



מאי 2019

רופא/ה, רוקח/ת נכבד/ה,

חברת טבע מבקשת להודיע על עדכון מידע המפורט להלן:

Atropine Teva 1mg/ml

אטרופין טבע 1 מ"ג/מ"ל

Solution for I.M. or I.V. Injection

תמיסה להזרקה לתוך השריר או לתוך הווריד

כל אמפולה של 1 מ"ל מכילה: Atropine sulfate 1mg

עדכוני רישום ועדכון עלון

התוויה כפי שאושרה בתעודת הרישום:

Preanesthetic medication to decrease excessive salivation and secretions of the respiratory tract.
Treatment of sinus bradycardia, particularly if complicated by hypotension.
Antidote in poisoning by organophosphorus.

עיקר העדכונים:

- שינוי בשמו של התכשיר מ- Atropine Sulfate ל- Atropine Teva 1mg/ml
- עדכון ההתוויה להתוויה כמפורט לעיל
- שינוי בכמות באריזה במקום אריזות של 5 ו-100 אמפולות, לאריזות של 10 אמפולות

העלון לרופא עודכן. בפירוט שלהלן כלולים העדכונים העיקריים בלבד. תוספות מידע מסומנות בצהוב:

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Preanesthetic medication to decrease excessive salivation and secretions of the respiratory tract.
Treatment of sinus bradycardia, particularly if complicated by hypotension.
Antidote in poisoning by organophosphorus.

4.2 Posology and method of administration

Preanesthetic medication

Adults: The recommended dose is 0.3-0.6 mg by intravenous injection immediately before the anesthesia induction or by intramuscular injection 30-60 minutes before the induction.

Children: The recommended dose is 0.02 mg/kg (maximum dose 0.6 mg).

טבע תעשיות פרמצבטיות בע"מ

רח' התאנה 1, פארק תעשייה חמ"ן ת.ד. 975, שוהם 6085001 | טל: 972-3-6864000 | www.tevapharm.com



Treatment of sinus bradycardia

The recommended dose is between 0.3 and 1.0 mg intravenously.

Antidote in poisoning by organophosphorus

Adults: The recommended dose is 2 mg (intramuscularly or intravenously, taking into account the severity of the poisoning) every 5-10 minutes, until the skin becomes red and dry, the pupils dilate and tachycardia appears.

Children: The recommended dose is 0.02 mg/kg.

[...]

4.4 Special warnings and precautions for administration

The solution should be clear, colorless and free of visible particles.

The ampoule is for a single, uninterrupted administration and any unused residual solution should be discarded.

Precautions must be taken in geriatric patients for whom you may need a dose adjustment for a possible occurrence of adverse events related to the cardiovascular system and the central nervous system.

Use with caution in patients with ileostomy or colostomy; the occurrence of diarrhea may indicate an incomplete intestinal obstruction. Use with caution in cases of myasthenia gravis, hyperthyroidism, coronary artery disease, acute myocardial ischemia, tachycardia, tachyarrhythmia, prostatic hypertrophy and other obstructive uropathies.

Important information about some of the excipients:

This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Contraindicated associations

Derivatives of Belladonna: increase of the anticholinergic activity.

Halothane: attenuation of the depressor effect on the heart rate.

Procainamide: increased vagal effects at atrioventricular level.

Methacholine: inhibition of the bronchoconstriction induced by methacholine inhalation.

[...]

4.8 Undesirable effects

Below are the side effects of atropine organized according to the MedDRA system organ classification. There are insufficient data to determine the frequency of the single effects listed.

Endocrine disorders

Change in the levels of the growth hormone.

Metabolism and nutrition disorders

Porphyria, hyperthermia, hypothermia.

Nervous system disorders

Sedation, disorientation, dizziness, impaired short-term memory, psychosis.

Eye disorders

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Diplopia, disturbances in accommodation, mydriasis, changes in intraocular pressure.

[...]

4.9 Overdose

Symptoms

In case of an overdose of the drug, you may have the intensification of the side effects described. In particular, dryness of mucous membranes, dilated pupils, tachycardia, fever and skin rash are possible; neurological symptoms such as confusion, hallucinations, etc., that can persist for 48 hours or more, can also be observed. In some cases respiratory depression, coma, circulatory collapse and death can be observed.

Treatment

At the first signs, in the case of respiratory depression, it is recommended to administer oxygen and, in the case of a persistence of seizures, if the circulatory conditions permit it, proceed with an intravenous administration of **short-acting barbiturates** (e.g. thiopental) or benzodiazepines (e.g. diazepam). Since atropine is excreted through the kidneys, an intravenous administration of fluids is recommended. In cases of delirium and coma, the administration of physostigmine by a slow intravenous infusion at a dose range of 1 to 4 mg (0.5 to 1 mg in children) is recommended.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות

וניתן לקבלו מודפס ע"י פניה לחברת טבע. <http://www.health.gov.il>

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