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** No specific information is available on the treatment of overdose with montelukast. The most frequently occurring adverse experiences were consistent with the safety profile of montelukast and included abdominal pain, somnolence, thirst, headache, vomiting, and psychomotor hyperactivity. **Price:** Montelukast 5mg Chewable Tablets, Pack of 28: £24.41. **Legal category:** POM. **Marketing Authorisation Number:** PL 00289/1118. **Marketing Authorisation Holder:** Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX. **Job Code:** MED-GB-00087. **Date of Preparation:** February 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 Teva UK Limited on 0207 540 7117 or medinfo@tevauk.com

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

Airomir® (Salbutamol) Metered Dose Inhaler (MDI) and Autohaler Abbreviated Prescribing Information **Presentation:** One metered dose of Airomir 100mcg MDI and Airomir 100mcg Autohaler contains salbutamol sulfate equivalent to 100mcg salbutamol. **Indications:** For the management of bronchial asthma, for the relief of wheezing and shortness of breath used on an as required basis. May be used as necessary to relieve attacks of acute dyspnoea and may be used prophylactically before exertion or to prevent exercise-induced asthma. Airomir may also be used in the treatment of the reversible component of airways obstruction. **Dosage and administration:** For inhalation use. The maximum recommended dose should not exceed eight inhalations in 24 hours. With repetitive dosing, inhalations should not usually be repeated more often than every 4 hours. *Adults*: For the relief of wheezing, shortness of breath and attacks of acute dyspnoea in patients with asthma, or the reversible component of airways obstruction , one or two inhalations may be administered as a single dose. For prophylaxis of exercise-induced asthma, two inhalations before exercise. *Children (under 12 years of age)*: For relief of acute bronchospasm one inhalation. This may be increased to two inhalations if required. For prevention of allergen or exercise-induced bronchospasm one inhalation before challenge or exertion. This may be increased to two inhalations if required. For chronic therapy up to two inhalations 4 times daily. *Children (ages 12 years and over)*: Dose as per adult population. *Elderly:* No special dosage recommendations. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Contraindicated for use in the management of premature labour and threatened abortion. **Precautions and warnings:** Instruct patients in the proper use of their inhaler and check their technique. Asthma management should normally follow a stepwise programme. Monitor patient response clinically and by lung function tests. Patients should seek medical advice if a previously effective dose ceases to be effective for at least three hours, and/or their asthma seems to be worsening. Patients requiring long-term management with Airomir should be kept under regular surveillance. Administer with caution to patients with thyrotoxicosis, coronary in sufficiency, hypertrophic obstructive cardiomyopathy, arterial hypertension, tachyarrhythmias, in concomitant use of cardiac glycosides or diabetes mellitus. Potentially serious hypokalaemia has been reported in patients taking β2-agonist therapy mainly from parenteral and nebulised administration. Care should be taken when treating acute asthma attacks or exacerbation of severe asthma as increased serum lactate levels and lactic acidosis have been reported after high doses of salbutamol. Unwanted stimulation of cardiac adrenoceptors can occur in patients taking β2-agonist therapy. Cardiovascular effects may be seen with sympathomimetic drugs, including salbutamol. Patients with underlying severe heart disease (e.g. ischaemic heart disease , arrhythmias or severe heart failure) who are receiving salbutamol should seek medical advice if they experience chest pain or other symptoms of worsening heart disease. If paradoxical bronchospasm develops Airomir should be discontinued immediately and alternative therapy given. Salbutamol can induce reversible metabolic changes such as increased blood glucose levels. **Interactions:** Propranolol and other non-cardioselective β-adrenoceptor blocking agents antagonise the effects of salbutamol. Monoamine oxidase inhibitors, tricyclic antidepressants and digoxin increase the risk of cardiovascular effects. Patients should discontinue salbutamol for at least 6 hours before an intended anaesthesia with halogenic anaesthetics. Hypokalaemia occurring with β2-agonist therapy may be exacerbated by treatment with xanthines, steroids, diuretics and long-term laxatives. Airomir contains a small amount ethanol, therefore, there is a theoretical potential for interaction in patients taking disulfiram or metronidazole and may precipitate a reaction in some sensitive patients. **Pregnancy and lactation:** Should not be used in pregnancy and lactation unless the expected benefit to the mother is thought to outweigh any risk to the foetus or neonate**. Effects on ability to drive and use machines:** May cause dizziness. Do not drive or operate machinery if affected. **Adverse reactions:** Hypersensitivity reaction (including angioedema), hypokalaemia, lactic acidosis, hallucination, cardiac arrhythmia, atrial fibrillation and myocardial ischaemia. *Common:* Tenseness, headache, dizziness and muscle tremor. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** May result in skeletal muscle tremor, tachycardia, tenseness, headache and peripheral vasodilatation. Hypokalaemia may occur following overdose with salbutamol. Hyperglycaemia, agitation and hyperactivity have also been reported following overdose with salbutamol. Lactic acidosis has been reported very rarely in patients receiving intravenous or nebulised salbutamol therapy. Please see SmPC for recommendations and considerations when treating overdose. **Price:** Per 200 dose unit: Airomir 100mcg MDI: £1.97, Airomir 100mcg Autohaler: £6.02. **Legal category:** POM. **Marketing Authorisation Number:** Airomir MDI PL 00289/1410, Airomir Autohaler PL 00289/1411. **Marketing Authorisation Holder:** Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX. **Job Code:** MED-GB-00073. **Date of Preparation:** January 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 Teva UK Limited on 0207 540 7117 or medinfo@tevauk.com

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:** Hypersensitivity reactions, anaphylactic reaction, bronchospasm, anticholinergic effects (glaucoma, constipation, intestinal obstruction including ileus paralytic as well as urinary retention and urinary tract infection), atrial fibrillation, angioedema. *Common:* Dry mouth. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** May lead to anticholinergic signs and symptoms. **Price:** Bottle containing 30 Braltus capsules and 1 Zonda inhaler; £25.80 **Legal category:** POM. **Marketing Authorisation Number:** PL 00289/1870 **Marketing Authorisation Holder:** Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom. **Job Code:** MED-GB-00072. **Date of Preparation:** January 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 Teva UK Limited on 0207 540 7117 or medinfo@tevauk.com

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

Salamol® (Salbutamol) Aerosol and Easi-Breathe® CFC-Free Inhalers Abbreviated Prescribing Information: P**resentation:** Salamol 100mcg Aerosol Inhaler. Salamol 100mcg Easi-Breathe Inhaler. One metered dose contains salbutamol sulfate equivalent to 100mcg salbutamol. **Indications:** Symptomatic treatment of asthma and other conditions with associated reversible airways obstruction. Use on an as required basis for relief of wheezing, shortness of breath. Prevention of asthma attacks induced by exercise or exposure to allergens. Can be used as relief medication to manage mild, moderate and severe asthma, provided its use does not delay the introduction and regular use of corticosteroid therapy where necessary. Indicated in adults, adolescents and children aged 4 to 11 years. **Dosage and Administration:** For optimum results in most patients use as required. Salamol 100mcg Aerosol inhaler can be used with a Volumatic® spacer. *Adults and Elderly:* For relief of acute asthma: One to two inhalations (100 to 200mcg). For prevention of exercise or allergen-induced asthma: Two inhalations (200mcg) 10 to 15 minutes before challenge. Do not exceed eight inhalations in 24 hours. Inhalations should not usually be repeated more often than every 4 hours. *Paediatric Population:* Relief of acute bronchospasm: Children under the age of 12 years: One inhalation (100mcg). The dose may be increased to two inhalations if required. Prevention of allergen or exercise-induced bronchospasm: Children under 12: one inhalation (100mcg) before challenge or exertion. The dose may be increased to two inhalations if required. Chronic therapy: Children under the age of 12 years: Up to two inhalations 4 times daily. Children aged 12 years and over: Dose as *per* adult population. **Contraindications:** Hypersensitivity to any of the components. Salbutamol inhalation is contraindicated in treatment of threatened abortion or premature labour. **Precautions and warnings:** Instruct patients' in the proper use of their inhaler and check their technique. Asthma management should normally follow a stepwise programme. Monitor the patient's response clinically and by lung function tests. Asthmatic patients whose conditions deteriorates despite Salbutamol therapy, or where a previously effective dose fails to give relief for at least three hours, should seek medical advice in order that any necessary additional steps may be taken. Administer with caution to patients with thyrotoxicosis, coronary insufficiency, hypertrophic obstructive cardiomyopathy, arterial hypertension, known tachyarrhythmias, concomitant use of cardiac glycosides, diabetes mellitus and in patients with a history of bronchospasm. If bronchospasm occurs the preparation should be discontinued immediately and an alternative therapy given. Solutions which are not of neutral pH may rarely cause paradoxical bronchospasm in some patients. Take care when treating acute asthma attacks or exacerbation of severe asthma, as increased serum lactate levels and rarely lactic acidosis have been reported after the use of high doses in emergency situations. This is reversible on reducing the dose. Salbutamol can induce reversible metabolic changes. Diabetic patients may be unable to compensate for the increase in blood glucose and may develop ketoacidosis. Concomitant administration of glucocorticoids can exaggerate this effect. Hypokalaemia may also occur. Monitor serum potassium levels. Not to be used for managing premature labour or for threatened premature labour or for threatened abortion. Contains ethanol (alcohol). **Interactions:** Propranolol and other non-cardioselective β-adrenoceptor blocking agents antagonise the effects of salbutamol. Increased risk of cardiovascular effects with monoamine oxidase inhibitors, tricyclic antidepressants and digoxin. Wherever possible, discontinue use at least six hours before anaesthesia with halogenic anaesthetics. Hypokalaemia occurring with β2-agonist therapy may be exacerbated by treatment with xanthines, steroids, diuretics and long-term laxatives. Because of the content of ethanol, there is theoretical potential for interaction in patients taking disulfiram or Metronidazole. **Pregnancy and Lactation:** The therapeutic benefits should be weighed against the potential risks to the foetus. Salbutamol inhalation is contraindicated in treatment of threatened abortion or premature labour. **Effects on ability to drive and use machines**: No studies on the effects on the ability to drive and use machines have been performed. **Adverse Reactions:** *Common:* Dose related tenseness and headaches, tachycardia, respiratory irritations (mouth and throat). *Serious:* Hypersensitivity reactions, potentially serious hypokalaemia, sleep disturbances and hallucinations

(especially in children), hyperactivity in children (rarely), dizziness, tachycardia with or without peripheral vasodilatation (rarely), cardiac arrhythmias, palpitations, peripheral vasodilatation, Supraventricular tachycardia and extrasystoles, especially if used concomitantly with other ß2-agonists. Paradoxical bronchospasm, nausea, vomiting, pruritus, fine tremor of skeletal muscle and myalgia. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** An overdose may result in skeletal muscle tremor, tachycardia, tenseness, headache and peripheral vasodilatation. The preferred antidote for overdosage with salbutamol is a cardioselective ß-adrenoceptor blocking agent. Beta-blocking drugs should be used with caution in patients with a history of bronchospasm, as these drugs are potentially life threatening. Hypokalaemia may occur following overdose with salbutamol. Serum potassium levels should be monitored. Hyperglycaemia and agitation have also been reported following overdose with salbutamol. **Price:** *Per* 200 dose unit: Salamol 100mcg Aerosol Inhaler: £1.46, Salamol 100mcg Easi-Breathe Inhaler: £6.30. **Legal Category:** POM. **Marketing Authorisation Number:** Salamol 100 mcg Aerosol Inhaler PL 00530/0555; Salamol 100mcg Easi-Breathe Inhaler PL 00530/0556. **Marketing Authorisation Holder**: Norton Healthcare Limited, T/A IVAX Pharmaceuticals UK, Ridings Point, Whistler Drive, Castleford, West Yorkshire, WF10 5HX **Job Code:** RESP-GB-00002. **Date of revision:** August 2020