



אוגוסט 2023

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רופא/ה, רוקח/ת נכבד/ה,

הנדון: עדכון עלון לרופא של אפדרין סינטטיקה 50 מ"ג/מ"ל

EPHEDRIN SINTETICA 50 MG/ML

אנו מבקשים להודיעכם כי העלון לרופא של התכשיר שבנדון עודכן. עדכון העלון כולל החמרות.

ההתוויה המאושרת:

Ephedrine Hydrochloride is used in the prevention and treatment of hypotension from spinal or epidural anaesthesia and during general anaesthesia, with or without a reduction in the heart rate, administered for a surgical or obstetric procedure.

הרכב וחוזק חומר פעיל:

EPHEDRINE HYDROCHLORIDE 50 MG/ML

בפירוט שלהלן מובא המידע בו בוצעו שינויים מהותיים בלבד.
תוספת טקסט או טקסט בעל שינוי משמעותי מסומן בצבע. מחיקת טקסט מסומנת בקו חוצה.

העדכונים בעלון לרופא נעשו בסעיפים הבאים:

4.3 Contraindications

Ephedrine should not be used in case of:

- Hyperexcitability, phaeochromocytoma, ~~arteriosclerosis and aneurism.~~

4.4. Special warnings and precautions for use

Special warnings

- ~~Coronary heart disease and chronic heart diseases,~~



Great care is also needed in patients with cardiovascular disease such as ischaemic heart disease, arrhythmia or tachycardia, occlusive vascular disorders including arteriosclerosis, or aneurysms. Angina pain may be precipitated in patients with angina pectoris.

Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Patients with impaired circulation of the cerebrum and autonomic dysfunction should be treated with special caution.

4.5 Interaction with other medicinal products and other forms of interaction

Contraindicated combinations

+ ~~alpha- and beta-adrenergic blocking agents (phentolamine): reduce the vasopressor effect of ephedrine.~~

Combinations not recommended

+ Selective MAO-A inhibitors (moclobemide, toloxatone): Risk of vasoconstriction and/or episodes of hypertension.

+ Linezolid: Risk of vasoconstriction and/or episodes of hypertension.

+ Ergot alkaloids: Risk of vasoconstriction and/or episodes of hypertension.

Combinations requiring precautions for use

+ Alpha- and beta-adrenergic blocking agents: Alpha blockers (e.g. phentolamine) reduce the vasopressor effect of ephedrine. Beta blockers may inhibit the cardiac and bronchodilator effects of ephedrine.

+ Corticosteroid: Ephedrine has been shown to increase the clearance of dexamethasone. ~~s.~~

+ Antiepileptics: increased plasma concentration of phenytoin and possibly of phenobarbitone and primidone.

+ Clonidine, atropine: augment the pressor effect of ephedrine.

+ Oxytocin and oxytocic drugs: serious postpartum hypertension has been described in patients who received both a vasopressor (i.e., methoxamine, phenylephrine, ephedrine) and an oxytocic (i.e., methylergonovine, ergonovine). Some of these patients experienced a stroke.

+ Cardiac glycosides: ephedrine with a cardiac glycoside, such as digitalis, may increase the possibility of arrhythmias.

+ Aminophylline or other xanthines, diuretic therapy: concomitant administration may result in hypokalaemia ~~Alcohol.~~



4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of ephedrine in pregnant women.

~~Teratogenicity studies in animals have shown reproductive toxicity (see section 5.3) demonstrated that ephedrine could cause cardiovascular defects, reduction in fertility, foetal loss and midline wall defects.~~

The use of ephedrine in pregnancy should be avoided as ephedrine crossed the placenta and this has been associated with an increase in fetal heart rate and beat-to-beat variability.

4.8 Undesirable effects

Frequency	Very common (≥1/10)	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Very rare (<1/10,000)	Not known
Organ system						
Blood and lymphatic system disorders		changes in primary haemostasis				changes in primary haemostasis
Immune system disorders		hypersensitivity reactions				hypersensitivity
Skin and subcutaneous tissue disorders						Skin rash

בנוסף, עודכן המידע הפרמקולוגי בסעיף 5.

העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות <http://www.health.gov.il>. ניתן לקבלם מודפסים על ידי פניה לחברת כצט בע"מ, רח' החרש 4 הוד השרון, 1-700-500-220

בברכה,
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