אוגוסט 2022

הנדון: ונטולין זריקות
Ventolin Injection

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

חברת גלקסוסמיתקליין ישראל בע"מ (GSK) מבקשת להודיע על עדכון העלון לרופא של התכשיר **Ventolin Injection.**

לשימת לבכם, חלו שינויים רבים בעלון, על כן חשוב לקרוא את העלון מתחילתו ועד סופו.
עדכון העלון כלל בין היתר אימוץ נוסח עלון הייחוס – UK והסרת כל המידע הנוגע לתכשיר Ventolin Infusion, שרישומו בישראל בוטל.

בהודעה זו כלולים השינויים המהותיים בעלון בלבד.

מרכיב פעיל וחוזקו:

Salbutamol (as sulfate) – 0.5 mg/ml

התוויה הרשומה לתכשיר בישראל:

Ventolin Injection in indicated for relief of severe bronchospasm associated with asthma and bronchitis status asthmaticus.

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא :

4.1. Therapeutic Indications

~~Salbutamol BP is a beta-adrenergic stimulant that has a selective action on the beta2-adrenoceptors in the bronchi and uterus and much less action on the beta1-adrenoceptors in the heart.~~

~~Salbutamol parenteral preparations are indicated for two distinct clinical situations under the direction of a physician:~~

~~1. For the relief of severe bronchospasm associated with asthma or bronchitis and for the management of status asthmaticus.~~

~~2. For the management of premature labour uncomplicated by conditions such as placenta praevia, ante-partum haemorrhage or toxaemia of pregnancy, in the last trimester of pregnancy.~~

Ventolin Injection is indicated for relief of severe bronchospasm associated with asthma and bronchitis status asthmaticus.

4.4. Special Warnings and Special 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.

Patients being treated with Ventolin Injection may also be receiving short-acting inhaled bronchodilators to relieve symptoms. Increasing use of bronchodilators, in particular short-acting inhaled β_2-agonists to relieve symptoms, indicates deterioration of asthma control.

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).

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As maternal pulmonary oedema has been reported during or following management of premature labour* with β_2-agonists, careful attention should be given to fluid balance and cardio-respiratory function should be monitored. If signs of pulmonary oedema develop, discontinuation of treatment should be considered (see section 4.8).

Ventolin Injection is not indicated for the management of pre-term labour.

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4.6. Pregnancy and Lactation

Pregnancy

Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

As with the majority of drugs, there is little published evidence of the safety of salbutamol in the early stages of human pregnancy, but in animal studies there was evidence of some harmful effects on the foetus at very high dose levels.

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4.8. Undesirable Effects

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Respiratory, thoracic and mediastinal disorders

Uncommon: Pulmonary oedema.

In the management of pre-term labour**, Ventolin Injection has uncommonly been associated with pulmonary oedema. Patients with predisposing factors including multiple pregnancies, fluid overload, maternal infection and pre-eclampsia may have an increased risk of developing pulmonary oedema.

**Ventolin Injection is not indicated for the management of pre-term labour.

4.9. Overdose

The most common signs and symptoms of overdose with salbutamol are transient beta agonist pharmacologically mediated events, including tachycardia, tremor, hyperactivity and metabolic effects including hypokalaemia and lactic acidosis (see sections 4.4 and 4.8).

Hypokalaemia may occur following overdose with salbutamol. Serum potassium levels should be monitored.

Lactic acidosis has been reported in association with high therapeutic doses as well as overdoses of short-acting beta-agonist therapy, therefore monitoring for elevated serum lactate and consequent metabolic acidosis (particularly if there is persistence or worsening of tachypnea despite resolution of other signs of bronchospasm such as wheezing) may be indicated in the setting of overdose.

Nausea, vomiting and hyperglycaemia have been reported, predominantly in children and when salbutamol overdose has been taken via the oral route.

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

מקרא לעדכונים המסומנים :
מידע שהוסר – מסומן בקו אדום חוצה ~~XXX~~
תוספת – כתב **כחול**
תוספת החמרה - כתב **כחול** – מסומן בצהוב מרקר
טקסט שאומץ מעלון ייחוס, אך מהווה החמרה - כתב שחור – מסומן בצהוב מרקר

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

בברכה,
טניה רשקובן
רוקחת ממונה