

## Symbicort (budesonide/formoterol) Asthma Licence and Dosing Guide

Medicine & strength	Maintenance <i>Children</i> 6+ years	Maintenance <i>Adolescents</i> 12 -17 years	Maintenance <i>Adults</i> 18+ years	Maintenance And Reliever Therapy (MART) <i>Children</i> 6 - 11 years	Maintenance And Reliever Therapy (MART) <i>Adolescents and adults</i> 12+ years	Reliever Therapy <i>Adolescents and adults</i> 12+ years
<b>Symbicort 100/6</b> <b>Turbohaler DPI<sup>1</sup></b> <i>120 doses</i> Shelf life: 3 years	1-2 inh. BD	1-2 inh. BD	1-2 inh. BD Some patients may require up to a max of 4 inh. BD	1 inh. per day, given either as 1 inh. in the morning <b>or</b> as 1 inh. in the evening. For some patients, a maintenance dose of 1 inh. BD may be appropriate. 1 additional inh. as needed in response to symptoms. If symptoms persist after a few minutes, 1 additional inh. should be taken. Not more than 4 inh. should be taken on any single occasion. A total daily dose of more than 4 inh. is not normally needed. However, total daily dose of up to 8 inh. could be used for a limited period. Patients using more than 4 inh. daily should be strongly recommended to seek medical advice. They should be reassessed and their maintenance therapy should be reconsidered. If necessary, dosage should be reassessed for patients who will shortly turn 12 years or have recently turned 12 to follow dosage regimen of adults and adolescents (12+ years).	2 inh. per day, given either as 1 in the morning and evening or as 2 inh. in either the morning or evening. 1 additional inh. as needed in response to symptoms. If symptoms persist after a few minutes, 1 additional inh. should be taken. Not more than 6 inh. should be taken on any single occasion. A total daily dose of more than 8 inh. is not normally needed. However, a total daily dose of up to 12 inh. could be used for a limited period. Patients using more than 8 inh. daily should be strongly recommended to seek medical advice. They should be reassessed and their maintenance therapy should be reconsidered.	
<b>Symbicort 200/6</b> <b>Turbohaler DPI<sup>2</sup></b> <i>120 doses</i> Shelf life: 3 years		1-2 inh. BD	1-2 inh. BD Some patients may require up to a max of 4 inh. BD		2 inh. per day, given either as 1 in the morning and evening or as 2 inh. in either the morning or evening. For some patients a maintenance dose of 2 inh. BD may be appropriate. 1 additional inh. as needed in response to symptoms. If symptoms persist after a few minutes, 1 additional inh. should be taken. Not more than 6 inh. should be taken on any single occasion. A total daily dose of more than 8 inh. is not normally needed. However, a total daily dose of up to 12 inh. could be used for a limited period. Patients using more than 8 inh. daily should be strongly recommended to seek medical advice. They should be reassessed and their maintenance therapy should be reconsidered.	1 inh. as needed in response to symptoms. If symptoms persist after a few minutes, 1 additional inh. should be taken. Not more than 6 inh. should be taken on any single occasion. If a patient finds the treatment less effective or experiences progressive deterioration of symptoms despite taking Symbicort as needed they should seek medical attention as soon as possible. A total daily dose of more than 8 inh. is not normally needed. However, a total daily dose of up to 12 inh. could be used for a limited period. Patients using more than 8 inh. daily should be reassessed.*
<b>Symbicort 400/12</b> <b>Turbohaler DPI<sup>3</sup></b> <i>60 doses</i> Shelf life: 3 years		1 inh. BD	1 inh. BD Some patients may require up to a max of 2 inh. BD			
<b>Symbicort 100/3 pMDI<sup>4</sup></b> <i>120 doses</i> Shelf life: 2 years, after 1 <sup>st</sup> open: 3 months		2-4 act. BD	2-4 act. BD Some patients may require up to a max of 8 act. BD		4 act. per day, given either as 2 act. in the morning and evening or as 4 act. in either the morning or evening. For some patients, a maintenance dose of 4 act. BD may be appropriate. 2 additional act. as needed in response to symptoms. If symptoms persist after a few minutes, 2 additional act. should be taken. Not more than 12 act. should be taken on any single occasion. A total daily dose of more than 16 act. is not normally needed. However, a total daily dose of up to 24 act. could be used for a limited period. Patients using more than 16 act. daily should be strongly recommended to seek medical advice. They should be reassessed and their maintenance therapy should be reconsidered.	

\*Patients should be assessed at regular intervals according to local practice to determine whether their as-needed treatment with Symbicort remains optimal or whether regular scheduled treatment with inhaled corticosteroid-containing maintenance medication should be initiated.

Symbicort® (budesonide/formoterol) Turbohaler® 100/6, 200/6 and 400/12 are indicated for regular treatment of asthma where the combined use of inhaled corticosteroids (ICS) and long-acting β2 adrenoceptor agonist (LABA) is appropriate:<sup>1-3</sup>

- Patients not adequately controlled with ICS and as needed inhaled short-acting β2 adrenoceptor agonists (SABA) **or**
- Patients already adequately controlled on both ICS and LABA.

Symbicort® Turbohaler® 100/6 is indicated for adult, adolescents and children aged 6 years and older.<sup>1</sup> Symbicort® Turbohaler® 200/6 and 400/12 are indicated for adults and adolescents 12 years and older.<sup>2</sup>

Symbicort® Turbohaler® 100/6 is not intended for the initial management of asthma. It is indicated in patients with asthma aged ≥6 years for regular maintenance treatment with a separate rapid-acting bronchodilator as rescue or as a Maintenance and Reliever Therapy (MART).<sup>1</sup>

Symbicort® Turbohaler® 200/6 is indicated for patients ≥12 years as reliever therapy for mild asthma and is indicated for maintenance therapy or MART.<sup>2</sup>

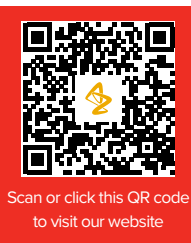
Symbicort® Turbohaler® 400/12 is indicated for maintenance therapy only in asthma patients ≥12 years and is not intended for the initial management of asthma.<sup>3</sup>

It's important to note, there is a pressurised metered dose inhaler Symbicort 100/3 pMDI available for the treatment of asthma, as an alternative for asthma patients who can't use a dry powder inhaler.<sup>4</sup>

**You are strongly advised to consult the respective SmPCs before prescribing for age related dosing, maximum dosage and method of administration for Symbicort Turbohaler 100/6, 200/6, 400/12 and Symbicort 100/3 pMDI.**<sup>1-5</sup>

act: actuation; BD: twice daily; DPI: Dry Powder Inhaler; inh.: Inhalation; MART: Maintenance And Reliever Therapy; pMDI: pressurised metered dose inhaler, SmPC: Summary of Product Characteristics.

**1.** Symbicort Turbohaler 100/6 Inhalation Powder Summary of Product Characteristics. **2.** Symbicort Turbohaler 200/6 Inhalation powder Summary of Product Characteristics. **3.** Symbicort Turbohaler 400/12 Inhalation powder Summary of Product Characteristics. **4.** Symbicort 100/3 actuation pressurised inhalation suspension Summary of Product Characteristics. **5.** Symbicort 200/6 actuation pressurised inhalation suspension Summary of Product Characteristics.



## PRESCRIBING INFORMATION – ASTHMA

### SYMBICORT® 100/3, 100/6, 200/6 and 400/12 (budesonide/formoterol fumarate dihydrate)

#### Consult Summary of Product Characteristics before prescribing.

**Indication:** Regular treatment of asthma where use of an inhaled corticosteroid (ICS) and long-acting  $\beta_2$  adrenoreceptor agonist (LABA) combination is appropriate: patients not adequately controlled with ICS and as needed short-acting  $\beta_2$  adrenoreceptor agonists (SABA) or patients already adequately controlled on both ICS and LABA. **Symbicort Turbohaler 200/6 only** is also indicated as reliever therapy for adults and adolescents (12 years and older) with mild asthma. **Symbicort Turbohaler 100/6 only:** Indicated in adults, adolescents, and children aged 6 years and older. **Symbicort 100/3 pressurised metered dose inhaler (pMDI), Symbicort Turbohaler 200/6 and 400/12 only:** Indicated in adults and adolescents (12 years and older). Symbicort Turbohaler 400/12, 100/6 and Symbicort 100/3 pMDI are not intended for the initial management of asthma.

**Presentation:** **Symbicort Turbohaler 100/6, 200/6 and 400/12:** Dry powder inhaler (DPI). **Symbicort Turbohaler 100/6:** Each metered dose contains 100 micrograms (mcg) budesonide and 6 mcg formoterol fumarate dihydrate (formoterol). **Symbicort Turbohaler 200/6:** Each metered dose contains 200 mcg budesonide and 6 mcg formoterol. **Symbicort Turbohaler 400/12:** Each metered dose contains 400 mcg budesonide and 12 mcg formoterol. **Symbicort 100/3 pMDI:** Each metered dose contains 100 mcg of budesonide and 3 mcg of formoterol.

**Dosage and Administration:** Titrate to the lowest effective dose. Regular review of patients as treatment is stepped down is important. Closely monitor patient taking frequent high doses for dose-related adverse events. Reassess patient if increased use of separate bronchodilator occurs. Patients with difficulty coordinating actuation with inhalation should use a spacer with Symbicort 100/3 pMDI. Advise patient to rinse mouth after inhalation. **Maintenance Therapy:** Advise patients to carry separate rapid-acting bronchodilator at all times for rescue. *Symbicort Turbohaler 100/6 and 200/6:* (12 years and older) 1-2 inhalations twice daily; some patients (18 years +) may require up to a maximum of 4 inhalations twice daily. *Symbicort Turbohaler 100/6* can be used in patients 6 years and older with the same dosing regime. *Symbicort Turbohaler 400/12:* (12 years and older) 1 inhalation twice daily; some patients (18 years +) may require up to a maximum of 2 inhalations twice daily. *Symbicort 100/3 pMDI:* (12 years and older) 2-4 actuations twice daily; some patients (18 years +) may require up to a maximum of 8 actuations twice daily. **Symbicort maintenance and reliever therapy (MART):** *Symbicort Turbohaler 100/6, 200/6 and Symbicort 100/3 pMDI* can be taken as a regular maintenance and as needed, as a reliever, in response to asthma symptoms for adults and adolescents (12 years and older). Symbicort Turbohaler 100/6 only is recommended for the same use in children aged 6 years and older. *Symbicort Turbohaler 100/6 and 200/6* (12 years and older): 2 inhalations per day, either as 1 inhalation in the morning and evening or as 2 inhalations once daily, either morning or evening. Take 1 additional inhalation as needed in response to symptoms. If symptoms persist after a few minutes, 1 additional inhalation should be taken. Not more than 6 inhalations should be taken on any single occasion. Patients using more than 8 inhalations daily should be reassessed. The maximum daily dose is 12 inhalations for a limited period. *Symbicort Turbohaler 100/6:* (6 – 11 years) 1 inhalation per day, either as 1 inhalation in the morning or evening. Take 1 additional inhalation as needed in response to symptoms. For some patients, a maintenance dose of 1 inhalation twice daily may be appropriate. If symptoms persist after a few minutes, 1 additional inhalation should be taken. Not more than 4 inhalations should be taken on any single occasion. Patients using more than 4 inhalations daily should be reassessed. The maximum daily dose is 8 inhalations for a limited period. Dosage should be reassessed for patients shortly turning 12, in order to follow dosing regimen of adults and adolescents (12 years and older). *Symbicort 100/3 pMDI:* 4 actuations per day, either as 2 actuations in the morning and evening or as 4 inhalations once daily, either morning or evening. For some patients, a maintenance dose of 4 actuations twice daily may be appropriate. Take 2 additional actuations as needed in response to symptoms. If symptoms persist after a few minutes, 2 additional actuations should be taken. Not more than 12 actuations should be taken on any single occasion. The maximum daily dose is 24 inhalations for a limited period. Patients using more than 16 actuations daily should be reassessed. **Symbicort reliever therapy (mild asthma):** *Symbicort 200/6 Turbohaler* only can be taken as needed in response to symptoms for adults and adolescents (12 years and older): 1 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. Patients using more than 8 inhalations daily should be reassessed. The maximum daily dose is 12 inhalations for a limited period.

**Contraindications:** Hypersensitivity to active substances or excipients.

**Warnings and Precautions:** Maintenance dose should be tapered when treatment is discontinued and the dosing should not be stopped abruptly. Take care when transferring patients from oral steroids if impaired adrenal function is suspected. Complete withdrawal of inhaled corticosteroids should not be considered unless it is temporarily required to confirm diagnosis of asthma. If treatment is ineffective, or more inhalations than usual are needed, medical attention must be sought. Treatment should not be initiated during exacerbations or if they have significantly worsening or acutely deteriorating asthma. Discontinue Symbicort immediately if the patient experiences a paradoxical bronchospasm and treat immediately. Observe caution in patients with thyrotoxicosis, pheochromocytoma, diabetes mellitus, untreated hypokalaemia, hypertrophic obstructive cardiomyopathy, idiopathic subvalvular aortic stenosis, severe hypertension, aneurysm or other severe cardiovascular disorders such as ischaemic heart disease, tachyarrhythmias or severe heart failure. Observe caution when treating patients with prolongation of the QTc-interval. Formoterol itself may induce prolongation of the QTc-interval. Potentially serious hypokalaemia may result from high doses of  $\beta_2$  adrenoreceptor agonists therapy and may also be potentiated by concomitant treatments (e.g. xanthine derivatives, steroids and

diuretics). Particular caution is recommended in unstable asthma with variable use of rescue bronchodilators, in acute severe asthma as the associated risk may be augmented by hypoxia and in other conditions when the likelihood for hypokalaemia is increased. It is recommended that serum potassium levels are monitored during these circumstances. Consider additional blood glucose controls in diabetic patients. Re-evaluate need for Symbicort in patients with active or quiescent pulmonary tuberculosis, fungal and viral infections in the airways. Systemic effects of ICS may occur, particularly at high doses for long periods, but are less likely than with oral steroids. These include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, 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). Consider effect on bone density in patients with osteoporosis risk factors, on high doses for prolonged periods. Consider referral of patients reporting blurred vision or visual disturbances to an ophthalmologist as causes may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy. Prolonged treatment with high doses of ICS may result in adrenal suppression and acute adrenal crisis. Consider additional systemic corticosteroid cover when body is under stress e.g. severe infection, elective surgery. Rapid reduction of steroid can induce acute adrenal crisis. Recommended that height of children receiving prolonged treatment is regularly monitored and if growth is slowed, therapy should be re-evaluated and consideration given to referring the patient to a paediatric respiratory specialist. **Symbicort Turbohaler:** The excipient lactose contains small amounts of milk proteins which may cause allergic reactions.

**Drug Interactions:** Potent CYP3A4 inhibitors are likely to increase plasma levels of budesonide and concomitant use should be avoided. In patients using potent CYP3A4 inhibitors, Symbicort maintenance and reliever therapy is not recommended. Beta-blockers should be avoided with asthma patients, unless there are compelling reasons. Concomitant treatment with quinidine, disopyramide, procainamide, phenothiazines, antihistamines (terfenadine) and tricyclic antidepressants can prolong the QTc-interval and increase the risk of ventricular arrhythmias. L-Dopa, L-thyroxine, oxytocin and alcohol can impair cardiac tolerance towards  $\beta_2$ -sympathomimetics. Concomitant treatment with monoamine oxidase inhibitors, including agents with similar properties such as furazolidone and procarbazine, may precipitate hypertensive reactions. Elevated risk of arrhythmias in patients receiving concomitant anaesthesia with halogenated hydrocarbons. Concomitant use of other beta-adrenergic drugs or anticholinergic drugs can have a potentially additive bronchodilating effect. Hypokalaemia may increase the disposition towards arrhythmias in patients taking digitalis glycosides. Interaction studies have only been performed in adults.

**Pregnancy and Lactation:** Use only when benefits outweigh potential risks for patient and child during pregnancy and breastfeeding. The lowest effective dose of budesonide should be given. Budesonide is excreted in breast milk; at therapeutic doses, no effects on child are anticipated. Not known whether formoterol passes into human breast milk.

**Undesirable Events:** Consult SmPC for full list of side effects. **Common:** Headache, palpitations, tremor, candida infections in the oropharynx, coughing, mild irritation in the throat and dysphonia including hoarseness. **Uncommon:** Tachycardia, aggression, psychomotor hyperactivity, anxiety, sleep disorders, dizziness, vision blurred, nausea, bruises and muscle cramps. **Rare:** Hypokalaemia, cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles, bronchospasm and immediate and delayed hypersensitivity reactions including exanthema, urticaria, pruritus, dermatitis, angioedema and anaphylactic reaction. **Very rare:** Depression, behavioural changes (predominantly in children), taste disturbances, angina pectoris, prolongation of QTc-interval, hyperglycaemia, Cushing's Syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and glaucoma, variations in blood pressure and paradoxical bronchospasm.

**Overdose:** An overdose of formoterol would likely lead to effects that are typical for  $\beta_2$  adrenoreceptor agonists: tremor, headache, palpitations. Acute overdosage with budesonide is not expected to be a clinical problem. When used chronically in excessive doses, systemic glucocorticosteroid effects, such as hypercorticism and adrenal suppression may appear. If Symbicort therapy has to be withdrawn due to overdose of the formoterol component, provision of appropriate inhaled corticosteroid therapy must be considered.

**Legal Category:** POM.

**Marketing Authorisation Number:** Symbicort 100/3 pMDI PL 17901/0349; Symbicort Turbohaler 100/6 PL 17901/0091; Symbicort Turbohaler 200/6 PL 17901/0092; Symbicort Turbohaler 400/12 PL 17901/0200.

**Presentation & Basic NHS Cost:** Symbicort 100/3 pMDI 1 pack x 120 doses: £14.00; Symbicort Turbohaler 100/6 1 pack x 120 doses: £28.00; Symbicort Turbohaler 200/6 1 pack x 120 doses: £28.00; Symbicort Turbohaler 400/12 1 pack x 60 doses: £28.00

**Business Responsible for Sale and Supply / Further Information:** AstraZeneca UK Limited, 2 Pancras Square, 8<sup>th</sup> Floor, London N1C 4AG, UK.

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Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to AstraZeneca by visiting <https://contactazmedical.astrazeneca.com> or by calling 0800 783 0033.