SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ephedrine Hydrochloride 30 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 30 mg of Ephedrine Hydrochloride.

Excipient(s) with known effect: Also contains 35mg of Lactose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Plain, white, bi-convex tablet, free from any visible contamination.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Ephedrine tablets are indicated for the treatment or prevention of attacks of bronchospasm in asthma.

4.2 Posology and method of administration

Posology

Adults

The adult dose is 15 - 60mg three times a day depending on response.

Elderly

The elderly dosage should be substantially reduced. Initial therapy should be 50% of adult dose.

Children

For children under 1 year: Not recommended

For children 1 - 5 years: 15 mg three times a day.

For children 6 - 12 years: 30 mg three times a day.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Ischaemic heart disease

Hypertension

Thyrotoxicosis

Prostatic hypertrophy

Ephedrine has positive inotropic and chronotropic effects on the heart and its use should be avoided in patients with ischaemic heart disease.

Ephedrine increases blood pressure in man. Over the counter acquisition of sympathomimetics should always be considered in hypertensive patients whose blood pressure control has suddenly deteriorated.

Patients with hyperthyroidism may be susceptible to the effects of ephedrine. Ephedrine may precipitate acute urinary retention in patients with prostatic hypertrophy.

4.4 Special warnings and precautions for use

Ephedrine should be given with care to patients with hyperthyroidism, diabetes mellitus, angle-closure glaucoma and renal impairment.

Ephedrine has potentially life threatening effects in its acute cardiovascular and central stimulant effects.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Other adrenoceptor stimulants: Concurrent use of ephedrine with theophylline may result in increased nausea, nervousness, and insomnia.

Anaesthetics: There may be an increased risk of arrhythmias when used with volatile liquid anaesthetics.

Antidepressants: Ephedrine should not be given to patients who are being treated with monoamine oxidase inhibitors as they may cause hypertensive crisis with marked headache, severe hypertension and subarachnoid haemorrhage. Noradrenaline is displaced by ephedrine with the release of large amounts of catecholamine. The interaction may occur up to two weeks after stopping MAOI therapy. There may be an increased risk of arrhythmias when ephedrine is used with tricyclic antidepressants.

Antihypertensives: Loss of blood pressure control has been detected in hypertensive patients undergoing concurrent therapy with ephedrine and adrenergic neurone blocking drugs and may also occur with other antihypertensives.

Antimigraine drugs: Enhanced vasoconstriction and pressor effects with ergotamine or methysergide; concurrent use of ergotamine not recommended (risk of gangrene).

Cardiac glycosides: Increased risk of arrhythmias in patients receiving ephedrine and cardiac glycosides.

Corticosteroids: Ephedrine has been shown to increase the clearance and prolong the half-life of dexamethasone in asthmatic patients.

Oxytocin: Increased risk of vasoconstrictor or pressor effects in patients receiving oxytocin and ephedrine.

Urinary acidifiers/alkalinisers: Effects of ephedrine may be reduced by acidification and increased by alkalinization of the urine.

4.6 Fertility, pregnancy and lactation

The use of ephedrine in pregnancy should be avoided as ephedrine crosses the placenta and this has been associated with an increase in foetal heart rate and beat to beat variability.
Ephedrine is excreted in breast milk and therefore its use during breast feeding should be avoided.
Irritability and disturbed sleep patterns have been reported in breast fed infants.

4.7 Effects on ability to drive and use machines

No significant effects.

4.8 Undesirable effects

The most common side-effects of ephedrine are tachycardia, anxiety, restlessness, difficulty in micturition, palpitations, nausea and insomnia. Tremor, dry mouth, impaired circulation to the extremities, hypertension, headache and cardiac arrhythmias may occur. Tolerance with dependence has been reported with prolonged administration.
Myocardial infarction has occurred very rarely in patients taking ephedrine or pseudoephedrine.

Ephedrine may act as stimulant in children with nocturnal enuresis and cause sleeplessness. It may have sedative effects in some children.

The elderly are more sensitive to the cardiovascular effects of ephedrine.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

4.9 Overdose

Symptoms
The symptoms of overdose are normally seen as nausea, vomiting, hypertension, fever, palpitations, tachycardia, restlessness, respiratory depression and convulsions. Paranoid psychosis, delusions and hallucinations may also follow ephedrine overdosage.

Treatment
The treatment of overdosage is normally supportive and symptomatic. In severe overdosage the stomach should be emptied and diazepam may be required to control CNS stimulation. Specific treatment such as propranolol may also be required for cardiac arrhythmias. For marked excitement or hallucinations, chlorpromazine may be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Ephedrine hydrochloride is a sympathomimetic agent acting on adrenergic receptors. It has alpha and beta adrenergic activity and pronounced CNS stimulating activity. It raises blood pressure by stimulating increase of cardiac output and inducing peripheral vasoconstriction. It also brings about bronchodilation, relaxes intestinal tone and motility and reduces bladder activity by relaxing bladder wall whilst contracting the sphincter muscle.

5.2 Pharmacokinetic properties

Ephedrine is rapidly and completely absorbed after oral administration and extensively distributed throughout the body with accumulation in the liver, lungs, kidneys, spleen and brain.
Peak plasma concentrations are attained during therapy in 1 - 2 hours of 65-120 ug/ml, effective bronchodilator plasma levels are in the range 35-80 ug/ml.
The plasma half-life is reported to be between 3-11 hours, with up to 95% being excreted in the urine.

5.3 Preclinical safety data

Studies in mice have shown that the lethal toxicity of ephedrine is increased by elevation of body temperature.
Ephedrine induces acute locomotor stimulatory activity in rats and mice. The estimated lethal dose in children up to 2 years of age is 200mg and for adults 2g. Fatalities are rare and single doses up to 400mg have been given without serious toxic effects.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose

Potato Starch

Magnesium Stearate

Stearic Acid

6.2 Incompatibilities

Do not use if MAOIs are being used and have been given within previous 14 days.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Store in a dry place below 25°C.

6.5 Nature and contents of container

The tablets are available in Securitainers and Tampertainers in pack sizes of 500 & 1000 tablets. The containers are made up of High Density Polypropylene body and Low Density Polyethylene cap.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

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