



אוגוסט 2023

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רופא/ה, רוקח/ת נכבד/ה,

הנדון: עדכון עלון לרופא של אדרנלין סינטטיקה 1 מ"ג/מ"ל

ADRENALINE SINTETICA 1 MG/ML

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

ההתוויה המאושרת:

ADRENALINE SINTETICA 1 MG/ML is indicated in the following situations:

- Spasm of the airways in acute asthma attacks.
- Rapid relief of allergic reactions to drugs or other substances.
- Emergency treatment of anaphylactic shock.
- Cardiac arrest and cardiopulmonary resuscitation (physical measures should be used first).

הרכב וחוזק חומר פעיל:

EPINEPHRINE 1 MG / 1 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:

Contraindications

- Adrenaline should not be used during labour or **with local anaesthesia of peripheral structures including digits, ear lobe.**
- **Use in the presence of ventricular fibrillation.**

Special warnings and precautions for use

Adrenaline should only be administered with great caution in:

elderly patients, **patients with hyperthyroidism**, diabetes mellitus, phaeochromocytoma, narrow angle



glaucoma, hypokalaemia, hypercalcaemia, severe renal impairment and prostatic adenoma leading to residual urine, cerebrovascular disease, organic brain damage, in patients with shock (other than anaphylactic shock) and in organic heart disease or cardiac dilatation (severe angina pectoris, obstructive cardiomyopathy, hypertension) as well as most patients with arrhythmias. Anginal pain maybe induced when coronary insufficiency is present.

Prolonged administration may induce metabolic acidosis, renal necrosis and adrenaline-fastness or tachyphylaxis.

Adrenaline should not be used during the second stage of labour (See Section 4.6). Accidental intravascular injection may result in cerebral haemorrhage due to the sudden rise in blood pressure.

Monitor the patient as soon as possible (pulse, blood pressure, ECG, pulse oximetry) in order to assess the response to adrenaline.

Interaction with other medicinal products and other forms of interaction

Sympathomimetic agents/ oxytocin:

Adrenaline should not be administered concomitantly with oxytocin or other sympathomimetic agents because of the possibility of additive effects and increased toxicity.

Alpha-adrenergic blocking agents:

Alpha-blockers such as phentolamine antagonise the vasoconstriction and hypertension effects of adrenaline. This effect may be beneficial in adrenaline overdose (see Section 4.9).

Phenothiazines:

Phenothiazines block alpha-adrenergic receptors. Adrenaline should not be used to counteract circulatory collapse or hypotension caused by phenothiazines since a reversal of the pressor effects of Adrenaline may result in further lowering of blood pressure.

Other drugs:

Adrenaline should not be used in patients receiving high dosage of other drugs (e.g. cardiac glycosides) that can sensitise the heart to arrhythmias. Some antihistamines (e.g. diphenhydramine) and thyroid hormones may potentiate the effects of Adrenaline, especially on heart rhythm and rate.

Undesirable effects

System organ class	Frequency	Undesirable effects
Immune System Disorders	Not known	Anaphylaxis, possibly with severe bronchospasm (see Section 4.4)
Metabolism and nutrition disorders	Not known	Hypokalaemia Metabolic acidosis Inhibition of insulin secretion (even with low doses) Hyperglycaemia (even with low doses) Gluconeogenesis Glycolysis Lipolysis Ketogenesis
Psychiatric disorders	Not known	Psychotic states Anxiety Fear Confusional state



		Irritability Insomnia
Nervous system disorders	Not known	Headache Dizziness Tremor Restlessness
Cardiac disorders	Not known	Disturbances of cardiac rhythm and rate Palpitation Tachycardia Chest pain/ angina potentially fatal ventricular arrhythmias Fibrillation Stress cardiomyopathy (such as Takotsubo syndrome) Decrease in T-wave amplitude
Vascular disorders	Not known	Hypertension (with risk of cerebral haemorrhage) Coldness of extremities
Respiratory disorders	Not known	Dyspnoea Pulmonary oedema
Gastrointestinal disorders	Not known	Dry mouth Reduced appetite Nausea Vomiting hypersalivation
Renal and urinary disorders	Not known	Difficulty in micturition Urinary retention
General disorders and administration site conditions	Not known	Sweating Weakness

In patients with Parkinsonian Syndrome, Adrenaline increases rigidity and tremor. Subarachnoid haemorrhage and hemiplegia have resulted from hypertension, even following subcutaneous administration of usual doses of Adrenaline.

Repeated injections of Adrenaline can cause necrosis as a result of vascular constriction at the injection site. Tissue necrosis may also occur in the extremities, kidneys and liver.

Overdose

Possible signs of overdosage include restlessness, confusion, pallor, tachycardia, bradycardia, cardiac arrhythmias and cardiac arrest.

בנוסף, עודכן המידע הפרמקולוגי בסעיף 5.

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

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