Summary of Product Characteristics for Pharmaceutical Products

1. Name of the Medicinal Product.

Isoryn Pediatric Nasal Drops 0.5%

2. Qualitative and Quantitative Composition

Ephedrine Hydrochloride 0.5% W/V

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

Nasal Drops.

Clear colorless liquid without any visible impurities.

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.

Method of administration

Instill one or two drops into each nostril.

4.3 Contraindications.

Ephedrine should not be given to patients who are being treated with monoamine oxidase inhibitors, or within two weeks of stopping such treatment

Ephedrine should not be taken with beta-blockers.

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 30°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.

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.

Anti-arrhythmics - including **beta-blockers** and **quinidine**: ephedrine may increase the risk of arrhythmias, and block the hypotensive effects of beta-blockers.

Adrenergic neuron 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

anesthesia with volatile anaesthetics – risk of hazardous arrhythmias.

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 antagonize the hypertensive effects of sympathomimetics

4.6 Fertility, 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.

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 minimized by avoiding prolonged or excessive use.

Metabolism and nutrition disorders: Hyperglycemia, hypokalemia.
Psychiatric disorders: hallucinations, paranoia.
Nervous system disorders: Anxiety, restlessness, irritability, tremors, headache, tolerance, dependence, insomnia, dizziness and fainting.
Eye disorders: Mydriasis.
Cardiac disorders: Palpitations, arrhythmias.
Vascular disorders: Hypertension (vasoconstriction with hypertension), vasodilation with hypotension, flushing, impaired circulation to the extremities.
Respiratory, thoracic and mediastinal disorders: dyspnea.
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.

4.8 Reporting of suspected adverse reactions.

Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org'

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 o 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

ATC CODE R01A A 03-Decongestants and other nasal preparations for topical use.

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.

5.2 Pharmacokinetic properties.

Not applicable.

6.Pharmaceutical particulars

6.1 List of excipients

- Chlorobutanol B
- Sodium Chloride BP
- Purified Water BP

6.2 Incompatibilitie

s

Not Applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at temperature not exceeding 30°C. Protect from light. Keep the medicine out of reach of children.

7. Marketing Authorization holder And Manufacturing site Addresses

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8. Marketing authorization number(s)

H95/073

9. Date of first authorization/renewal of the authorization

15/01/2026

10. Date of revision of the text

15/01/2026