

# הודעה על החמרה (מידע בטיחות) בעלון לרופא

תאריך \_\_\_\_\_ December 26, 2012 \_\_\_\_\_

שם תכשיר באנגלית \_\_ ADRENALINE INJECTION 1mg/1ml \_\_

מספר רישום 027 62 21638 21\_\_

שם בעל הרישום Teva Pharmaceutical Industries Ltd. ,P.O. Box 3190 Petach Tikva.

## פרטים על השינויים המבוקשים

טקסט חדש	טקסט נוכחי	פרק בעלון
<p>(see also Precautions)</p> <p>Use with caution in patients with ventricular fibrillation, prefibrillatory rhythm, tachycardia, myocardial infarction, phenothiazine induced circulatory collapse and prostatic hypertrophy (1).</p> <p>Adrenaline is ordinarily administered with extreme caution to patients who have a heart disease. Use of adrenaline with drugs that may sensitise the heart to arrhythmias, e.g., digitalis, mercurial diuretics, or quinidine, ordinarily is not recommended. Anginal pain may be induced by adrenaline in patients with coronary insufficiency (3).</p> <p>Administer slowly with caution to elderly patients and to patients with hypertension, diabetes mellitus, hyperthyroidism and psychoneurosis. Use with extreme caution in patients with long-standing bronchial asthma and emphysema who have developed degenerative heart disease (1, 2) (see also Contraindications) .</p> <p>Adrenaline may delay the second stage of labour by inhibiting contractions of the uterus (1).</p> <p>Syncope has occurred following administration to asthmatic children (1).</p> <p>In patients with Parkinsonian syndrome the drug increases rigidity and tremor. Intra-arterial administration should be avoided since marked vasoconstriction may result in gangrene (1).</p> <p>Intramuscular injection into the buttocks should be avoided as gas gangrene is a possibility (1).</p> <p>Accidental injection into the hands or feet may result in loss of blood flow to the affected area and should be avoided. If there is an accidental injection into these areas, advise the patient to go immediately to the nearest emergency room or hospital casualty department for treatment (3).</p> <p>Local ischaemic necrosis can occur from repeated injections in one site (1).</p>		<p><b>Warnings</b></p>
		<p><b>Precautions</b></p>
<p>Known hypersensitivity to adrenaline or to any other ingredient of the preparation, or known hypersensitivity to sympathetic amines (1). Narrow-angle glaucoma.</p>		<p><b>Contraindications</b></p>

<p>Shock.</p> <p>Adrenaline should not be used in most patients with arrhythmias and cerebral arteriosclerosis, where vasopressor drugs may be contraindicated e.g., in thyrotoxicosis, in obstetrics when maternal blood pressure is in excess of 130/80 (1).</p> <p>During general anesthesia with halogenated hydrocarbons or cyclopropane.</p> <p>Individuals with organic brain damage.</p> <p>In labor, because it may delay the second stage.</p> <p>Cardiac dilatation.</p> <p>Coronary insufficiency.</p> <p>Adrenaline is contraindicated with local anesthesia of certain areas e.g. fingers and toes, because of the danger of vasoconstriction producing sloughing of tissue.</p> <p>The following contraindications should be considered: Hyperthyroidism, hypertension, ischaemic heart disease, diabetes mellitus, (1)</p>		
<p>The potentially severe adverse reactions of adrenaline arise from its effect upon blood pressure and cardiac rhythm. Ventricular fibrillation may occur and severe hypertension may lead to cerebral hemorrhage and pulmonary edema. Symptomatic adverse reactions are anxiety, dyspnea, restlessness, palpitations, tachycardia, sweating, nausea and vomiting, respiratory difficulty, pallor, apprehension, nervousness, anxiety (3), sleeplessness, hallucinations (1), flushing or redness of face and skin (1), tremor, weakness, dizziness, headache and cold extremities, especially in hyperthyroid individuals. Biochemical effects include inhibition of insulin secretion, and stimulation of growth hormone secretion, hyperglycemia (2) hypoglycemia (even with low doses), gluconeogenesis, glycolysis, lipolysis and ketogenesis.</p> <p>Psychomotor agitation, disorientation, impaired memory and psychosis may occur (1)</p> <p>Cardiac arrhythmias may follow administration of adrenaline (3).</p> <p>Accidental injection into hands or fingers resulting in peripheral ischaemia has been reported. Patients may need treatment following accidental injection (3) (see also Warnings)</p>	<p>The potentially severe adverse reactions of adrenaline arise from its effect upon blood pressure and cardiac rhythm. Ventricular fibrillation may occur and severe hypertension may lead to cerebral hemorrhage and pulmonary edema. Symptomatic adverse reactions are anxiety, dyspnea, restlessness, palpitations, tachycardia,, tremor, weakness, dizziness, headache and cold extremities, especially in hyperthyroid individuals. Biochemical effects include inhibition of insulin secretion, and hypoglycemia (even with low doses), gluconeogenesis, glycolysis, lipolysis and ketogenesis.</p>	<p><b>Adverse events</b></p>
<p>Adrenaline should not be administered with other sympathomimetic agents because of the danger of additive effects and increased toxicity (1).</p> <p>The effects of adrenaline may be potentiated by tricyclic antidepressants, certain antihistamines (e.g. diphenhydramine, tripeleminamine and d-chlorpheniramine) and sodium L-thyroxine.</p> <p>Volatile liquid anaesthetics such as halothane increase the risk of adrenaline-induced ventricular arrhythmias and acute pulmonary oedema if hypoxia is present (2).</p> <p>Rapidly-acting vasodilators such as nitrites or <math>\alpha</math>-blocking agents, or alpha-adrenergic blocking drugs (3) may counteract the pressor effects of adrenaline.</p> <p>The vasoconstrictor and pressor effects of adrenaline, mediated by its alpha-adrenergic action, may be enhanced by concomitant administration of drugs with similar effects, such as ergot alkaloids or oxytocin. Adrenaline specifically reverses the antihypertensive effects of adrenergic neurone blockers such as guanethidine with the risk of</p>	<p>The effects of adrenaline may be potentiated by tricyclic antidepressants, certain antihistamines (e.g. diphenhydramine, tripeleminamine and d-chlorpheniramine) and sodium L-thyroxine.</p> <p>Rapidly-acting vasodilators such as nitrites or <math>\alpha</math>-blocking agents, or may counteract the pressor effects of adrenaline.</p> <p>The vasoconstrictor and pressor effects of adrenaline, mediated by its alpha-adrenergic action, may be enhanced by concomitant</p>	<p><b>Drug Interactions</b></p>

<p>severe hypertension (2). adrenaline.</p> <p>Patients on monoamine oxidase inhibitors should not receive sympathomimetic treatment (1).</p> <p>The risk of cardiac arrhythmias is higher when adrenaline is given to patients receiving digoxin or quinidine. Use of adrenaline with excessive dosage of digitalis, mercurial diuretics and other drugs that sensitize the heart to arrhythmias is not recommended.</p> <p>Adrenaline inhibits the secretion of insulin, thus increasing the blood glucose level. It may be necessary for diabetic patients receiving adrenaline to increase their dosage of insulin or oral hypoglycaemic drugs (3).</p> <p>Patients on monoamine oxidase inhibitors should not receive sympathomimetic treatment (1).</p> <p>The risk of cardiac arrhythmias is higher when adrenaline is given to patients receiving digoxin or quinidine. Use of adrenaline with excessive dosage of digitalis, mercurial diuretics and other drugs that sensitize the heart to arrhythmias is not recommended.</p> <p>Adrenaline inhibits the secretion of insulin, thus increasing the blood glucose level. It may be necessary for diabetic patients receiving adrenaline to increase their dosage of insulin or oral hypoglycaemic drugs (3).</p> <p><del>Adrenaline-induced hypoglycemia may lead to loss of blood-sugar control in diabetic patients treated with hypoglycemic agents.</del></p> <p>The patient's ability to drive and use machines may be affected by the anaphylactic reaction as well as by possible adverse reactions to adrenaline (3).</p>	<p>administration of drugs with similar effects, such as ergot alkaloids or oxytocin. Adrenaline specifically reverses the antihypertensive effects of adrenergic neurone blockers such as guanethidine with the risk of severe hypertension (2). adrenaline.</p> <p>The risk of cardiac arrhythmias is higher when adrenaline is given to patients receiving digoxin or quinidine. Use of adrenaline with excessive dosage of digitalis, mercurial diuretics and other drugs that sensitize the heart to arrhythmias is not recommended.</p> <p>The risk of cardiac arrhythmias is higher when adrenaline is given to patients receiving digoxin or quinidine. Use of adrenaline with excessive dosage of digitalis, mercurial diuretics and other drugs that sensitize the heart to arrhythmias is not recommended.</p> <p>Adrenaline-induced hypoglycemia may lead to loss of blood-sugar control in diabetic patients treated with hypoglycemic agents.</p>	
<p>Overdose or inadvertent intravascular injection of adrenaline may cause cerebral haemorrhage resulting from a sharp rise in blood pressure. Fatalities may also result from pulmonary oedema because of peripheral vascular constriction together with cardiac stimulation (3).</p> <p><i>Treatment</i></p> <p>Combined <math>\alpha</math> and <math>\beta</math>-adrenergic blocking agents (such as labetalol) may counteract the effects of adrenaline, or a <math>\beta</math>-blocking agent may be used to treat any supraventricular arrhythmias, and phentolamine to control the <math>\alpha</math>-mediated effects on the peripheral circulation. Rapidly acting vasodilators such as nitrates and sodium nitroprusside may also be helpful. If prolonged hypotension follows such measures, it may be necessary to administer another pressor drug, such as levarterenol (3).</p> <p>Adrenaline overdose can also cause transient bradycardia followed by tachycardia, and these may be accompanied by potentially fatal cardiac arrhythmias. Treatment of arrhythmias may consist of administration of beta-adrenergic blocking drugs (3).</p> <p>Immediate resuscitation support must be available.</p>	<p><i>Treatment</i></p> <p>Combined <math>\alpha</math> and <math>\beta</math>-adrenergic blocking agents (such as labetalol) may counteract the effects of adrenaline, or a <math>\beta</math>-blocking agent may be used to treat any supraventricular arrhythmias, and phentolamine to control the <math>\alpha</math>-mediated effects on the peripheral circulation. Rapidly acting vasodilators such as nitrates and sodium nitroprusside may also be helpful</p> <p>Immediate resuscitation support must be available.</p>	<p><b>Overdosage</b></p>

