



מאי 2021

הנידון:

Symbicort Turbuhaler 80/4.5 mcg/dose, 160/4.5 mcg/dose, 320/9 mcg/dose

רופא/ה נכבד/ה
רוקח/ת נכבד/ה שלום רב,

פרסום עדכון בעלון לרופא והעלון לצרכן של התכשיר

הרכב:

Budesonide micronized 80mcg/dose, 160mcg/dose, 320mcg/dose
Formoterol Fumarate (dihydrate) 4.5mcg/dose, 4.5mcg/dose, 9mcg/dose

התוויה:

80/4.5 mcg/dose

Symbicort turbuhaler is indicated in the regular treatment of asthma where use of a combination (inhaled corticosteroid and long acting beta-agonist) is appropriate:

- Patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short acting beta2-agonists.
- Or patients already adequately controlled on both inhaled corticosteroids and long acting beta2-agonists.

NOTE: Symbicort turbuhaler 80/4.5 mcg/dose is not appropriate in patients with severe asthma.

160/4.5 mcg/dose

Asthma

Symbicort Turbuhaler 160/4.5 mcg/dose is indicated in adults and adolescents (12 years and older), for the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long acting $\beta 2$ adrenoceptor agonist) is appropriate:

Patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short acting $\beta 2$ adrenoceptor agonists.

Or

Patients already adequately controlled on both inhaled corticosteroids and long acting $\beta 2$ adrenoceptor agonists.

Chronic Obstructive Pulmonary Disease (COPD)

Symbicort Turbuhaler 160/4.5 mcg/dose is indicated in adults, aged 18 years and older, for the Symptomatic treatment of patients with COPD with forced expiratory volume in 1 second (FEV1) < 70% predicted normal (post-bronchodilator) and an exacerbation history despite regular bronchodilator therapy

320/9 mcg/dose

Symbicort Turbuhaler 320/9 mcg/dose is indicated in adults and adolescents, age 12 -17 for the regular treatment of asthma where use of a combination (inhaled corticosteroid and long acting $\beta 2$ adrenoceptoragonist) is appropriate:

-Patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short acting $\beta 2$ adrenoceptor-agonists.

Or

- Patients already adequately controlled on both inhaled corticosteroids and long acting $\beta 2$ adrenoceptoragonists.

Chronic Obstructive Pulmonary Disease (COPD)

Symbicort Turbuhaler 320/9 mcg/dose is indicated in adults, aged 18 years and older, for the symptomatic treatment of patients with COPD with forced expiratory volume in 1 second (FEV1) < 70% predicted normal (post-bronchodilator) and an exacerbation history despite regular bronchodilator therapy

חברת אסטרזהניקה ישראל מבקשת להודיע על עדכון העלונים בהתאם להוראות משרד הבריאות בתאריך מאי 2021

העדכונים המהותיים בעלון לרופא הם:

4.8 Undesirable effects

...

Respiratory, thoracic and mediastinal disorders	Common	Mild irritation in the throat, coughing, dysphonia including hoarseness
	Rare	Bronchospasm

הוספת טקסט מהותי מסומנת בקו תחתון. מחיקת טקסט מסומנת בקו חוצה.
העלונים מפורסמים במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום.

בכבוד רב,

שרית רוזן

רוקחת ממונה

אסטרזהניקה (ישראל) בע"מ

אסטרזהניקה (ישראל) בע"מ, ת.ד. 8044, כפר סבא 4464301

טלפון 073-2226099 פקס 09-7406527