SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ephedrine Hydrochloride 30 mg per 1 ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ephedrine Hydrochloride 3% w/v.

Each ml of Solution for Injection contains:
Ephedrine hydrochloride .....30 mg
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Clear, colorless solution for injection.
pH = 5.0 – 7.0

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Reversal of hypotension from spinal or epidural anesthesia.

4.2 Posology and method of administration

Posology

Adults and the elderly
Up to 30 mg in increments of 3 - 7.5 mg.
After the development of hypotension, by slow intravenous administration.

Pediatric Population
0.5 - 0.75 mg / kg body weight or 17 - 25 mg / m^2 body surface. After the development of hypotension, by slow intravenous administration.

4.3 Contraindications

Hypersensitivity to Ephedrine Hydrochloride or to any of the excipients listed in section 6.1
- In combination with other indirect sympathomimetic agents such as phenylpropanolamine, phenylephrine, pseudoephedrine and methylphenidate.
- In combination with alpha sympathomimetic agents.
- In combination with non-selective Monoamine Oxidase Inhibitors (MAOI) or within 14 days of their withdrawal.

4.4 Special warnings and precautions for use

Warnings

Ephedrine should be used with caution in patients who

may be particularly susceptible to their effects, particularly those with hyperthyroidism. Great care is also needed in patients with cardiovascular disease such as ischaemic heart disease, arrhythmia or tachycardia, occlusive vascular disorders including arteriosclerosis, hypertension, or aneurysms. Angina pain may be precipitated in patients with angina pectoris.

Care is also required when Ephedrine is given to patients with diabetes mellitus, closed-angle glaucoma or prostatic hypertrophy.
Ephedrine should be avoided or used with caution in patients undergoing anaesthesia with cyclopropane, halothane, or other halogenated anaesthetics, as they may induce ventricular fibrillation. An increased risk of arrhythmias may also occur if Ephedrine is given to patients receiving cardiac glycosides, quinidine, or tricyclic antidepressants.

Many sympathomimetics interact with monoamine oxidase inhibitors, and should not be given to patients receiving such treatment or within 14 days of its termination. It is advisable to avoid sympathomimetics when taking selective MAO inhibitors.

Ephedrine increases blood pressure and therefore special care is advisable in patients receiving antihypertensive therapy. Interactions of Ephedrine with alpha- and beta-blocking drugs may be complex. Propranolol and other beta- adrenoceptor blocking agents antagonise the effects of beta2 adrenoceptor stimulants (beta2 agonists) such as salbutamol.

Adverse metabolic effects of high doses of beta2 agonists may be exacerbated by concomitant administration of high doses of corticosteroids; patients should therefore be monitored carefully when the 2 forms of therapy are used together although this

precaution is not so applicable to inhaled corticotherapy. Hypokalaemia associated with high doses of beta2 agonists may result in increased susceptibility to digitalis-induced cardiac arrhythmias. Hypokalaemia may be enhanced by concomitant administration of aminophylline or other xanthines, corticosteroids, or by diuretic therapy.

Precautions for use
Ephedrine should be used with caution in patients with a history of cardiac disease.
Athletes should be informed that this preparation contains an active substance which might give a positive reaction in anti-doping tests.
Check that the solution is clear and contains no visible particles before infusion.

4.5 Interaction with other medicinal products and other forms of interaction

Contraindicated combinations:

Indirect sympathomimetic agents (phenylpropanolamine, pseudoephedrine, phenylephrine, methylphenidate)

Risk of vasoconstriction and/or of acute episodes of hypertension.

Alpha sympathomimetics (oral and/or nasal route of administration)

Risk of vasoconstriction and/or episodes of hypertension.

Non-selective MAO inhibitors

Paroxysmal hypertension, hyperthermia possibly fatal.

Combinations not recommended:

Ergot alkaloids (dopaminergic action)

Risk of vasoconstriction and/or episodes of hypertension.

Ergot alkaloids (vasoconstrictors)
Risk of vasoconstriction and/or episodes of hypertension.

Selective MAO-A inhibitors (administered concomitantly or within the last 2 weeks)

Risk of vasoconstriction and/or episodes of hypertension.

Linezolid
Risk of vasoconstriction and/or episodes of hypertension

Tricyclic antidepressants (e.g. imipramine)
Paroxysmal hypertension with possibility of arrhythmias (inhibition of adrenaline or noradrenaline entry in sympathetic fibres).

Noradrenergic-serotoninergic antidepressants
(minalcipran, venlafaxine)

Paroxysmal hypertension with possibility of arrhythmias (inhibition of adrenaline or noradrenaline entry in sympathetic fibres).

Guanethidine and related products

Substantial increase in blood pressure (hyper reactivity linked to the reduction in sympathetic tone and/or to the inhibition of adrenaline or noradrenaline entry in sympathetic fibres).
If the combination cannot be avoided, use with caution lower doses of sympathomimetic agents.

Sibutramine

Paroxysmal hypertension with possibility of arrhythmia (inhibition of adrenaline or noradrenaline entry in sympathetic fibres).

Halogenated volatile anaesthetics

Risk of perioperative hypertensive crisis and serious ventricular arrhythmias. Combinations requiring precautions for use: Theophylline

Concomitant administration of ephedrine and theophylline may result in insomnia, nervousness and gastrointestinal complaints.

Corticosteroids

Ephedrine has been shown to increase the clearance of dexamethasone.
Antiepileptics: increased plasma concentration of phenytoin and possibly of phenobarbitone and primidone.

Doxapram: risk of hypertension.
Oxytocin: hypertension with vasoconstrictor sympathomimetics.
Hypotensive agents**:** reserpine and methyldopa may reduce the vasopressor action of ephedrine.

4.6 Fertility, pregnancy and lactation

Pregnancy
Studies in animals have shown a teratogenic effect.

Clinical data from epidemiological studies on a limited number of women appear to indicate no particular effects of ephedrine with respect to malformation.

Isolated cases of maternal hypertension have been described after abuse or prolonged use of vasoconstrictor amines.

Ephedrine crosses the placenta and this has been associated with an increase in foetal heart rate and beat-to-beat variability.

Therefore, ephedrine should be avoided or used with caution, and only if necessary, during pregnancy.

Breast-feeding
Ephedrine is excreted in breast milk. Irritability and disturbed sleep patterns have been reported in breast-fed infants. There is evidence that ephedrine is eliminated within 21 to 42 hours after administration, therefore a decision needs to be made on whether to avoid ephedrine therapy or lactation should be suspended for 2 days following its administration taking into account the benefit of breastfeeding for the child and the benefit of therapy for the woman.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Very common: ≥1/10; Common: ≥1/100, <1/10;

Uncommon: ≥1/1,000,
<1/100; Rare: ≥1/10,000, <1/1,000; Very rare: <1/10,000; Not known: cannot be estimated from the available data.

Blood and lymphatic system disorders:
Not known: primary hemostasis modifications
Immune system disorders:
Not known: hypersensitivity
Psychiatric disorders:
Common: confusion, anxiety,
depression Not known:
psychotic states, fear Nervous
system disorders:
Common: nervousness, irritability, restlessness, weakness, insomnia, headache, sweating

Not known:
tremor,
hypersalivation
Eye disorders:
Not known: episodes of angle-closure glaucoma

Cardiac disorders:
Common: palpitations,
hypertension, tachycardia
Rare: cardiac arrhythmias
Not known: angina pain, reflex bradycardia, cardiac arrest, hypotension, Vascular disorders:
Not known: cerebral haemorrhage

Respiratory, thoracic and mediastinal disorders:
Common: dyspnoea
Not known: pulmonary
oedema

Gastrointestinal disorders:
Common:
nausea,
vomiting Not
known:
reduced appetite

Renal and urinary
disorders:
Rare: acute urinary retention

Investigations:
Not known: hypokalaemia, changes in blood glucose levels

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 requested to report any suspected adverse reactions via the Pharmacy and Poisons Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9. 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 50-200mg may be given with electrocardiograph monitoring for the treatment of supraventricular tachycardia. Marked hypokalaemia ($<2.8 mmol.l^{-1}$) 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Adrenergic and Dopaminergic Agent. ATC Code : C01CA26

Ephedrine is a sympathomimetic amine acting directly on the alpha and beta receptors and indirectly by increasing the release of noradrenaline by the sympathetic nerve endings. As with any sympathomimetic agent, ephedrine stimulates the central nervous system, the cardiovascular system, the respiratory system, and the sphincters of the digestive and urinary systems. Ephedrine is also a monoamine oxidase (MAO) inhibitor.

5.2 Pharmacokinetic properties

After intravenous administration, ephedrine is completely biologically available, and after oral administration, the bioavailability of ephedrine has been reported to be above 90%.

Excretion depends on urine pH:
From 73 to 99% (mean: 88%) in acidic urine,

From 22 to 35% (mean: 27%) in alkaline urine.
After oral or parenteral administration, 77% of ephedrine is excreted in unchanged form in the urine.
The half-life depends on urine pH. When the urine is acidified at pH = 5, the half-life is 3 hours; when the urine is rendered alkaline at pH = 6.3, the half- life is approximately 6 hours.

5.3 Preclinical safety data

There is no pre-clinical data of relevance to the prescriber which is additional to that already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Water for Injections

6.2 Incompatibilities

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

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25 0C, Keep in outer carton and out of reach of children

6.5 Nature and contents of container

1 ml in type 1 colourless neutral glass ampoules. Fusion sealed. Packed into cartons of 10 ampoules.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

7. MARKETING AUTHORISATION HOLDER

Macarthys Laboratories Ltd. T/A
Martindale Pharma Bampton Road,

Harold Hill, Romford, Essex, RM3 8UG
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

H2010/20871/084

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of initial Authorization: 01/04/2010

10 DATE OF REVISION OF THE TEXT

January 2026