Phenylephrine **10%** w/v hydrochloride

BP Eye Drops

1. Name of the medicinal product
Phenylephrine Hydrochloride 10% w/v Ophthalmic Drops, Solution
2. Qualitative and quantitative composition
Phenylephrine Hydrochloride B.P. 10% w/v
Benzalkonium Chloride B.P. 0.01% w/v
(As a preservative)
Water for Injections B.P. q.s.
3. Pharmaceutical form
Sterile ophthalmic drop solution for single use.
4. Clinical particulars
4.1 Therapeutic indications
Phenylephrine is a direct-acting sympathomimetic agent used topically in the eye as a mydriatic. It may be indicated for pupil dilation during diagnostic or therapeutic procedures.
4.2 Posology and method of administration
Posology
Adults
Apply one drop to each eye. If necessary, this dose may be repeated only once, at least one hour after the first drop.
Pediatric and elderly populations
The use of 10% phenylephrine solution is contraindicated in these groups due to the increased risk of systemic toxicity (see section 4.3).
Method of administration
The use of a drop of topical anesthetic a few minutes prior to phenylephrine instillation is recommended to avoid a stinging sensation.
4.3 Contraindications
Patients with heart disease, hypertension, aneurysms, thyrotoxicosis, long-standing insulin-dependent diabetes mellitus, and tachycardia.
Children and the elderly, due to the increased risk of systemic toxicity.
Patients undergoing treatment with monoamine oxidase inhibitors, tricyclic antidepressants, and antihypertensive agents (including beta-blockers).
Patients with closed-angle glaucoma (unless previously treated with iridectomy) and patients with a narrow angle prone to mydriatic-induced glaucoma. Hypersensitivity to phenylephrine or to any of the excipients listed in section 6.1.
4.4 Special warnings and precautions for use
Use with caution in the presence of diabetes, cerebral arteriosclerosis, or long-standing bronchial asthma.
To reduce the risk of precipitating an attack of angle-closure glaucoma, assess the anterior chamber angle before use.
Ocular hyperemia may increase the absorption of topically administered phenylephrine.
Corneal haze may occur if 10% phenylephrine is instilled when the corneal epithelium has been denuded or damaged.
Systemic absorption can be minimized by compressing the lacrimal sac at the medial canthus for one minute during and after instillation of the drops. This blocks the passage of the drops through the nasolacrimal duct to the large absorption area of the nasal and pharyngeal mucosa.
4.5 Interaction with other medicinal products and other forms of interaction
Antihypertensive agents
Topical phenylephrine should not be used, as it may reverse the action of many antihypertensive agents, with potentially fatal consequences.
Monoamine oxidase inhibitors
There is an increased risk of adrenergic reactions when used concomitantly or within three weeks of MAOI administration.
Tricyclic antidepressants
The pressor response to adrenergic agents and the risk of cardiac arrhythmia may be potentiated in patients treated with tricyclic antidepressants (or for several days after their discontinuation).
Halothane
Due to the increased risk of ventricular fibrillation, phenylephrine should be used with caution during general anesthesia with anesthetic agents that sensitize the myocardium to sympathomimetics.
Cardiac glycosides or quinidine
There is an increased risk of arrhythmias.
4.6 Fertility, pregnancy and lactation
Safety during pregnancy and lactation has not been established. This product should only be used during pregnancy if considered essential by the physician.
4.7 Effects on ability to drive and use machines
It may cause a stinging sensation and temporary blurred vision. Advise patients not to drive or operate dangerous machinery until their vision is clear.
4.8 Undesirable effects
The frequency of undesirable effects is unknown (cannot be estimated from the available data).
Immune system disorders
Hypersensitivity
Eye disorders
Eye pain, eye irritation, blurred vision, photophobia, allergic conjunctivitis.
Cardiac disorders
Palpitations, tachycardia, extrasystoles, arrhythmias.
Coronary artery spasm, ventricular arrhythmia, and myocardial infarction. These reactions, which are sometimes fatal, generally occur in patients with pre-existing cardiovascular disease.
Vascular disorders
Hypertension
Paediatric population
Respiratory, thoracic and mediastinal disorders
Pulmonary oedema
4.9 Overdose
As a severe toxic reaction to phenylephrine is rapid in onset and short-lived, treatment is primarily supportive. Immediate injection of a rapid-acting alpha-adrenergic blocking agent, such as phentolamine (dose of 2 to 5 mg IV), is recommended.
5. Pharmacological properties
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Sympathomimetics, excluding antiglaucoma preparations.
Mechanism of action
Phenylephrine is a direct-acting sympathomimetic agent. It causes mydriasis through stimulation of alpha-receptors. There is virtually no cycloplegic effect.
Pharmacodynamic effects
Maximum mydriasis occurs within 60–90 minutes, with recovery after 5–7 hours.
The mydriatic effects of phenylephrine can be reversed with thymoxamine.
5.2 Pharmacokinetic properties
Absorption
Phenylephrine is a weak base at physiological pH. The extent of ocular penetration is determined by the condition of the cornea. A healthy cornea presents a physical barrier; furthermore, some metabolic activity may occur. If the corneal epithelium is damaged, the barrier effect and the extent of metabolism are reduced, leading to increased absorption.
5.3 Preclinical safety data
The use of phenylephrine in ophthalmology has been well established for several years. No unexpected adverse safety issues were identified during the development of the formulation.
6. Pharmaceutical particulars
6.1 List of excipients
Purified water
Sodium metabisulfite
Disodium edetate
6.2 Incompatibilities
Not applicable.
6.3 Shelf life
15 months
6.4 Special precautions for storage
Store in a cool place, protected from light.
6.5 Nature and contents of container
A sealed, conical polypropylene container fitted with a twist-and-pull cap. Each unit is packaged in an individual polypropylene/paper pouch.
6.6 Special precautions for disposal and handling
Each unit must be discarded after a single use.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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