Adrenalin® (epinephrine injection)

1. INDICATIONS AND USAGE
Adrenalin® is indicated for a single dose of 1 mL and a multiple dose of 3 mL for immediate intravenous and intramuscular use.

Emergency treatment of allergic reactions (Type I) including anaphylaxis, which may present with one or more of the following: angioedema, urticaria, bronchospasm, hypotension, lightheadedness, laryngeal edema, palpitations, anxiety, tremor, and syncope. Adrenalin® should be used as an adjunct to, and not a substitute for, first aid or other measures required to control the allergic reaction.

Adrenalin® is indicated in the treatment of pheochromocytoma, acute asthma, and pruritus. Adrenalin® should be used as an adjunct to and not a substitute for, other measures required to control the disease.

Adrenalin® is indicated in the treatment of a wide variety of other conditions.

2. DOSAGE AND ADMINISTRATION
Injection into the anterolateral aspect of the thigh, up to a maximum of 0.5 mg (0.5 mL) per injection, of undiluted Adrenalin® administered intramuscularly or subcutaneously is recommended.

3. WARNINGS AND PRECAUTIONS

3.1 Cardiac Disease
Adrenalin® should be administered cautiously to patients with cardiac disease, particularly in patients with coronary artery disease, congestive heart failure, cardiomyopathy, or who are on medications that may increase the risk of cardiac adverse effects.

3.2 Hypertension
Adrenalin® should be administered cautiously to patients with hypertension.

3.3 Diabetes
Adrenalin® should be administered cautiously to patients with diabetes.

4. ADVERSE REACTIONS
Adrenalin® may cause transient increases in blood sugar.

5. DRUG INTERACTIONS
Epinephrine may potentiate the effects of tricyclic antidepressants, beta-adrenergic blocking drugs, and certain antihistamines.

6. CONTRAINDICATIONS
Adrenalin® is contraindicated in patients with known hypersensitivity to epinephrine.

7. PATIENT COUNSELING INFORMATION

7.1 Injection Site
Use an alternate site for subsequent injections if the injection site shows signs of irritation.

7.2 Pregnancy
Adrenalin® should be administered cautiously to women during pregnancy.

7.3 Breastfeeding
Adrenalin® is not recommended for use during breastfeeding.

7.4 Children
Adrenalin® should be administered cautiously to children, particularly those with cardiac disease.

7.5 Geriatric Use
Adrenalin® should be administered cautiously to elderly patients, particularly those with cardiac disease.

7.6 Renal or hepatic impairment
Adrenalin® should be administered cautiously to patients with renal or hepatic impairment.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
Adrenalin® should be administered cautiously to pregnant women, particularly those with cardiac disease.

8.2 Lactation
Adrenalin® should be administered cautiously to women who are breastfeeding.

8.3 Children
Adrenalin® should be administered cautiously to children, particularly those with cardiac disease.

8.4 Geriatric Use
Adrenalin® should be administered cautiously to elderly patients, particularly those with cardiac disease.

8.5 Pediatric Use
Adrenalin® should be administered cautiously to children, particularly those with cardiac disease.

8.6妇用
Adrenalin® should be administered cautiously to women, particularly those with cardiac disease.

8.7 Nursing
Adrenalin® should be administered cautiously to women, particularly those with cardiac disease.

9. PATIENT COUNSELING INFORMATION

9.1 Injection Site
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9.2 Pregnancy
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9.3 Breastfeeding
Adrenalin® is not recommended for use during breastfeeding.

9.4 Children
Adrenalin® should be administered cautiously to children, particularly those with cardiac disease.

9.5 Geriatric Use
Adrenalin® should be administered cautiously to elderly patients, particularly those with cardiac disease.

9.6 Renal or hepatic impairment
Adrenalin® should be administered cautiously to patients with renal or hepatic impairment.

10. OVERDOSAGE
Adrenalin® should be administered cautiously to patients with cardiac disease, particularly in patients with cardiac disease, congestive heart failure, cardiomyopathy, or who are on medications that may increase the risk of cardiac adverse effects.

11. CLINICAL PHARMACOLOGY

11.1 Pharmacokinetics
Adrenalin® is rapidly absorbed after intramuscular or subcutaneous administration.

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13. NONCLINICAL TOXICOLOGY

13.1 Mutagenesis, Impairment of Fertility
Adrenalin® is not associated with mutagenic or teratogenic effects.

14. USE IN SPECIFIC POPULATIONS

14.1 Pregnancy
Adrenalin® should be administered cautiously to women during pregnancy.

14.2 Nursing
Adrenalin® should be administered cautiously to women who are breastfeeding.

14.3 Children
Adrenalin® should be administered cautiously to children, particularly those with cardiac disease.

14.4 Geriatric Use
Adrenalin® should be administered cautiously to elderly patients, particularly those with cardiac disease.

14.5 Renal or hepatic impairment
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15. ADVERSE REACTIONS

15.1 Injection Site
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15.2 Pregnancy
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15.3 Breastfeeding
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16. HOW SUPPLIED/STORAGE

16.1 HOW SUPPLIED/STORAGE
Adrenalin® is supplied in a 1 mL and a multiple dose of 3 mL for intravenous and intramuscular use.

16.2 STABILITY
Adrenalin® should be stored at room temperature and is stable for at least 1 year.

17. PATIENT CONSENT

17.1 PATIENT CONSENT
Patients should be informed of the potential side effects of Adrenalin®.

18. ORTHOPEDIC/ARThROSCOPIc USE
Adrenalin® should be administered cautiously to patients undergoing orthopedic or arthroscopic procedures.

19. OTHER USES
Adrenalin® should be administered cautiously to other uses, particularly in patients with cardiac disease, congestive heart failure, cardiomyopathy, or who are on medications that may increase the risk of cardiac adverse effects.

20. PATIENT COUNSELING INFORMATION

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Epinephrine is a sympathomimetic catecholamine. The chemical name of epinephrine is: 1,2-Benzenediol, 4-[(1R)-1-hydroxy-2-(methylamino)ethyl]-, or -[2-(methylamino)ethyl]benzyl alcohol. α-epinephrine is: 1,2-Benzenediol, 4-[1-hydroxy-2-(methylamino)ethyl]-, or -[2-(methylamino)ethyl]benzyl alcohol.

Epinephrine acts on both alpha and beta-adrenergic receptors.

Epinephrine causes vasoconstriction, decreased uterine blood flow, and fetal anoxia. The potential for epinephrine to impair reproductive performance has not been evaluated, but epinephrine has been shown to decrease implantation in female rats following oral administration. In pregnant rabbits dosed subcutaneously with 1.2 mg/kg/day (15-fold the highest human dose), epinephrine has been shown to decrease implantation in female rabbits. Epinephrine has been shown to decrease implantation in female rabbits following oral administration.

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Epinephrine overdose can also cause transient bradycardia followed by tachycardia. The heart rate may be depressed by beta-blockers, and it may be necessary to administer an arteriovenous blocking agent and a pressor drug.

Overdosage may also cause transient bradycardia followed by tachycardia in the absence of signs of impending cardiac arrest. Epinephrine has been shown to produce a dose-dependent increase in heart rate and blood pressure. In addition, it has been shown to produce a dose-dependent increase in systolic blood pressure and diastolic blood pressure. Overdosage may be associated with vasodilation, decreased uterine blood flow, and fetal anoxia. The potential for epinephrine to impair reproductive performance has not been evaluated, but epinephrine has been shown to decrease implantation in female rabbits following oral administration.

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