1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

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1. NAME OF MEDICINE

EYE-GENE EYE DROPS 0,043 g per 100 ml

2. QUALITATIVE AND QUANTITAIVE COMPOSITION

Each 100 ml of EYE-GENE EYE DROPS contains 0,043 g phenylephrine hydrochloride

Preservatives:

Benzalkonium chloride 0,02 % *m/v*

Disodium edetate 0,02 % *m/v*

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops.

EYE-GENE EYE DROPS is a clear, colourless solution that is odourless or have a slight characteristic odour.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

EYE-GENE EYE DROPS is indicated as a topical ocular vasoconstrictor for the symptomatic relief of tired, red and itching eyes.

4.2. Posology and method of administration

Posology

Wipe the eyelids clean. Tip head well back and while closing the eyes, instil one to two drops of EYE-GENE EYE DROPS into the corners closest to the nose. Now open and close the eyelids several times.

Instil 1 to 2 drops every 3 to 4 hours.

Discard 30 days after first opening (see section 6.4).

Do not use continuously for longer than 7 days without consulting your doctor.

Method of administration

Eye drops.

4.3. Contraindications

EYE-GENE EYE DROPS is contraindicated in:

- Patients with hypersensitivity to phenylephrine hydrochloride or to any of the excipients in EYE-GENE EYE DROPS (see section 6.1)
- Patients with:
  - cardiac disease;
  - hypertension;
  - hyperthyroidism as tachycardia or reflex bradycardia may be induced;
  - partial heart block;
  - advanced arteriosclerosis
  - serious impairment of coronary circulation;
  - aneurysms;
  - thyrotoxicosis;
  - long-standing insulin dependent diabetes mellitus;
  - bradycardia; and

- tachycardia.

- Children under 12 years of age and elderly, because of the increased risk of systemic toxicity.
- Patients on monoamine oxidase inhibitors, tricyclic anti-depressants and anti-hypertensive agents (including beta-blockers).
- Patients with closed angle glaucoma (unless previously treated with iridectomy) and patients with a narrow angle prone to glaucoma (narrow-angle glaucoma) precipitated by mydriatics.
- Eye infection.
- Eye surgery.
- Eye injury.

4.4. Special warnings and precautions for use

If symptoms persist, consult a doctor.

Cardiovascular disorders

EYE-GEN EYE DROPS must be used with caution in patients suffering from severe ischaemic heart disease.

Fatalities have been reported in patients with pre-existing cardiovascular disease.

EYE-GENE EYE DROPS should not be used in infants, the elderly and in patients with cardiac rate or rhythm disturbances, hypertension, arteriosclerosis and tachycardia. Significant increase in blood pressure may occur.

EYE-GENE EYE DROPS should be avoided in phaeochromocytoma.

Preservative effects

Adverse effects on the corneal permeability and the danger of disruption of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride preserved ophthalmological

preparations cannot be excluded, regular ophthalmological examination is required. Caution should be exercised in the use of benzalkonium chloride preserved topical medicine over an extended period in patients with extensive ocular surface disease.

Systemic effects

Since phenylephrine is absorbed through the mucosa, systemic effects may follow after treatment with EYE-GENE EYE DROPS.

Systemic absorption may be minimised by compressing the lacrimal sac at the medial canthus for one minute during and after the instillation of the drops. This blocks the passage of the drops via the naso-lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa.

Prostate disorders

EYE-GENE EYE DROPS should be used with caution in patients with prostate disorders, who may be at increased risk of urinary retention.

Ocular effects

EYE-GENE EYE DROPS can cause intense irritation and a local anaesthetic should be instilled into the eye a few minutes beforehand.

The use of EYE-GENE EYE DROPS may liberate pigment granules from the iris, especially when given in high doses to elderly patients.

Corneal clouding may occur if corneal epithelium has been denuded or damaged.

To reduce the risk of precipitating an attack of narrow angle glaucoma evaluate the anterior chamber angle before use.

Ocular hyperaemia can increase the absorption of phenylephrine given topically.

Asthmatics

Use with caution in long standing bronchial asthma.

Paediatric population:

Use of EYE-GENE EYE DROPS in children aged below 12 years is contraindicated, since serious systemic adverse reactions have been reported with ophthalmic medicines containing phenylephrine.

Use of EYE-GENE EYE DROPS in children aged 12 to 18 years is not recommended as adequate clinical experience is missing.

4.5. Interaction with other medicines and other forms of interaction

Antihypertension medicines

EYE-GENE EYE DROPS should not be used with anti-hypertensive medicines as they may reverse the action of many of these medicines with possibly fatal consequences.

Direct-acting sympathomimetics with alpha-agonist action such as phenylephrine in EYE-GENE EYE DROPS, specifically reverse the hypotensive effect of adrenergic neurone blockers and severe hypertension may occur.

Monoamine oxidase inhibitors

Since phenylephrine is absorbed through the mucosa, interactions may also follow topical application, particularly in patients receiving a MOAI (including a RIMA) e.g. phenelzine and moclobemide.

There is an increased risk of adrenergic reactions (hypertension) when used simultaneously with, or up to three weeks after, the administration of MAOIs (see section 4.3).

Tricyclic antidepressants

Tricyclic antidepressants block the inactivation of direct-acting sympathomimetics by uptake into the nerve endings and may increase their effects (during concomitant use or within several days of discontinuation of tricyclic antidepressants). Hypertension and dysrhythmias may occur.

Anaesthesia

Dysrhythmias may occur with volatile anaesthetics. Because of the increased risk of ventricular fibrillation, EYE-GENE EYE DROPS should be used with caution during general anaesthesia with anaesthetic agents, like halothane which sensitize the myocardium to sympathomimetics.

Cardiac conduction and dysrhythmias.

Caution is required with thyroid hormones, and with medicines that affect cardiac conduction, such as digoxin and antidysrhythmic medicines, such as quinidine.

There is an increased risk of dysrhythmias.

Ergot alkaloids and oxytocin

Vasoconstrictor and pressor effects of phenylephrine may be enhanced by medicines with similar effects, such as ergot alkaloids or oxytocin.

Halothane

Because of the increased risk of ventricular fibrillation, EYE-GENE EYE DROPS should be used with caution during general anaesthesia with anaesthetic agents, like halothane which sensitise the myocardium to sympathomimetics.

4.6. Fertility, pregnancy and lactation

The safety of EYE-GENE EYE DROPS in pregnancy and lactation has not been established.

4.7. Effects on ability to drive and use machines

Since adverse reactions such as dizziness, drowsiness and visual disturbances have been reported in patients receiving EYE-GENE EYE DROPS patients should not drive, use machinery or perform any tasks that require concentration, until they are certain that EYE-GENE EYE DROPS do not adversely affect their ability to do so (see section 4.8).

4.8. Undesirable effects

Ophthalmic phenylephrine, as contained in EYE-GENE EYE DROPS, may be systemically absorbed.

Table 1: Listing of reported adverse events

System organ class	Frequent	Less frequent	Frequency unknown
Immune system disorders		Hypersensitivity and cross-sensitivity to phenylephrine have been reported in a patient hypersensitive to pseudoephedrine.	
Endocrine disorders		Hyperglycaemia	
Metabolism and nutrition disorders	Anorexia	Lactic acidosis	
Psychiatric disorders	Anxiety, fear, restlessness, insomnia, confusion, irritability, psychotic states	Drowsiness	
Nervous system disorders	Headache	Dizziness, tremor	
Eye disorders	Acute and chronic allergic conjunctivitis, corneal clouding, burning, eye irritation or pain, stinging or watering of the eyes, brow-ache, blurred vision, photophobia, conjunctival sensitisation and allergy.	Pupillary dilation, increased intraocular pressure, mydriasis, temporarily blurred vision, conjunctival sensitisation	
Cardiac disorders		Cardiac irregularities such as palpitations, tachycardia, extrasystoles, dysrhythmias, reflex bradycardia	
Vascular disorders		Hypertension, cerebral	Periorbital pallor in

		haemorrhage, peripheral vasoconstriction	preterm patients.
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Pulmonary oedema (in paediatric patients)	
Gastrointestinal disorders	Nausea, vomiting	Increased salivation	
Skin and subcutaneous tissue disorders		Piloerection	
Renal and urinary disorders		Difficulty in micturition, urinary retention	
General disorders and administrative site conditions		Cold extremities, increased sweating, pallor	

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/ +27 (0)11 239-6200

4.9. Overdose

Symptoms

Accidental ingestion (especially in children) may cause depression of the central nervous system with reduction in body temperature and symptoms of bradycardia, sweating, drowsiness and coma**.** Hypertension may be followed by rebound hypotension.

Treatment

Treatment is symptomatic and supportive.

Because a severe toxic reaction to EYE-GENE EYE DROPS is of rapid onset and short duration, treatment is primarily supportive. Prompt injection of a rapidly acting alpha-adrenergic blocking medicine such as phentolamine (dose 2 to 5 mg IV) may be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 15.4 Ophthalmic Preparations: Others.

Pharmacotherapeutic group: Sympathomimetics excl. antiglaucoma preparations, ATC code: S01FB01

Phenylephrine acts on alpha-adrenergic receptors in the arterioles of the conjunctiva producing vasoconstriction and decongestion.

Phenylephrine hydrochloride is a sympathomimetic amine with a predominantly direct alpha-adrenergic action. Relaxation of the iris sphincter muscle, resulting in mydriasis with little or no cycloplegic effect. Phenylephrine also has an intraocular pressure-lowering effect due to slowing of the influx of aqueous humour. Mydriasis is apparent approximately 15 minutes after drop instillation and maximal after 60-90 minutes. The duration of response is around 5 hours.

Ocular use of phenylephrine may result in transconjunctival systemic absorption, leading to systemic cardiovascular reactions.

5.2 Pharmacokinetic properties

Systemic absorption is increased when the corneal epithelium is damaged.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Benzalkonium chloride, borax (for pH adjustment), boric acid (for pH adjustment), disodium edetate, sodium chloride

6.2. Incompatibilities

Not applicable

6.3. Shelf life

24 months

6.4. Special precautions for storage

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

Do not use more than 30 days after opening.

6.5 Nature and contents of container

5 ml, 10 ml and 15 ml packed into a white high density polyethylene bottle with a white screw-on polypropylene cap and natural low density polyethylene plug or natural high density polyethylene bottle with a high density polyethylene white screw-on cap and natural low density polyethylene plug. Each filled bottle is packed into a unit carton together with a leaflet.

Not all pack sizes are necessarily marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Telephone: 0800 122 912

8. REGISTRATION NUMBER

H1246 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION

Date of registration: Old medicine

10. DATE OF REVISION OF THE TEXT

11 June 2026

Die Afrikaanse Professionele Inligting is op versoek beskikbaar. Mediese Blitslyn: 0800 118 088.

Botswana: BOT9900369 S3

Namibia: NS0 14/15/0578

Zimbabwe: H.R. 76/19.9/0658