



## הנדון: ונטולין דיסקוס Ventolin Diskus

רופא/ה נכבד/ה  
רוקח/ת נכבד/ה,

חברת גלקסוסמיתקליין ישראל בע"מ (GSK) מבקשת להודיע על עדכון העלון של התכשיר **Ventolin Diskus** בהודעה זו כלולים השינויים המהותיים בעלון לרופא. בעלון ישנם שינויים נוספים.

מרכיב פעיל וחוזקו:

Salbutamol (as sulfate) – 200 mcg/dose

התוויה הרשומה לתכשיר בישראל:

Relief of bronchospasm in bronchial asthma of all types, chronic, bronchitis and emphysema.

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא: 

### 4.4 Special warnings and precautions for use

Bronchodilators should not be the only or main treatment in patients with severe or unstable asthma. Severe asthma requires regular medical assessment, including lung-function testing, as patients are at risk of severe attacks and even death. Physicians should consider using the maximum recommended dose of inhaled corticosteroid and/or oral corticosteroid therapy in these patients.

The dosage or frequency of administration should only be increased on medical advice.

Increasing use of bronchodilators, in particular short-acting inhaled  $\beta_2$ -agonists to relieve symptoms, indicates deterioration of asthma control. - Under these conditions, the patient's therapy plan should be reassessed.

Sudden and progressive deterioration in asthma control is potentially life-threatening and consideration should be given to starting or increasing corticosteroid therapy. In patients considered at risk, daily peak flow monitoring may be instituted.

The patient should be instructed to seek medical advice if short-acting relief bronchodilator treatment becomes less effective, or more inhalations than usual are required. In this situation the patient should be assessed and consideration given to the need for increased anti-inflammatory therapy (e.g. higher doses of inhaled corticosteroid or a course of oral corticosteroid).

Severe exacerbations of asthma must be treated in the normal way.

Cardiovascular effects may be seen with sympathomimetic drugs, including salbutamol. There is some evidence from post-marketing data and published literature of rare occurrences of myocardial ischaemia associated with salbutamol. Patients with underlying severe heart disease (e.g. ischaemic heart disease, arrhythmia or severe heart failure) who are receiving salbutamol should be warned to seek medical advice if they experience chest pain or other symptoms of worsening heart disease. Attention should be paid to assessment of symptoms such as dyspnoea and chest pain, as they may be of either respiratory or cardiac origin.

Salbutamol should be administered cautiously to patients suffering from thyrotoxicosis.

Increasing use of  $\beta_2$ -agonists may be a sign of worsening asthma. Under these conditions a reassessment of the patient's therapy plan may be required and concomitant glucocorticosteroid therapy should be considered.

As there may be adverse effects associated with excessive dosing, the dosage or frequency of administration should only be increased on medical advice.

העלונים לרופא ולצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:  
25 פתח תקוה בטלפון: 03-9297100. <https://data.health.gov.il/drugs/index.html#/byDrug> וניתן לקבלם מודפסים על-ידי פניה לחברת גלקסוסמיתקליין רח' בזל

בברכה,  
טניה רשקובן  
רוקחת ממונה