SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ephedrine Hydrochloride Tablets BP 60mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ephedrine Hydrochloride 60mg

For excipients see 6.1

3 PHARMACEUTICAL FORM

Tablet
White, circular tablets marked E60 on one face and CP on the reverse.

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

Adults		15-60mg three times daily
Children	under 1 year	not recommended
	1 - 5 years	15mg three times daily
	6 - 12 years	30mg three times daily
Elderly	Dosage should be substantially reduced. Initial therapy should be 50% of adult dose.	

4.3 Contraindications

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 lactose
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 alkalinisation of the urine

4.6 Fertility, Pregnancy and lactation

The use of ephedrine in pregnancy should be avoided as ephedrine crossed 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 lactation 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

Not applicable

4.8 Undesirable effects

The most common side-effects of ephedrine are tachycardia, anxiety, nausea, restlessness 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.

4.9 Overdose

a) 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.

b) Treatment
In severe overdosage, the stomach should be emptied by emesis and lavage. Management is by supportive symptomatic therapy.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ephedrine is a sympathomimetic agent with direct and indirect effects on adrenergic receptors.
When given by mouth in therapeutic doses, ephedrine constricts the peripheral vessels, thus increasing blood pressure. It also relaxes bronchioles.

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 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
Maize Starch
Acacia spray-dried

Stearic Acid
Magnesium Stearate

6.2 Incompatibilities

None known

6.3 Shelf life

Polypropylene and polyethylene containers - Three years.
Blister strips - Two years.

6.4 Special precautions for storage

Do not store above 25 °C.

Store in the original container in order to protect from light.

6.5 Nature and contents of container

Polypropylene or polyethylene containers with tamper evident closure. Each pack
contains 28, 30, 56, 60, 84, 90, 100, 250 or 1000 tablets.

Blister strips of 28, 30, 56, 60, 84, 90 tablets.

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Austin McNeil Ltd.,
772 Fulham Road, London,
SW6 5SJ, United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 53797/0076

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/06/1990 / 06/10/2006

10 DATE OF REVISION OF THE TEXT

15/09/2025