1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

VYZULTA™ 0,024 % eye drops, solution

Latanoprostene bunod

Read all of this leaflet carefully before you start using VYZULTA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- VYZULTA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What VYZULTA is and what it is used for
2. What you need to know before you use VYZULTA
3. How to use VYZULTA
4. Possible side effects
5. How to store VYZULTA
6. Contents of the pack and other information

1. What VYZULTA is and what it is used for

VYZULTA belongs to a group of medicines known as prostaglandin analogues. It works by increasing the natural outflow of fluid from inside the eye into the bloodstream.

VYZULTA is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

2. What you need to know before you use VYZULTA

Do not use VYZULTA:

- if you are hypersensitive (allergic) to latanoprostene bunod or any of the other ingredients of VYZULTA (listed in section 6).

Warnings and precautions

Immediately contact your doctor or pharmacist for advice on whether you should continue using VYZULTA if you:

- develop a new eye condition (e.g. trauma or infection)
- experience a sudden decrease in visual acuity (clarity of vision)
- are planning to have eye surgery
- develop any eye reactions, particularly conjunctivitis (pink eye) and eyelid reactions

Special care should be taken with VYZULTA:

- If you have a history of eye inflammation. You should not use VYZULTA if you have active eye inflammation, as it may make the condition worse.
- If you do not have a lens in your eye, you have a fake lens in your eye or if you have other risk factors (such as a complication of diabetes that affects your eyes, or blockage of the small veins that carry blood away from the retina), as the use of medicines like VYZULTA may cause macular oedema (swelling in the eye)
- Contact lenses may absorb benzalkonium chloride (the preservative in VYZULTA) which may change the colour of the contact lenses. They should be removed before you administer VYZULTA and may be reinserted 15 minutes after administration

- Do not let the tip of the bottle touch your eye, fingers or any other surfaces

Pigmentation

The use of VYZULTA may cause increased brown pigmentation of the iris (the round, coloured part of your eye), which may be permanent. It can also cause darkening of the eyelid skin, which is usually reversible after you stop using VYZULTA. You should inform your doctor if you notice any changes in the colour of your eyes or eyelids. Your doctor may need to examine your eyes regularly.

Eyelash changes

The use of VYZULTA may also lead to changes in your eyelashes and fine hair around your eyes. This might affect the length, thickness, colour or number of hair, as well as misdirection of hair growth. These changes are usually reversible when you stop using VYZULTA.

Children

The use of VYZULTA below the age of 16 years is not recommended because of potential safety concerns relating to the increased pigmentation following long-term chronic use.

Other medicines and VYZULTA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

If you use other eye drops, you should wait at least five (5) minutes between applications.

You should not use two or more medicines in the same group (known as prostaglandin analogues), as this may cause an opposite effect and increase your IOP.

Pregnancy, breastfeeding and fertility

No studies were performed on the use of VYZULTA in pregnant or breastfeeding women.

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 health care provider for advice before using this medicine.

Driving and using machines

You may experience temporary blurred vision or irritation, pain or itching when you instil VYZULTA into your eye. If you experience blurred vision, wait until your vision clears before driving or using machinery.

VYZULTA contains benzalkonium chloride

The preservative in VYZULTA, benzalkonium chloride, may cause certain side effects or damage to your cornea (the clear, front layer of your eye) if it is used repeatedly or for long periods of time. If you feel stinging or pain in the eye after using this medicine, talk to your doctor. Your doctor may need to examine your eyes regularly.

Your doctor should be extra cautious if you have extensive ocular (eye) surface disease.

3. How to use VYZULTA

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

Always use VYZULTA exactly as your doctor or pharmacist has told you. Check with our doctor or pharmacist if you are not sure.

The usual dose is: one drop in the affected eye(s) once daily in the evening.

Do not use VYZULTA more than once daily as it may cause a reduction in the effect of the medicine.

If VYZULTA is used together with other eye drops, you should administer each eye drop at least five (5) minutes apart.

If you have the impression that the effect of VYZULTA is too strong or too weak, tell your doctor or pharmacist.

If you use more VYZULTA than you should

In the event of overdosage, or if someone accidentally swallowed the eye drops, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use VYZULTA

Do not instil a double dose into your eyes to make up for forgotten individual doses.

Continue with your usual dose the next evening.

4. Possible side effects

VYZULTA can have side effects.

Not all side effects reported for VYZULTA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using VYZULTA, please consult your health care provider for advice.

Frequent side effects

Tell your doctor, pharmacist or nurse, if you notice any of the following effects in your eyes**:**

- redness (this could be a sign of increased blood flow to your eye)
- irritation (feeling of burning, grittiness, itching or the sensation of a foreign body in the eye)
- pain
- itching

- foreign body sensation in your eye
- pain at the site where the eye drop was instilled

Less frequent side effects

VYZULTA can have effects on various parts of your eyes, including the conjunctiva (the clear membrane that lines the outer eye and inner part of the eyelid), cornea (the clear, front layer of your eye), uvea (the middle layer of the eye), meibomian glands (the small oil glands in the eyelid), or your eyelids.

Tell your doctor if you notice any of the following:

- ***General effects on your eyes:*** abnormal sensation in your eye, eye strain, dry eye, eye discharge, increased tearing, increased intraocular pressure, sensitivity to light, eye colour changes [see **Pigmentation** in section 2. What you need to know before you use VYZULTA]
- ***Effects on your vision:*** blurred vision, reduced clarity of vision
- ***Effects at the instillation site (where the eye drop was instilled):*** discomfort, redness, hypersensitivity, irritation, tearing, reactions
- ***Effects on your eyelids or skin around your eyes:*** redness, pain, swelling, itching, crusting at the margins of the eyelids, rash, pigmentation or hypopigmentation (darkening or lightening of the eyelid skin) [see **Pigmentation** and **Eyelash changes** in section 2. What you need to know before you use VYZULTA]
- ***Effects on your eyelashes and the hair around your eyes:*** abnormal hair growth, hair colour changes, eyelashes turning inwards, loss of eyelashes

VYZULTA can also have side effects that do not affect your eyes.

Tell your doctor if you notice any of the following:

- infections of the ears, teeth, urinary tract or vagina
- insomnia (difficulty sleeping)
- changes in your sense of taste
- headache
- difficulty breathing
- cough
- sinus congestion (a blocked nose)
- excessive sweating
- hives, rash or skin colour changes
- breast mass
- chest discomfort
- fatigue

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 **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

You can also report side effects directly to the company, using the following e-mail address: PV-SouthAfrica@bausch.com

By reporting side effects, you can help provide more information on the safety of VYZULTA.

5. How to store VYZULTA

Store all medicines out of reach of children.

- The unopened bottle should be stored in a refrigerator between 2 – 8 °C.
- Once a bottle is opened, it may be stored at 2 – 25 °C.
- Protect from light.
- Do not freeze
- Do not use after the expiry date stated on the carton and bottle.
- Do not use more than 8 weeks after opening.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VYZULTA contains

The active substance is latanoprostene bunod 0,24 mg per 1 mL (0,024 % *m/v*).

The preservative is benzalkonium chloride 0,2 mg per 1 mL (0,02 % *m/v*).

The other ingredients are Polysorbate 80, edetate disodium dihydrate, sodium citrate dihydrate, citric acid anhydrous, glycerine and water for injection.

What VYZULTA looks like and contents of the pack

VYZULTA is a clear and colourless to slightly yellow solution.

VYZULTA is supplied as a 5 mL solution in a 75 mL clear, low density polyethylene (LDPE) bottle with a controlled dropper tip and turquoise polypropylene cap.

Tamper evidence is provided with a shrink band around the cap and neck area of the package.

Holder of Certificate of Registration

Soflens (Pty) Ltd

254 Hall Street

Centurion

0157

South Africa

Tel: +27 10 025 2100

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