1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

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

Phenylephrine hydrochloride

Contains preservatives: Benzalkonium chloride 0,02 % *m/v* and Disodium edetate 0,02 % *m/v*

Read all of this leaflet carefully because it contains important information for you

EYE-GENE EYE DROPS is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use EYE-GENE EYE DROPS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share EYE-GENE EYE DROPS with any other person.
- Ask your pharmacist if you need more information or advice.

You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet:

1. What EYE-GENE EYE DROPS is and what it is used for

2. What you need to know before you use EYE-GENE EYE DROPS

3. How to use EYE-GENE EYE DROPS

4. Possible side effects

5. How to store EYE-GENE EYE DROPS

6. Contents of the pack and other information

1. What EYE-GENE EYE DROPS is and what it is used for:

EYE-GENE EYE DROPS contains phenylephrine hydrochloride that belongs to a group of medicines called alpha-1-adrenergic receptor agonists.

EYE-GENE EYE DROPS is used for the symptomatic relief of tired, red and itching eyes.

2. What you need to know before you use EYE-GENE EYE DROPS:

Do not use EYE-GENE EYE DROPS:

- If you are hypersensitive (allergic) to phenylephrine hydrochloride or to any of the other ingredients of EYE-GENE EYE DROPS (see section 6);
- If you have an eye disorder called glaucoma;
- If you have an eye infection, eye surgery or an eye injury.
- If you suffer from any heart disease, irregular heart rates (slow or fast heart rates), high blood pressure, diabetes mellitus or an overactive thyroid gland;
- If you are using medicine for high blood pressure (see **Other medicines and EYE-GENE EYE DROPS**);
- If you are using medication called monoamine oxidase inhibitors (MAOIs) (used to treat depression) or tricyclic antidepressants (used to treat depression) (see **Other medicines and EYE-GENE EYE DROPS**);
- Aneurysm (indicated severe headache, neck pain/stiffness, vision changes, numbness);
- If you have a blood vessel condition called arteriosclerosis (a thickening and hardening of the arteries, symptoms may include chest pain, shortness of breath, pain radiating to jaw or arms);
- For children 12 years of age or the elderly.

Warnings and precautions:

EYE-GENE EYE DROPS can cause intense irritation, and a local anaesthetic should be instilled into the

eye a few minutes beforehand. Seek advice from your doctor or pharmacist beforehand.

Take special care with EYE-GENE EYE DROPS:

- If your eye symptoms do not clear up in 7 days consult your doctor. Do not use continuously for longer than 7 days without consulting your doctor.
- If you are using EYE-GENE EYE DROPS for long periods of time as it may affect your eyes. Consult your doctor;
- If you have phaeochromocytoma (a tumour of the adrenal glands) and you get frequent episodes of high blood pressure;
- If you have a prostate disorder or a disorder that affects your ability to urinate normally;
- If you have long-standing bronchial asthma;
- If you have a condition called ocular hyperaemia, where there is excess blood in the white part of the eye.

Children and adolescents:

Do not use EYE-GENE EYE DROPS in children younger than 12 years of age due.

Children aged ≥ 12 years old: EYE-GENE EYE DROPS is not recommended, consult your doctor before administering EYE-GENE EYE DROPS in this age group.

Other medicines and EYE-GENE EYE DROPS:

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Do not use EYE-GENE EYE DROPS:

- Antihypertensives (used to treat high blood pressure) (see Do not use EYE-GENE EYE DROPS);
- Tricyclic antidepressants (used to treat mood disorders such as depression) (see Do not use EYE-GENE EYE DROPS), when used or concurrently or recently;

- Monoamine oxidase inhibitors (MOAIs) like phenelzine or moclobemide (used to treat depression) (see Do not use EYE-GENE EYE DROPS)- when used or concurrently or within the last 3 weeks

Tell your doctor if you are taking any of the following medicines:

- Halothane (anaesthetic used during operations to put you to sleep);
- Digoxin, quinidine or other similar medicines (used to treat heart rhythm disorders);
- Ergot alkaloids (used to treat migraine);
- Oxytocin (used to induce labour).

Pregnancy, breastfeeding and fertility:

The safety of EYE-GENE EYE DROPS during pregnancy and whilst breastfeeding has not been established.

You should not take EYE-GENE EYE DROPS if you are pregnant or breastfeeding your baby.
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking EYE-GENE EYE DROPS.

Driving and using machines

Since adverse reactions such as dizziness, drowsiness and visual disturbances have been reported in patients receiving EYE-GENE EYE DROPS, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that EYE-GENE EYE DROPS does not adversely affect your ability to do so (see section 4).
It is not always possible to predict to what extent EYE-GENE EYE DROPS may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which EYE-GENE EYE DROPS affects you.

EYE-GENE EYE DROPS contains the preservative, benzalkonium chloride:

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using EYE-GENE EYE DROPS and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using EYE-GENE EYE DROPS, talk to your doctor.

3. How to use EYE-GENE EYE DROPS

Do not share medicines prescribed for you with any other person.

Always use EYE-GENE EYE DROPS exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are unsure.

Wipe eyelids clean. Tip head well back and close eyes, squeeze one to two drops of EYE-GENE EYE DROPS into corners closest to the nose.
Now open and close your eyelids several times.
Instil 1 to 2 drops every 3 to 4 hours.

Discard 30 days after first opening.

If you have the impression that the effect of EYE-GENE EYE DROPS is too strong or too weak, tell your doctor or pharmacist.

If you use or instil more EYE-GENE EYE DROPS than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use or instil a dose of EYE-GENE EYE DROPS

Instil your missed dose as soon as you remember, if within a few hours after missing a dose. Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects:

EYE-GENE EYE DROPS can have side effects.

Not all side effects reported for EYE-GENE EYE DROPS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EYE-GENE EYE DROPS, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using EYE-GENE EYE DROPS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to EYE-GENE EYE DROPS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- heart palpitations, abnormal heartbeat, higher than normal heart rate,
- higher than normal blood pressure,
- higher than normal blood sugar levels,

- tightness of the chest, difficulty breathing, shortness of breath or breathlessness,
- difficulty to urinate (less urine than is normal for you),
- yellowing of the skin and eyes, also called jaundice,
- severe headache followed by vomiting as this is one of the more common symptoms of bleeding in the brain.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- lack /loss of appetite,
- mood disorders such as anxiety, fear, restlessness, confusion, irritability, psychotic behaviour,
- trouble sleeping,
- headache,
- burning, stinging or watering of eyes, brow-ache, photophobia, eye irritation,
- nausea (feeling sick) and vomiting (being sick).

The following side effects have been reported less frequently:

- too much sugar in the blood,
- low pH in body tissues and blood,
- drowsiness,
- dizziness,
- tremor,
- increased pressure in the eye,
- extreme dilation/widening of pupil,
- high blood pressure,
- excessive fluid accumulation in lungs,

- increase saliva in your mouth,
- piloerection also known as goose bumps,
- cold limbs (arms and legs),
- sweating,
- pallor,
- blurred vision.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects 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

5. How to store:

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.

Do not store in a bathroom.

Do not use after the expiry date printed on the bottle or carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information:

What EYE-GENE EYE DROPS contains:

The active substance is phenylephrine hydrochloride 0,043 g per 100 ml eye drops solution.

The other ingredients are benzalkonium chloride, borax (for pH adjustment), boric acid (for pH adjustment), disodium edetate, sodium chloride.

Preservatives:

Benzalkonium chloride 0,02 % *m/v*

Disodium edetate 0,02 % *m/v*

What PROPRIETARY NAME looks like and contents of the pack:

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

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.

Holder of Certificate of Registration:

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912/ +27 (0)11 239-6200

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Access to the corresponding Professional Information:

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Botswana: BOT9900369 S3

Namibia: NS0 14/15/0578

Zimbabwe: H.R. 76/19.9/0658