DOSEAGE AND ADMINISTRATION

The physician who prescribes Adrenaclick® should review this Prescribing Information insert in detail with the patient. This review should include the proper use of Adrenaclick to ensure that subcutaneous or intramuscular injections are given into the anterolateral aspect of the thigh, through clothing if necessary. The accompanying Patient Information Leaflet and Wrap Label should also be reviewed with the patient.

Adrenaclick is capable of delivering one dose of either 0.15 mg or 0.3 mg (0.15 mL or 0.3 mL) of epinephrine. This dose is available for auto-injection by the patient.

Selection of the appropriate Adrenaclick dosage strength is determined according to patient body weight.

Adrenaclick 0.15 mg  For use by patients who weigh 15 - 30 kilograms (approximately 33 - 66 pounds)

Adrenaclick 0.3 mg For use by patients who weigh 30 kilograms (approximately 66 pounds) or greater

The usual dose of epinephrine for allergic emergencies in patients who weigh 30 kilograms or greater is 0.3 mg (0.3 mL) of epinephrine.

Since the doses of epinephrine delivered from Adrenaclick are fixed, the physician should consider other forms of injectable epinephrine if doses lower than those available from Adrenaclick are felt to be necessary. The prescribing physician should carefully assess each patient to determine the most appropriate dose of epinephrine, recognizing the life-threatening nature of the reactions for which this drug is being prescribed.

Patients should be instructed to periodically visually inspect the epinephrine solution for particulate matter and discoloration. If the solution contains particulate matter or develops a pinkish color or becomes darker than slightly yellow, the patient should immediately contact their physician for a replacement, since these changes indicate that the effectiveness of the drug product may be decreased.

HOW SUPPLIED

Adrenaclick is a patient (or caregiver) actuated product that contains 1.1 mL of epinephrine injection, USP (1 mg/mL), of which one dose can be delivered by auto-injection. THE REMAINING VOLUME THAT IS LEFT AFTER THIS FIXED DOSE CANNOT BE FURTHER ADMINISTERED AND SHOULD BE DISCARDED WITH THE DEVICE AS OUTLINED IN THE PATIENT INFORMATION LEAFLET.

Adrenaclick 0.15 mg is available in a Two-Pack carton, NDC 52054-803-02, containing two Adrenaclick 0.15 mg auto-injectors.

Adrenaclick 0.3 mg is available in a Two-Pack carton, NDC 52054-804-02, containing two Adrenaclick 0.3 mg auto-injectors.

PROTECT FROM LIGHT. STORE AT ROOM TEMPERATURE, 20°-25°C (68°-77°F) WITH EXCURSIONS PERMITTED TO 15°-30°C (59°-86°F). PROTECT FROM FREEZING. DO NOT REFRIGERATE.

Rx only.

DESCRIPTION

Adrenaclick® auto-injector contains 1.1 mL epinephrine injection, USP (1 mg/mL), from which one dose of either 0.15 mg (0.15 mL) or 0.3 mg (0.3 mL) each is available for use by injection. The dose is administered by auto-injection after the patient prepares and fires Adrenaclick® as directed. The remaining volume is not available for use and should be discarded. See PATIENT DIRECTIONS FOR USE on the accompanying Patient Information Leaflet.

This single, available dose of epinephrine injection, USP contains either 0.15 mg or 0.3 mg l-epinephrine, sodium chloride, chlorobutanol and sodium bisulfite, all sealed under nitrogen.

Epinephrine is a sympathomimetic catecholamine. Its naturally occurring l-isomer, which is twenty times as active as the d-isomer, is obtained in pure form by separation from the synthetically produced racemate.

Chemically, epinephrine is 1-(3,4-dihydroxyphenyl)-2-(methylamino)ethanol with the following structure:

![Epinephrine structure]

Epinephrine deteriorates rapidly on exposure to air or light, turning pink from oxidation to adrenochrome and brown from the formation of melanin. Epinephrine solutions that show evidence of discoloration should be discarded.

Adrenaclick contains no latex.

CLINICAL PHARMACOLOGY

Epinephrine is the drug of choice for the emergency treatment of severe allergic reactions (Type I) to allergens, such as those present in certain insect venoms, foods, or drugs. It can also be used in the treatment of anaphylaxis of unknown cause (idiopathic anaphylaxis) or exercise-induced anaphylaxis. Epinephrine, when given intramuscularly or subcutaneously, has a rapid onset and short duration of action. Epinephrine acts on both alpha and beta adrenergic receptors. Through its action on alpha adrenergic receptors, epinephrine lessens the vasodilation and increased vascular permeability that occurs during an anaphylactic reaction and can lead to loss of intravascular fluid volume and hypotension. Through its action on beta adrenergic receptors, epinephrine causes bronchial smooth muscle relaxation that helps alleviate bronchospasm, wheezing, and dyspnea that may occur during anaphylaxis. Epinephrine also helps alleviate pruritus, urticaria, and angioedema, and may be effective in relieving gastrointestinal and genitourinary symptoms of anaphylaxis because of its relaxing effects on the smooth muscle of the stomach, intestine, uterus and urinary bladder.

INDICATIONS AND USAGE

Adrenaclick (epinephrine injection, USP) is indicated in the emergency treatment of severe allergic reactions (Type I) including anaphylaxis to stingling insects (e.g. order Hymenoptera, which includes bees, wasps, hornets, yellow jackets and fire ants), and biting insects (e.g. triatomia, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g. radiocontrast media), and other allergens, as well as anaphylaxis to unknown substances (idiopathic anaphylaxis) or exercise-induced anaphylaxis. Adrenaclick is intended for immediate administration in patients with a history of anaphylactic reactions. Selection of the appropriate dosage strength is determined according to patient body weight (See DOSAGE AND ADMINISTRATION section).

Such reactions may occur within minutes after exposure and consist of flushing, apprehension, syncope, tachycardia, thready or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal spasm, pruritus, rashes, urticaria, or angioedema. Adrenaclick is designed as emergency supportive therapy only and is not a replacement or substitute for immediate medical care.
CONTRAINDICATIONS

There are no absolute contraindications to the use of epinephrine in a life-threatening allergic reaction.

WARNINGS

Adrenaclick should only be injected into the anterolateral aspect of the thigh. Accidental injection into the hands or feet may result in loss of blood flow to the affected area and should be avoided. DO NOT INJECT INTO BUTTOCK. If there is an accidental injection into these areas, advise the patient to inform the healthcare provider of the accidental injection when he/she goes to the nearest emergency room for further treatment of anaphylaxis.

Avoid possible inadvertent intravascular administration. Large doses or accidental intravenous injection of epinephrine may result in cerebral hemorrhage due to a sharp rise in blood pressure. DO NOT INJECT INTRAVENOUSLY. Rapidly acting vasoconstrictors can counteract the marked pressor effects of epinephrine if there is such inadvertent administration.

Epinephrine is the preferred treatment for serious allergic reactions or other emergency situations even though this product contains sodium bisulfite, a sulfite that may, in other products, cause allergic-type reactions including anaphylactic symptoms or life-threatening or less severe asthmatic episodes in certain susceptible persons. The alternatives to using epinephrine in a life-threatening situation may not be satisfactory. The presence of a sulfite in this product should not deter administration of the drug for treatment of serious allergic or other emergency situations, even if the patient is sulfite-sensitive.

Epinephrine should be administered with caution to patients with cardiac arrhythmias, coronary artery or organic heart disease, or hypertension. In patients with coronary insufficiency or ischemic heart disease, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias. It should be recognized that the presence of these conditions is not a contraindication to epinephrine administration in an acute, life-threatening situation.

Epinephrine is light sensitive and should be stored in the carrying-case provided. Store at room temperature (20°-25°C/68°-77°F) with excursions permitted to 15°-30°C (59°-86°F). Do not refrigerate; protect from freezing. Patients should periodically check the solution in Adrenaclick for any discoloration and/or precipitates. If the solution is discolored or contains a precipitate, the patient should replace their Adrenaclick.

ADVERSE REACTIONS

Epinephrine is rapidly inactivated in the body, and treatment following overdose with epinephrine is primarily supportive. If necessary, pressor effects may be counteracted by rapidly acting vasoconstrictors or alpha-adrenergic blocking drugs. If prolonged hypertension follows such measures, it may be necessary to administer another pressor drug.

Overdosage of epinephrine may produce extremely elevated arterial pressure, which may result in cerebrovascular hemorrhage, particularly in elderly patients.

If an epinephrine overdose induces pulmonary edema that interferes with respiration, treatment consists of a rapidly acting alpha-adrenergic blocking drug and/or respiratory support.

Epinephrine overdose can also cause transient bradycardia followed by tachycardia, and these may be accompanied by potentially fatal cardiac arrhythmias. Premature ventricular contractions may appear within one minute after injection and may be followed by multiform ventricular tachycardia (pre-fibrillation rhythm). Subsidence of the ventricular effects may be followed by atrial tachycardia and occasionally by atrioventricular block. Treatment of arrhythmias consists of administration of a beta-adrenergic blocking drug such as propranolol.

Overdose sometimes results in extreme pallor and coldness of the skin, metabolic acidosis, and kidney failure. Suitable corrective measures must be taken in such situations.