Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Phadrin - Ephedrine Hydrochloride 30 mg in 1ml solution for injection

2. Qualitative and quantitative composition

Each 1 ml of solution for injection contains:
Ephedrine hydrochloride……30mg
For the full list of excipients, see section 6.1

3. Pharmaceutical form

Solution for injection. Clear, colourless, and free of visible particles.

4. Clinical particulars

4.1 Therapeutic indications

Reversal of hypotension from spinal or epidural anaesthesia.

4.2 Posology and method of administration

Adults and the elderly
Up to 30mg in increments of 3mg - 7.5mg.
After the development of hypotension, by slow intravenous injection.
Paediatric population
Ephedrine Hydrochloride 30mg/ml Solution for Injection is generally not recommended for use in children due
to insufficient data on efficacy, safety, and dosage recommendations.
• Children under 12 years
The safety and efficacy of Ephedrine in paediatric patients under 12 years have not been established. No data
are available.
• Children over 12 years
The posology and method of administration is the same as for adults.
Method of administration
Intravenous use.
For instructions on dilution of the medicinal product before administration, see section 6.6.

4.3 Contraindications

Ephedrine Hydrochloride 30 mg/ml Solution for Injection should not be used in case of:
• Hypersensitivity to the active substance 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

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 cortico-therapy. 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 xanthine, 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 administration

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 (milnacipran, 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 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.

Breastfeeding

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.

Fertility

No data available

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Adverse reactions reported in the following table by MedDRA System Organ Class (SOC), Preferred Term and frequency. The following frequency categories are used.

Term	Frequency of occurrence
Very common	(≥1/10)
Common	(≥1/100 to <1/10)
Uncommon	(≥1/1 000 to <1/100) (≥1/10 000 to <1/1 000) (<1/10 000)
Rare	
Very rare	
Not known	(Cannot be estimated from the available data)

System Organ Class	Frequency	Undesirable Effects
Blood and lymphatic system disorders	Not Known	Primary haemostasis 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 disorder	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

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 3.5mg/l to 20mg/l.

Treatment

The treatment of ephedrine overdose with this product may require intensive supportive treatment. Slow intravenous injection of labetalol 50mg -200mg may be given with electrocardiograph monitoring for the treatment of supraventricular tachycardia. Marked hypokalaemia (<2.8mmol/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.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Adrenergic and dopaminergic agents,
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

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.

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.

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sections of the SmPC.

6. Pharmaceutical Particulars

6.1 List of Excipients

Sodium citrate dihydrate
Citric acid
Water for Injections

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section
6.6.

6.3 Shelf-Life

2 years

6.4 Special Precautions for storage

Do not store above 30°C.
Keep the container in the outer carton in order to protect from light.
For storage conditions after dilution of the medicinal product, see section 6.3**.**

6.5 Nature and Content of container

Colourless type I glass one-point-cut (OPC) ampoules, containing 1ml of solution for injection. Packed into cartons of 5 or 10 ampoules. Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

7. Marketing Authorization Holder

Tasa Pharma Limited, Unit C1-C3,
Kay complex
Nairobi, Kenya

8. Marketing Authorization Number

H2025/CTD11317/24818

9. Date of first authorization/renewal of the authorization

8/10/2025

10. Date of revision of the text

8/10/2025