SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ephedrine Nasal Drops 1.0%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ephedrine Hydrochloride BP 1.0% W/V

3. PHARMACEUTICAL FORM

Nasal Drops.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the relief of nasal congestion.

4.2 Posology and method of administration

Nasal, by application to the mucous membranes.

RECOMMENDED DOSE

Instil one or two drops into each nostril.

DOSAGE SCHEDULE

As required, but not more than 4 times a day.
The above dose and schedule are recommended for adults, the elderly and children over 12 years.

4.3. Contra-indications

Ephedrine should not be given to patients who are being treated with monoamine oxidase inhibitors, or within two weeks of stopping such treatment (see section 4.5).
Ephedrine should not be taken with beta-blockers (see section 4.5)
It should be used with caution in patients receiving halogenated anaesthetics.

Ephedrine nasal drops should not be used concomitantly with other sympathomimetic decongestants.

It should also be avoided in patients with cardiovascular disease, cardiac arrhythmias, cardiomyopathy and peripheral vascular disease, hypertension, hyperthyroidism, hyperexcitability, phaeochromocytoma, closed-angle glaucoma and urinary retention.
Ephedrine nasal drops should not be used after nasal or sinus surgery.
Excessive and/or frequent use of a nasal decongestant should be avoided.

Children under 12 years of age.
Hypersensitivity to ephedrine or to any of the excipients.

4.4 Special warnings and precautions for use

Store below 25°C. Do not allow to freeze.
Keep all medicines away from children.
Warning: asthmatics should consult their doctor before using this product.
Ephedrine should be used with care in the elderly and in patients with prostatic hypertrophy, diabetes mellitus or renal impairment.
The product should not be used for longer than 7 days. Avoid contamination during use. Keep away from eyes.
10ml pack label states: do not share the drops with anyone.
10ml pack states: discard any unused drops 2 months after opening.
Do not give to children under 12 years.

4.5 Interaction with other medicinal products and other forms of interaction

Medicinal products, the use of which may be affected by ephedrine nasal drops:

MAOIs: Risk of hypertensive crisis. Sympathomimetics such as ephedrine should not be given with MAOIs or within 14 days of stopping treatment (see Section 4.3).
Anti-arrhythmics - including **beta-blockers** and **quinidine**: ephedrine may increase the risk of arrhythmias, and block the hypotensive effects of beta-blockers (see Section 4.3);
Adrenergic neurone blockers (such as guanethidine): ephedrine may block the hypotensive effects.
Cardiac glycosides (such as digoxin or digitoxin), or **tricyclic antidepressants**: ephedrine may increase the risk of arrythmias.
Ergotamine and **methysergide**: ephedrine may increase the risk of ergotism.
Oxytocin: there is increased risk of hypertension when vasoconstrictor sympathomimetics are given with oxytocin.
Doxapram: there is increased risk of hypertension when sympathomimetics are given with doxapram.

Dexamethasone: ephedrine accelerates the metabolism of dexamethasone.
MAO-B inhibitors (such as rasagiline and selegiline): risk of hypertension.
Theophylline: concomitant use with ephedrine may potentiate the adverse effects.
Volatile anaesthetics: ephedrine should be avoided in patients undergoing anaesthesia with volatile anaesthetics – risk of hazardous arrhythmias (see Section 4.3).
Thyroid hormones: Caution is required with sympathomimetics and thyroid hormones.
Appetite suppressants and amphetamine-like psychostimulants: risk of hypertension.

Medicinal products potentially affecting the activity of ephedrine:

Antihypertensives such as guanethidine, reserpine and probably methyldopa may diminish the effects of ephedrine.
Tricyclic antidepressants may reduce the effect of sympathomimetics.
Caffeine may enhance the side effects of ephedrine.
Antipsychotics may antagonise the hypertensive effects of sympathomimetics.

4.6 Pregnancy and lactation

This product should not be used in pregnancy or whilst breast feeding unless recommended by a doctor. Ephedrine crosses the placenta and has been associated with an increase in foetal heart rate. Ephedrine has been reported to cause irritability and disturbed sleep in infants when used during breast feeding.

4.7. Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

The following undesirable effects have been reported following use of ephedrine and may arise following use of ephedrine nasal drops. The frequency of adverse effects cannot be estimated from available data, but adverse effects may be minimised by avoiding prolonged or excessive use (see section 4.4).

Metabolism and nutrition disorders: Hyperglycaemia, hypokalaemia.

Psychiatric disorders: hallucinations, paranoia.

Nervous system disorders: Anxiety, restlessness, irritability, tremors, headache, tolerance, dependence, insomnia, dizziness and fainting.

Eye disorders: Mydriasis.

Cardiac disorders: Palpitations, arryhythmias.

Vascular disorders: Hypertension (vasoconstriction with hypertension), vasodilation with hypotension, flushing, impaired circulation to the extremities.

Respiratory, thoracic and mediastinal disorders: dyspnoea.

Gastrointestinal disorders: Nausea, thirst, dry mouth, anorexia, vomiting, increased salivation.

Skin & subcutaneous tissue disorders: Sweating, dermatitis, piloerection.

Musculoskeletal and connective tissue disorders: Muscular weakness.

Renal and Urinary disorders: Difficulty in micturition in patients with prostatic enlargement, urinary retention.

General disorders and administration site conditions: Local irritation, dryness, pain, rebound congestion and drug-induced rhinitis.

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

The estimated minimal lethal dose of ephedrine in children up to 2 years of age is 200mg, and for adults 2g, but fatalities due to ephedrine overdose are rare and not likely to occur following administration of the nasal drops. Single doses of up to 400mg of ephedrine have been given without serious toxic effects. In large doses ephedrine may cause giddiness, headache, nausea, vomiting, sweating, thirst, tachycardia, precordial pain, palpitations, difficulty in micturition, muscular weakness and tremors, anxiety, restlessness and insomnia. Paranoid psychosis, delusions, and hallucinations may follow overdosage. Treatment of overdosage should include supportive and symptomatic therapy. In severe cases the stomach should be emptied by aspiration and lavage. Diazepam may be given to control central nervous system stimulation.

Chlorpromazine may be given for excitement or the management of hallucinations. A beta-adrenoceptor blocking agent may be required to control cardiac arrhythmias. Acute poisoning with chlorobutanol is also highly improbable considering the concentration in the drops and the method of administration, however treatment for overdosage would be aspiration and lavage.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Ephedrine hydrochloride is applied locally to relieve congestion of mucous membranes in acute sinusitis and hay fever. It has a stimulant action on the respiratory centre. Ephedrine releases norepinephrine from storage sites in the sympathetic nerves to the effector organ. It exhibits tachyphylaxis; repeated infusions become less effective as the releasable stores of norepinephrine are depleted.

Ephedrine redistributes the blood flow and causes cardiac stimulation, without markedly raising the blood pressure.

Sympathomimetic drugs exert their effect by vasoconstriction of the mucosal blood vessels, which in turn reduces the thickness of the nasal mucosa. However, they can give rise to a rebound phenomenon as their effects wear off, due to a secondary vasodilation with a subsequent temporary increase in nasal congestion.

5.2. Pharmacokinetic properties

Ephedrine is readily and completely absorbed from the gastro-intestinal tract. It is resistant to metabolism by monoamine oxidase and is largely excreted unchanged in the urine, together with small amounts of metabolites produced by hepatic metabolism. Ephedrine has been variously reported to have a plasma half-life ranging from 3 to 6 hours depending on urinary pH; elimination is enhanced and half-life accordingly shorter in acid urine

5.3. Preclinical safety data

No data of relevance, which is additional to that included on other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Chlorobutanol BP, Sodium Chloride BP, Purified Water BP.

6.2. Incompatibilities

None known.

6.3. Shelf life

10 ml: 18 months unopened, 2 months after first opening.
500 ml: 18 months unopened.

6.4. Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

10 ml: amber glass, winchester bottle with 20mm R3 plastic wadded cap.

6.6. Instructions for use/handling

None.

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd
Linthwaite Laboratories,
Huddersfield,
HD7 5QH.

8. MARKETING AUTHORISATION NUMBER(S)

PL 00240/ 5006R

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

29.03.90 / 24.06.97

10 DATE OF REVISION OF THE TEXT

09/03/2015