For the only use of Registered medical Practitioner, Laboratory & Hospital

AMERICAN

Phenylcan 10

Injection

Composition: For I.M./I.V. use only

Each ml contains:

Phenylephrine Hydrochloride I.P. 10 mg

Sterile Water for Injection I.P. q.s.

Phenylephrine 10 mg/ml Injection

Phenylephrine Hydrochloride

Phenylephrine Injection is a sterile solution of Phenylephrine Hydrochloride in purified water.

Phenylephrine is a sympathomimetic agent with mainly direct effects on adrenergic receptors. It has predominantly alpha-adrenergic activity and is without significant stimulating effects on the central nervous system at usual doses. After injection, it produces peripheral vasoconstriction and an increase in arterial pressure. It also produces reflex bradycardia.

Indications

Phenylephrine Injection is indicated in adults and children to treat hypotensive states, for example circulatory failure during spinal anaesthesia, or drug induced hypotension.

Contraindications, Warnings, etc.

Phenylephrine Injection is contraindicated in the presence of severe hypertension and hyperthyroidism. It should not be given to patients being treated with monoamine oxidase inhibitors, nor within two weeks of stopping such treatment. Extreme caution is required in patients with pre-existing cardiovascular disease, such as ischaemic heart disease, arrhythmias and occlusive vascular disease. Anginal pain may be precipitated in patients with angina pectoris. Care is also required in patients with diabetes mellitus or closed angle glaucoma. Use of Phenylephrine Injection in patients with shallow anterior chamber, a history of acute narrow angle glaucoma and/or insufficient pupil dilation can increase the risk of both iridocele and floppy iris syndrome. Avoid in patients with prostatic enlargement.

Interactions

Phenylephrine may interact with cyclopropane, halothane and other halogenated inhalational anaesthetics to induce ventricular fibrillation. There may be an increased risk of arrhythmias with concomitant use of cardiac glycosides, quinidine and tricyclic antidepressants. Phenylephrine, by increasing the blood pressure, may reverse the effect of many antihypertensives. Interactions of phenylephrine with alpha receptor agonists/antagonists and beta receptor blocking drugs may be complex. Caution should be applied when administering atomoxetine concurrently, as there is potential for synergistic pharmacological effects. Severe hypertension may occur following the use of phenylephrine and atropine or other antimuscarinics. The pressor effects of phenylephrine may be slightly reduced by lithium carbonate. The effects of phenylephrine may be potentiated by the use of monoamine oxidase inhibitors or reversible inhibitors of monoamine oxidase.

Use in Pregnancy and Lactation

The safety of phenylephrine during pregnancy has not been established. Due to the vasoconstrictive properties of phenylephrine, the product should be used with caution in patients with a history of pre-eclampsia. Administration in late pregnancy or labour may cause foetal hypoxia and bradycardia.

Breast-feeding

The safety of phenylephrine during lactation has not been established. Excretion of phenylephrine in breast milk appears to be minimal.

Dosage and Administration

Adults:

By subcutaneous or intramuscular injection: 2 to 5 mg, with further doses of 1 to 10 mg if necessary, according to response.

By slow intravenous injection: 100 to 500 micrograms as a 0.1% solution, repeated as necessary after at least 15 minutes.

By intravenous infusion: 10 mg in 500 ml of glucose 5% or sodium chloride 0.9% infused initially at a rate of up to 180 micrograms per minute. This should be reduced to 30 – 60 micrograms per minute according to response.

Elderly: No special dosage reduction necessary.

Paediatric population: 100 micrograms per kilogram of body weight subcutaneously or intramuscularly.

Adverse Effects

- Immune system disorders
- Hypersensitivity
- Metabolism and nutrition disorders
- Metabolic disorders
- Psychiatric disorders
- Nervousness, insomnia
- Nervous system disorders
- Headache, cerebral haemorrhage, paraesthesia
- Eye disorders
- Mydriasis, angle-closure glaucoma
- Cardiac disorders
- Pulmonary oedema, bradycardia, tachycardia, arrhythmia, angina pectoris, palpitations, cardiac arrest
- Vascular disorders
- Hypotension, dizziness, syncope, flushing
- Respiratory, thoracic and mediastinal disorders
- Dyspnoea
- Gastrointestinal disorders
- Vomiting, salivary hypersecretion
- Renal and urinary disorders
- Dysuria, urinary retention
- General disorders and administration site conditions
- Extravasation, infusion site necrosis, hyperhidrosis
- Investigations
- Increased blood pressure, abnormal blood glucose
- Phenylephrine is without significant stimulating effects on the central nervous system at usual doses.

Treatment of Overdosage

Symptoms of overdosage include headache, vomiting, hypertension and reflex bradycardia and other cardiac arrhythmias. In severe cases confusion, hallucinations and seizures may occur. Treatment should consist of symptomatic and supportive measures. Hypertensive effects may be treated with an alpha-blocker such as phentolamine, 5 to 60 mg given intravenously over 10 to 30 minutes, repeated as necessary.

Additional information

Phenylephrine acts within 10 to 15 minutes following subcutaneous or intramuscular injection. Subcutaneous injections are effective for up to around 1 hour and intramuscular injections for up to

Storage: Store in a cool & dry place. Below 25°C., protect from light and moisture. Do not freeze.

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