EDELINE INJECTION 30MG/ML

DESCRIPTION: A clear and colourless solution.

COMPOSITION: Each ml contains Ephedrine Hydrochloride 30mg.

PHARMACODYNAMICS: Ephedrine is a sympathomimetic which stimulates both alpha and beta adrenergic receptors, and also releases noradrenaline from storage site. The main effects of therapeutic doses of ephedrine are relaxation of bronchial smooth muscle, cardiac stimulation and increased systolic and usually diastolic blood pressure via an increase in cardiac output and peripheral vasoconstriction. Ephedrine also decreases intestinal tone and motility, relaxes the bladder wall, contracts the sphincter muscle, relaxes the detrusor muscle, and decreases uterine activity. Ephedrine also has central nervous system stimulant effects. Tachyphylaxis to the effects of ephedrine may also occur after use for a short while possibly due to the depletion of catecholamine stores.

PHARMACOKINETICS: Ephedrine is rapidly absorbed after intramuscular or subcutaneous administration. The onset of action after intramuscular administration is 10-20 minutes, and the duration of pressor and cardiac responses to ephedrine is 1 hour after intravenous administration of 10-25 mg or intramuscular or subcutaneous administration of 25-50mg. Small quantities of Ephedrine are metabolised in the liver, but the majority of ephedrine is excreted unchanged in the urine. The plasma half-life of ephedrine is 3-6 hours. Elimination of ephedrine is increased (and hence the half-life is decreased) with decreasing pH of the urine. Ephedrine is presumed to cross the placenta, and to be excreted into breast milk.

INDICATION: Treatment of bronchial spasm in asthma, adjunct to correct haemodynamic imbalances and treat hypotension in epidural and spinal anaesthesia.

RECOMMENDED DOSAGE: Ephedrine Hydrochloride Injection is administered by the intramuscular, subcutaneous or intravenous route. When administered intravenously, the injection should be given slowly. Care should be taken to avoid extravasation, since this may result in tissue necrosis and sloughing. Ephedrine Hydrochloride should be administered in the lowest effective dose. The parenteral adult dose should not exceed 150mg in 24 hours.
If ephedrine is administered parenterally to relieve severe, acute bronchospasm, the smallest effective dose (usually 12.5 to 25 mg) should be given. Further dosage should be determined by patient response.

As a pressor:

Adult dose: The usual adult dose is 25-50mg (range 10-50 mg) administered intramuscularly or subcutaneously. Additional dose should be based on patient response. The intravenous route may be used if an immediate response is required. The dosage for the intravenous route is 10-25mg which may be repeated every 5-10 minutes until the desired response is obtained.

Paediatric dose: The recommended paediatric dose is 3mg/kg/day or 100mg/m^2/day via the intravenous or subcutaneous route, given in 4-6 divided doses. During therapy with pressor agent, blood pressure should be elevated to slightly less than the patient's normal blood pressure. In previously normotensive patients, systolic blood pressure should be maintained at 80-100 mm Hg. In previously hypertensive patients, systolic blood pressure should be maintained at 30-40 mm Hg below their usual blood pressure. In some patients with very severe hypotension, maintenance of even lower blood pressure may be desirable if blood or fluid volume replacement has not been completed.

ROUTE OF ADMINISTRATION: Intramuscular, subcutaneous or intravenous administration.

CONTRAINDICATIONS:

1) Ephedrine HCl Injection is contraindicated in closed angle glaucoma, since ephedrine may exacerbate the condition.
2) Ephedrine HCl is contraindicated in patients with pheochromocytoma, since severe hypertension may result.
3) Ephedrine HCl is contraindicated in patients with asymmetric septal hypertrophy (idiopathic hypertrophic subaortic stenosis) since the obstruction may increase as myocardial contractility improves.
4) Ephedrine HCl is contraindicated in patients undergoing therapy with monoamine oxidase inhibitors (MAO inhibitors), or within 14 days of ceasing such therapy, since MAO inhibitors may prolong and intensify the cardiac and pressor effects of ephedrine.
5) Ephedrine HCl is contraindicated in patients undergoing general anaesthesia with cyclopropane or halothane or other halogenated hydrocarbons, since anaesthesia may increase cardiac irritability which may lead to arrhythmias.
6) Ephedrine HCl is contraindicated in patients with tachyarrhythmias or ventricular fibrillation, since exacerbation of these conditions may occur.
7) Ephedrine HCl is also contraindicated in patients with hypersensitivity to ephedrine and in patients with psychoneurosis.

WARNINGS & PRECAUTIONS: The use of ephedrine as a pressor agent is not a substitute for replacement of blood, plasma, fluids and/or electrolytes. Blood volume depletion should be corrected as fully as possible before ephedrine therapy is instituted. In an emergency, ephedrine may be used as an adjunct to fluid volume replacement or as a temporary supportive measure to maintain coronary and cerebral artery perfusion until volume replacement therapy can be completed, but ephedrine must not be used as sole therapy in hypovolemic patients.
Ephedrine may deplete noradrenaline stores in sympathetic nerve endings resulting in reduced cardiac and pressor effects of the drug. Consequently, it may be necessary to administer noradrenaline to replace tissue stores for restoration of the pressor effects of ephedrine.
Prolonged administration of pressor agents has been associated with oedema, haemorrhage, focal myocarditis, sub pericardial haemorrhage, necrosis of the intestine and hepatic and renal necrosis. Since these effects have generally been observed in patients with severe shock and it is not clear if the drug or the shock state itself was responsible, they should therefore be taken into consideration before Ephedrine HCl is used.
Hypoxia, hypercapnia and acidosis may also reduce the effectiveness or increase the incidence of adverse effects of ephedrine, and should be identified and corrected prior to or concurrently with administration of the drug.
Ephedrine HCl should be used with caution, if at all, in patients with hypertension or hyperthyroidism, since there is an increased risk of adverse effects in these patients.
Ephedrine HCl should also be used with caution in geriatric males, especially those with prostatic hypertrophy, since ephedrine may cause acute urinary retention.
Ephedrine HCl should also be used with caution in diabetic patients since drug induced hyperglycaemia may result in loss of diabetic control.
Ephedrine HCl should also be used with caution in patients with cardiovascular disease including angina, cardiac arrhythmia and coronary insufficiency, since the cardiovascular effects of ephedrine may exacerbate these conditions. Ephedrine may intensify the ischaemia in myocardial infarction by increasing myocardial oxygen demands.
Patients Monitoring: Cardiovascular parameters, including blood pressure, ECG, cardiac output, central venous pressure and pulmonary artery pressure should be monitored during therapy with ephedrine. Urinary output should also be monitored.

INTERACTION WITH OTHER MEDICAMENTS:

α-blockers: α-blockers may decrease the vasopressor effect of ephedrine.
Atropine sulfate: Atropine sulfate may increase the vasopressor effect of ephedrine.
β-blockers: β-blockers may inhibit the cardiac and bronchodilator effects of ephedrine.
Cardiac glycosides: Concurrent use of cardiac glycosides and ephedrine may increase the risk of arrhythmias.
Ergotamine, ergometrine, methylergometrine, oxytocin: Concurrent use of these drugs with Ephedrine HCl may result in a potentiation of the pressor effect of ephedrine. Concurrent use of ergotamine and Ephedrine HCl may also produce peripheral vascular ischemia and gangrene.

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Guanethidine: Ephedrine HCl may decrease the antihypertensive effect of guanethidine.
Hydrocarbon inhalation anaesthetics, such as cyclopropane, halothane: These drugs may increase cardiac irritability, and concurrent use with Ephedrine HCl may lead to increased risk of arrhythmia.
Methyldopa: Concurrent use of methyldopa with Ephedrine HCl may result in a reduced pressor effect.
Monoamine Oxidase (MAO) Inhibitors: Concurrent use of MAO inhibitors and Ephedrine HCl may result in potentiation of the cardiac and pressor effects of ephedrine.
Reserpine: Concurrent use of reserpine with Ephedrine HCl may result in a reduced pressor effect.
Sympathomimetic Agents: Concurrent use of Ephedrine HCl and other sympathomimetics may result in increased cardiovascular and pressor effects and an increased risk of adverse effects.
Tricyclic antidepressants: Concurrent use of tricyclic antidepressant and ephedrine may result in potentiation of the cardiovascular and pressor effects of ephedrine.
Clonidine: Pre-treatment with clonidine may increase the pressor effect of ephedrine.
Urinary Alkalinizers, such as acetazolamide, dichlorphenamide, sodium bicarbonate and sodium citrate: These drugs may increase the half-life and decrease the elimination of ephedrine leading to enhanced therapeutic or toxic effects of ephedrine.
Theophylline: Concurrent use of ephedrine and theophylline may result in an increased incidence of adverse effects than when either drug is used alone. Adverse effects include those in the central nervous and the gastrointestinal systems.

USE IN PREGNANCY & LACTATION:

Use in Pregnancy: Ephedrine HCl Injection may accelerate the foetal heart rate when used to control maternal hypotension during spinal anaesthesia for delivery. Ephedrine HCl Injection should not be used if the maternal blood pressure is greater than 130/80 Hg.
Use in Lactation: Ephedrine HCl is distributed into breast milk, and therefore Ephedrine HCl Injection is not recommended for use during lactation because of the risk of adverse effects in the infant.

SIDE EFFECTS:

Body as a whole: pallor, fever, headache, dryness of nose, mouth and throat.
Ephedrine is reported to cause physical addiction after excessive long term use. Addiction is more likely to occur after oral use, since intramuscular, subcutaneous or intravenous administration of ephedrine would not normally occur over long periods.
Cardiovascular system: angina, palpitations, bradycardia, tachycardia, hypertension, hypotension, extrasystole and pericardial pain. Arrhythmias, including ventricular fibrillation, may occur, especially in patients with organic heart disease or those receiving other drugs that sensitise the heart to arrhythmias.
Digestive system: nausea, vomiting, mild epigastric distress.
Nervous system: nervousness, anxiety, restlessness, insomnia, mood or mental changes, fear, irritability, trembling. Large doses may cause dizziness, light headedness, vertigo**,** confusion, delirium, euphoria. Long-term therapy in large doses may lead to psychosis characterized by paranoia, hallucinations, depression and bizarre mentation.
Genito-urinary system: difficult or painful urination, acute urinary retention (especially with prostatic hypertrophy).
Respiratory system: shortness of breath, respiratory difficulty, dyspnoea.
Skin and appendages: sweating.

SYMPTOMS AND TREATMENT OF OVERDOSE:

Symptoms
In the event of overdose, the occurrence of nausea, vomiting, fever, paranoid psychosis, ventricular and supraventricular arrhythmias, hypertension, respiratory depression, convulsions and coma is observed.
The lethal dose in humans is approximately 2 g corresponding to blood concentrations of approximately 3.5 to 20 mg/l.
Treatment
The treatment of ephedrine overdose with this product may require intensive supportive treatment. Slow intravenous injection of labetalol 50-200 mg may be given with electrocardiograph monitoring for the treatment of supraventricular tachycardia. Marked hypokalaemia (<2.8 mmol/l) due to compartmental shift of potassium predisposes to cardiac arrhythmias and may be corrected by infusing potassium chloride in addition to propranolol and correcting respiratory alkalosis, when present. A benzodiazepine and/or a neuroleptic agent may be required to control CNS stimulant effects.
For severe hypertension, parenteral antihypertensive options include intravenous nitrates, calcium channel blockers, sodium nitroprusside, labetalol or phentolamine. The choice of antihypertensive drug is dependent on availability, concomitant conditions and the clinical status of the patient.

INCOMPATIBILITIES: In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

STORAGE CONDITIONS: Store below 30ºC. Protect from light. KEEP OUT OF REACH OF CHILDREN. *JAUHKAN DARIPADA KANAK-KANAK*.

SHELF LIFE: Please refer to outer package.

PACK SIZE: Pack in 10 ampoules of 1 ml in a box, 100 ampoules of 1 ml in a box.

PRODUCT REGISTRATION HOLDER & MANUFACTURER:

DUOPHARMA (M) SDN BHD
Lot 2599, Jalan Seruling 59 Kawasan 3,
Taman Klang Jaya, 41200 Klang, Selangor, MALAYSIA.

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