אפריל 2019

רופא/ה, רוקח/ת נכבד/ה ,

חברת טבע מודיעה שמשרד הבריאות אישר עדכונים בעלון לרופא וכן עלון חדש לצרכן לתכשיר:

Papaverine Teva Injection 40 mg/2 ml

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

פאפאוורין טבע להזרקה 40 מ"ג/ 2 מ"ל

תמיסה להזרקה לתוך השריר או לתוך הוריד

כל אמפולה של 2 מ"ל מכילה: Papaverine hydrochloride 40 mg

התוויה כפי שאושרה בתעודת הרישום:

Antispasmodic in visceral spasm, e.g. gastrointestinal colic, biliary and urinary tract spasms.
Peripheral vascular disease with vasospastic element.
Vascular spasm associated with acute myocardial infarction, angina pectoris, peripheral and pulmonary embolism.

עלון לרופא

בפירוט שלהלן כלולים והעדכונים העיקריים בלבד (תוספות מסומנות בצהוב):

4.3 Contraindications

- Hypersensitivity to papaverine or any of the other ingredients mentioned in section 6.1.
- Intravenous injection: contraindicated in patients with complete atrioventricular block.
- Severe heart failure.
- Recent myocardial infarction.
- Recent heart attack.
- Heart rhythm disorders (bradycardia).
- In case of intracranial hypertension.
- Hepatic disease.

4.4 Special warnings and precautions for use

- A too rapid intravenous injection may lead to arrhythmias and fatal apnea.
- Due to the risk of heart rhythm disorders, caution should be exercised in cases of cardiac conduction disorders or unstable cardiovascular diseases.
- Administration of papaverine should be discontinued if symptoms of hepatotoxicity occur.
- Liver and blood tests should be regularly monitored in patients on chronic papaverine treatment.
- Papaverine should be administered with caution to patients with decreased gastrointestinal motility as they are more exposed to digestive disorders.
- Intravenous injection is not recommended for children under 15 years of age.

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

4.5 Interaction with other medicinal products and other forms of interaction

Papaverine reduces the therapeutic effect of levodopa (antiparkinsonian agent).
If papaverine is given while being treated with calcium antagonists, it is possible that they may increase the effect of papaverine.
Due to its weak antiarrhythmic properties, papaverine may increase the effects of similar medicinal products such as hypotensive agents.
Nicotine can reduce or even abolish the vasodilator effects of papaverine.
The effects of papaverine may be slightly potentiated by concomitant use of central nervous system depressants and a synergistic effect may be expected when combined with morphine.

4.8 Undesirable effects

The adverse effects of papaverine described in the literature are listed below and classified by system organ class and frequency. The frequencies are defined as follows: very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1,000, <1/100); rare (≥1/10,000, <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data).

Table: Known side effects

System organ class	Undesirable effects	Frequency
Nervous system disorders (Autonomic Nervous System)	increased depth of breathing, depression, dizziness, lightheadedness, headache, drowsiness, sedation, lassitude, alertness disorder, malaise, weakness and lethargy.	Rare
Cardiac disorders	increased heart rate, arrhythmias (too rapid injection or injection of too high doses), atrioventricular block, tachycardia	Rare

Vascular disorders	hypotension or increased blood pressure	Rare
Gastrointestinal disorders*	constipation, nausea, diarrhea, abdominal distress and anorexia, vomiting	Rare
Skin and subcutaneous disorders	pruritus, rash,	Rare
Hepatobiliary disorders	Hepatotoxicity: Hepatitis and increased hepatic enzymes (alkaline phosphatase, SGOT) suggesting hepatotoxicity.	Not known
General disorders and administration site conditions	Hypersensitivity reactions	Very rare
	General discomfort, redness in the face, sweating, dry mouth and throat	Rare
	Thrombosis at the injection site.	Not known

* subjects with bowel movement disorders are more easily exposed to digestive disorders.

עלון לצרכן

העלון לצרכן רצ"ב.

העלון לצרכן והעלון לרופא נשלחו לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות

http://www.health.gov.il, וניתן לקבלם מודפסים ע"י פניה לחברת טבע.