

(DCA 329 – 4 Desember 2018)

O	(ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	<p>1.1 <b>Symbicort turbuhaler 80/4.5 mcg/dose</b> [Budesonide 80mcg/Formoterol fumarate dihydrate 4.5mcg]</p> <p>1.2 <b>Symbicort turbuhaler 160/4.5 mcg/dose</b> [Budesonide 160mcg/Formoterol fumarate dihydrate 4.5mcg]</p>	<p>➤ Posology:</p> <p><u><i>Symbicort maintenance and reliever therapy</i></u> <i>Patients take a daily maintenance dose of Symbicort and in addition take Symbicort as needed in response to symptoms. Patients should be advised to always have Symbicort available for rescue use.</i></p> <p><i>Symbicort maintenance and reliever therapy should especially be considered for patients with:</i></p> <ul style="list-style-type: none"> <li>• <i>inadequate asthma control and in frequent need of reliever medication</i></li> <li>• <i>asthma exacerbations in the past requiring medical intervention</i></li> </ul> <p><i>Close monitoring for dose-related adverse effects is needed in patients who frequently take high numbers of Symbicort as-needed inhalations.</i></p> <p><i>Recommended doses:</i></p> <p><i>Symbicort Turbuhaler 80/4.5 micrograms/inhalation</i></p> <p><i>Adults and adolescents (12 years and older):</i> <i>Maintenance Therapy</i> <i>The recommended maintenance dose is 2 inhalations per day, given either as one inhalation in the morning and evening or as 2 inhalations in either the morning or evening.</i></p> <p><i>Reliever Therapy (in addition to Maintenance Therapy)</i> <i>Patient 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.</i></p>	<p><b>ASTRAZENECA SDN. BHD.</b> Level 12, Surian Tower 1 Jalan PJU 7/3 Mutiara Damansara 47810 Petaling Jaya, Selangor</p>

#### *Maximum Daily Symbicort Dose*

*A total daily dose of more than 8 inhalations is not normally needed; however, 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. They should be reassessed and their maintenance therapy should be reconsidered.*

*Children under 12 years: Symbicort maintenance and reliever therapy is not recommended for children.*

#### *Symbicort Turbuhaler 160/4.5 micrograms/inhalation*

##### *Adults and adolescents (12 years and older):*

##### *Maintenance Therapy*

*The recommended maintenance dose is 2 inhalations per day, given either as one inhalation in the 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.*

##### *Reliever Therapy (in addition to Maintenance Therapy)*

*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.*

#### *Maximum Daily Symbicort Dose*

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*Children under 12 years: Symbicort maintenance and reliever therapy is not recommended for children.*