

Generic Name: Latanoprost  
Trade Name: Xalatan®  
CDS Effective Date: February 25, 2022  
Superseded: June 14, 2016  
Approved by BPOM: February 2, 2023

**PT. Pfizer Indonesia  
Local Product Document**

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**Special Warning and Special Precaution for Use:**

Benzalkonium chloride, which is commonly used as a preservative in ophthalmic products, has been reported to cause punctate keratopathy and/or toxic ulcerative keratopathy. Since this drug contains benzalkonium chloride, close monitoring is required with frequent or prolonged use in dry eye patients, or in conditions where the cornea is compromised.

**Contact Lenses**

Patients should be advised not to wear a contact lens if their eye is red. This drug should not be used to treat contact lens related irritation. The preservative in this drug, benzalkonium chloride, may be absorbed by soft contact lenses. Patients who wear soft contact lenses and **whose eyes are not red** should be instructed to wait at least ten minutes after instilling this drug before they insert their contact lenses.

**1. NAME OF THE MEDICINAL PRODUCT**

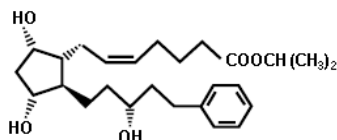
Xalatan® eye drops, solution.

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

<u>1 mL</u>	<u>One bottle with 2.5 mL</u>
Latanoprost 50 micrograms	125 micrograms

One drop contains approximately 1.5 micrograms latanoprost.

The structural formula is represented below:



**3. PHARMACEUTICAL FORM**

Eye drops, solution

**4. CLINICAL PARTICULARS**

**4.1 THERAPEUTICS INDICATIONS**

Reduction of elevated intraocular pressure in patients with open angle glaucoma, chronic angle closure glaucoma and ocular hypertension who are intolerant of other intraocular

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pressure lowering medications or insufficiently responsive (failed to achieve target IOP determined after multiple measurements over time) to another intraocular pressure lowering medication.

#### **4.2 POSOLOGY AND METHOD OF ADMINISTRATION**

Recommended dosage for adults (including the elderly):

Recommended therapy is one eye drop in the affected eye(s) once daily. Optimal effect is obtained if Xalatan® is administered in the evening. If one dose is missed treatment should continue with the next dose as normal.

##### *Administration:*

Pivotal studies have demonstrated that Xalatan® is effective as a single drug therapy.

Although definitive clinical trials of combination use have not been done a three-month study shows that latanoprost is effective in combination with beta-adrenergic antagonists (timolol).

Short-term studies suggest that the effect of latanoprost is additive in combination with adrenergic agonists (dipivalyl epinephrine), oral carbonic anhydrase inhibitors (acetazolamide) and at least partly additive with cholinergic agonist (pilocarpine).

Xalatan® may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. In case of combined therapy the eye drops should be administered with an interval of at least five minutes apart. The dosage of Xalatan® should not exceed once daily since it has been shown that more frequent administration decreases the intra ocular pressure lowering effect.

##### *Children:*

Safety and effectiveness in children has not been established. Therefore Xalatan® is not recommended for use in children.

#### **4.3 CONTRAINDICATIONS**

Known hypersensitivity to any component in Xalatan®. *In vitro* studies have shown that precipitation occurs when eye drops containing thiomerosal are mixed with Xalatan®. If such drugs are used, the eye drops shall be administered with an interval of at least five minutes.

#### **4.4 SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE**

Benzalkonium chloride, which is commonly used as a preservatives in ophthalmic products, has been reported to cause punctate keratopathy and/or toxic ulcerative keratopathy. Since this drug contains benzalkonium chloride, close monitoring is required with frequent or prolonged use in dry eye patients, or in conditions where the cornea is compromised.

##### *Contact Lenses*

Patients should be advised not to wear a contact lens if their eye is red. This drug should not be used to treat contact lens related irritation. The preservative in this drug, benzalkonium chloride, may be absorbed by soft contact lenses. Patients who wear soft contact lenses and whose eyes are not red should be instructed to wait at least ten minutes after instilling this drug before they insert their contact lenses.

##### *Iris pigmentation changes*

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Xalatan® may gradually change the eye colors by increasing the amount of brown pigment in the iris. This effect has predominantly been seen in patients with mixed coloured irides, i.e., blue-brown, grey-brown, green-brown or yellow-brown, and is due to increased melanin content in the stromal melanocytes of the iris. A permanent heterochromia can happen. Typically the brown pigmentation around the pupil spreads concentrically towards the periphery in affected eyes, but the entire iris or parts of it may become more brownish. In patients with homogeneously blue, grey, green or brown eyes, the change has only rarely been seen during two years of treatment in clinical trials. The change in iris color occurs slowly and may not be noticeable for several months to years. It has not been associated with any symptom or pathological changes in clinical trials. No further increase in brown iris pigment has been observed after discontinuation of treatment, but the resultant color change may be permanent.

The potential for heterochromia exists for patients receiving unilateral treatment.

Until further long term data is obtained it is recommended that in patients with mixed colored irides only those who are intolerant or insufficiently responsive to another intraocular lowering medication be treated.

Neither nevi nor freckles of the iris have been affected by treatment. Accumulation of pigment in the trabecular meshwork or elsewhere in the anterior chamber has not been observed in clinical trials, but until further long term experience about increased iris pigmentation is available, patients should be examined regularly and, depending on the clinical situation, treatment may be stopped if increased iris pigmentation ensues.

Before treatment is instituted patients should be informed of the possibility of a change in eye color.

### *Glaucoma*

There is no experience of Xalatan® in inflammatory, neovascular, angle closure or congenital glaucoma and only limited experience in open angle glaucoma of pseudophakic patients and in pigmentary glaucoma. Xalatan® has no or little effect on the pupil but there is no experience in accurate attacks of closed angle glaucoma. Therefore it is recommended that Xalatan® should be used with caution in these conditions until more experience is obtained.

### *Macular edema*

Macular edema, including cystoid macular edema, has been reported during treatment with Xalatan®. These reports have mainly occurred in aphakic patients, in pseudophakic patients with torn posterior lens capsule, or in patients with known risk factors for macular edema. Xalatan® should be used with caution in these patients.

Xalatan® contains benzalkonium chloride which may be absorbed by contact lenses. The contact lenses should be removed before instillation of the eye drops and maybe reinserted after 15 minutes (see section **4.4 SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE**). Xalatan® should not be administered while wearing contact lenses. Xalatan® has not been studied in patients with renal or hepatic impairment and should therefore be used with caution in such patients.

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Trade Name: Xalatan®  
CDS Effective Date: February 25, 2022  
Superseded: June 14, 2016  
Approved by BPOM: February 2, 2023

### *Herpetic keratitis*

Xalatan® should be used with caution in patients with a history of herpetic keratitis, and should be avoided in cases of active herpes simplex keratitis and in patients with a history of recurrent herpetic keratitis specifically associated with prostaglandin analogues.

## **4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTIONS**

The intraocular pressure reducing effect of latanoprost has been shown to be additive to that of beta-adrenergic antagonists (timolol), adrenergic agonists (dipivalyl epinephrine), carbonic anhydrase inhibitors (acetazolamide), and at least partly to cholinergic agonists (pilocarpine) in short term clinical trials.

There have been reports of paradoxical elevations in IOP following the concomitant ophthalmic administration of two prostaglandin analogs. Therefore, the use of two or more prostaglandins, prostaglandin analogs, or prostaglandin derivatives is not recommended.

## **4.6 PREGNANCY AND LACTATION**

### *Fertility*

Latanoprost has not been found to have any effect on male or female fertility in animal studies (see section **5.3 Preclinical Safety Data – Impairment of Fertility – Latanoprost**).

### *Pregnancy*

This medicinal product does not increase the spontaneous incidence of birth defects, but it has potential hazardous pharmacological effects with respect to the course of pregnancy, to the unborn or neonate.

Latanoprost has been shown to cause embryofetal toxicity in rabbits characterized by increase incidences of late resorption and abortion and reduced foetal weight when given in intravenous doses approximately 100 times the human dose.

Xalatan® should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus (see section **5.3 Preclinical Safety Data – Impairment of Fertility**).

### *Lactation*

The active substance in Xalatan® and its metabolites may pass into breast milk and Xalatan® should therefore be used with caution in nursing women.

## **4.7 EFFECTS ON ABILITY TO DRIVE AND USE OF MACHINES**

In common with other preparations, instillation of eye drops may cause transient blurring of vision. Until this has resolved, patients should not drive or use machines.

## **4.8 UNDESIRABLE EFFECTS**

Generic Name: Latanoprost  
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**ADRs by SOC and CIOMS frequency category (i.e., Very common, Common, Uncommon, Rare, and Very rare) and in order of decreasing medical seriousness within each frequency category and SOC.**

<b>System Organ Class</b>	<b>Common ≥1/100 to &lt;1/10</b>	<b>Uncommon ≥1/1,000 to &lt;1/100</b>	<b>Rare ≥1/10,000 to &lt;1/1,000</b>	<b>Frequency not known (cannot be estimated from available data)</b>
Infections and infestations				Herpetic keratitis*
Nervous system disorders		Dizziness*; headache*		
Eye disorders	Eye irritation (burning, grittiness, itching, stinging and foreign body sensation); eye pain; eyelash and vellus hair changes of the eyelid (increased length, thickness, pigmentation, and number of eyelashes)*; ocular hyperaemia; iris hyperpigmentation; blepharitis; conjunctivitis*	Macular edema including cystoid macular edema*; photophobia* ; eyelid edema; keratitis*; uveitis*	Corneal edema*; iritis*	Punctate keratitis*; corneal erosion*; trichiasis*; vision blurred*; periorbital and lid changes resulting in deepening of the eyelid sulcus*; darkening of the palpebral skin of the eyelids*; localised skin reaction on the eyelids*; iris cyst*; pseudopemphigoid of the ocular conjunctiva*
Cardiac disorders		Angina; palpitations*		Angina unstable*
Respiratory, thoracic and mediastinal disorders		Asthma*; dyspnoea*		Asthma aggravation*; acute asthma attacks*
Gastrointestinal disorders		Nausea*	Vomiting*	

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 Superseded: June 14, 2016  
 Approved by BPOM: February 2, 2023

System Organ Class	Common ≥1/100 to <1/10	Uncommon ≥1/1,000 to <1/100	Rare ≥1/10,000 to <1/1,000	Frequency not known (cannot be estimated from available data)
Skin and subcutaneous tissue disorders		Rash	Pruritus	
Musculoskeletal and connective tissue disorders		Myalgia*; arthralgia*		
General disorders and administration site conditions		Chest pain*		

\*ADR identified post-marketing

#### *Adverse reactions reported with the use of eye drops containing phosphate buffers*

Cases of corneal calcification have been reported very rarely in association with the use of phosphate-containing eye drops in some patients with significantly damaged corneas.

#### **4.9 Overdose**

If overdosage with Xalatan® occurs, treatment should be symptomatic.

Apart from ocular irritation and conjunctival hyperemia no other ocular side effects are known if Xalatan® is overdosed.

If Xalatan® is accidentally ingested the following information may be useful: One bottle contains 125 micrograms latanoprost. More than 90% is metabolized during the first pass through the liver. Intravenous infusion of 3 micrograms/kg in healthy volunteers induced no symptoms but a dose of 5.5-10 micrograms/kg caused nausea, abdominal pain, dizziness, fatigue, hot flushes and sweating.

### **5. PHARMACOLOGY**

#### **5.1 Pharmacodynamic Properties**

The active substance latanoprost, a prostaglandin F<sub>2α</sub> analogue, is a selective prostanoid FP receptor agonist which reduces the IOP by increasing the outflow of aqueous humour. Studies in animals and man indicate that the main mechanism of action is increased uveoscleral outflow, although some increase in out-flow facility (decrease in out flow resistance) has been reported in man. Pivotal studies have demonstrated that XALATAN is effective as a single drug therapy. Although definitive clinical trials of combination use have not been done a three month study shows that latanoprost is additive in combination with adrenergic agonists (dipivalyl epinephrine), oral carbonic anhydrase inhibition (acetazolamide) and at least partly additive with cholinergic agonist (pilocarpine).

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Trade Name: Xalatan®  
CDS Effective Date: February 25, 2022  
Superseded: June 14, 2016  
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Clinical trials have shown that latanoprost has no significant effect on the production of aqueous humour. Latanoprost has not been found to have any effect on the blood-aqueous barrier.

Latanoprost has no or negligible effects on the intraocular blood circulation when used at the clinical dose and studied in monkeys. However, mild to moderate conjunctival or episcleral hyperaemia may occur during topical treatment.

Chronic treatment with latanoprost in monkey's eyes which had undergone extracapsular lens extraction did not affect the renal blood vessels as determined by fluorescein angiography.

Latanoprost has not induced fluorescein leakage in the posterior segment of pseudophakic human eyes during short term treatment.

Latanoprost in clinical doses has not been found to have any significant pharmacologic effects on the cardiovascular or respiratory system.

## 5.2 Pharmacokinetic Properties

### *Absorption*

Latanoprost (MW 432.58) is an isopropyl ester prodrug which per se is inactive but after hydrolysis to the acid of latanoprost becomes biologically active.

The prodrug is well absorbed through the cornea and all drug that enters the aqueous humor is hydrolysed during the passage through cornea.

Studies in man indicate that the peak concentration in the aqueous humour is reached about two hours after topical administration.

### *Distribution*

The distribution volume in humans is  $0.16 \pm 0.02$  L/kg. The acid of latanoprost can be measured in aqueous humor during the first four hours, and in plasma only during the first hour after local administration.

### *Metabolism*

Latanoprost, an isopropyl ester prodrug, is hydrolyzed by esterases in the cornea to the biologically active acid. The active acid of latanoprost reaching the systemic circulation is primarily metabolized by the liver to the 1,2-dinor and 1,2,3,4-tetranor metabolites via fatty acid  $\beta$ -oxidation.

### *Excretion*

The elimination of the acid of latanoprost from human plasma is rapid ( $t_{1/2}=17$  min) after both intravenous and topical administration. Systemic clearance is approximately 7 mL/min/kg.

Following hepatic  $\beta$ -oxidation, the metabolites are mainly eliminated via the kidneys.

Approximately 88% and 98% of the administered dose is recovered in the urine after topical and intravenous dosing, respectively.

## 5.3 Preclinical safety data

### *Systemic/Ocular Effects*

The ocular as well as systemic toxicity of latanoprost has been investigated in several animal species. Generally latanoprost is well tolerated with a safety margin between clinical ocular

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CDS Effective Date: February 25, 2022  
Superseded: June 14, 2016  
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dose and systemic toxicity of at least 1000 times. In monkeys, latanoprost has been infused intravenously in doses up to 500 micrograms/kg without major effects on the cardiovascular system. High doses of latanoprost, approximately 100 times the clinical dose/kg body weight, administered intravenously to unanesthetized monkeys have been shown to increase the respiration rate probably reflecting bronchoconstriction of short duration. In the eye no toxic effects have been detected with doses of up to 100 micrograms/eye/day in rabbits or monkeys (clinical dose is approximately 1.5 micrograms/eye/day). In monkeys, however, latanoprost has been shown to induce increased pigmentation of the iris. The mechanism of increased pigmentation seems to be stimulation of melanin production in melanocytes of the iris with no proliferative changes observed. The change in iris color may be permanent or slowly reversible, (see section **4.4 SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE**).

In chronic ocular toxicity studies administration of latanoprost 6 micrograms/eye/day has also been shown to induce palpebral fissure.

This effect is reversible and occurs at doses above the clinical dose level. The effect has not been shown in humans.

#### *Carcinogenesis*

Carcinogenicity studies in mice and rats were negative.

#### *Mutagenesis*

Latanoprost was found negative in reverse mutation tests in bacteria, gene mutation in mouse lymphoma and mouse micronucleus test.

Chromosome aberrations were observed in vitro with human lymphocytes. Similar effects were observed with prostaglandin F<sub>2α</sub>, a naturally occurring prostaglandin, and indicates that this is a class effect. Additional mutagenicity studies on in vitro/in vivo unscheduled DNA synthesis in rats were negative and indicate that latanoprost does not have mutagenic potency. Carcinogenicity studies in mice and rats were negative.

#### *Impairment of Fertility*

Latanoprost has not been found to have any effect on male or female fertility in animal studies. In the embryotoxicity study in rats no embryotoxicity was observed at intravenous doses (5,50 and 250 micrograms/kg/day) of latanoprost. However, latanoprost induced embryo-lethal effects in rabbits in doses of 5 micrograms/kg/day and above. The dose of 5 µg/kg/day (approximately 100 times the clinical dose) caused significant embryofetal toxicity characterized by increased incidence of late resorption and abortion and by reduced foetal weight.

#### *Teratogenesis*

No teratogenic potential has been detected.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of Excipients**

Sodium chloride.

Generic Name: Latanoprost  
Trade Name: Xalatan®  
CDS Effective Date: February 25, 2022  
Superseded: June 14, 2016  
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Benzalkonium chloride.  
Sodium dihydrogen phosphate monohydrate.  
Disodium phosphate anhydrous.  
Water for injection

## **6.2 Shelf-life**

3 years

## **6.3 Special precautions for storage**

Store unopened bottle under refrigeration at 2°C to 8°C (36°F to 46°F).

Protect from light.

Once opened the container shall be used within 4 weeks and may be stored at room temperature up to 25°C.

## **6.4 Nature and contents of container**

Bottle (5 mL), dropper applicator (dropper tip), screw cap, tamper evident overcap of polyethylene.

Each bottle contains 2.5 mL eye drop solution corresponding to approximately 80 drops of solution.

## **6.5 Instruction for use/handling**

The tamper evident overcap should be removed before use.

## **Supply**

Xalatan® Eye Drops 0.005%; Box, plastic bottle 2.5 mL

Reg No.: DKI0186101046A1

## **HARUS DENGAN RESEP DOKTER**

*Manufactured by:*

Pfizer Manufacturing Belgium NV/SA, Puurs, Belgium

*Imported by:*

PT. Pfizer Indonesia

Jakarta, Indonesia

## Leaflet kemasan: Informasi untuk pengguna

### Xalatan® 50 mikrogram/ml Obat tetes mata, larutan Latanoprost

**Baca semua bagian leaflet ini dengan cermat sebelum mulai menggunakan obat ini karena berisi informasi penting bagi Anda.**

- Simpan leaflet ini. Anda mungkin perlu membacanya kembali.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter, apoteker, atau perawat Anda.
- Obat ini telah diresepkan hanya untuk Anda. Jangan memberikannya kepada orang lain. Obat ini dapat membahayakan mereka, sekali pun gejala-gejala penyakit mereka sama dengan Anda.
- Jika Anda mengalami efek samping apa pun, konsultasikan dengan dokter, apoteker, atau perawat Anda. Termasuk setiap kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Lihat bagian 8.

#### Isi leaflet ini:

1. Nama produk
2. Deskripsi produk
3. Apa kandungan obat ini?
4. Kekuatan obat
5. Apa kegunaan obat ini?
6. Berapa banyak dan seberapa sering Anda seharusnya menggunakan obat ini? Apa yang harus dilakukan jika ada dosis yang terlewat?
7. Kapan seharusnya Anda tidak menggunakan obat ini?
8. Apa yang harus dipertimbangkan saat menggunakan obat ini?
9. Apa saja obat lain atau makanan yang harus dihindari selama menggunakan obat ini?
10. Apakah obat tersebut aman bagi ibu hamil dan menyusui?
11. Apakah pasien diizinkan mengemudi dan mengoperasikan mesin saat menggunakan obat ini?
12. Apa saja potensi efek yang tidak diinginkan dari penggunaan obat ini?
13. Tanda-tanda dan gejala-gejala overdosis
14. Apa yang harus dilakukan jika Anda menggunakan lebih dari dosis yang dianjurkan?
15. Bagaimana cara menyimpan obat ini?
16. Nomor Izin Edar
17. Nama produsen/importir/Pemilik Izin Edar
18. Tanggal revisi
19. Peringatan khusus

#### 1. Nama produk

Xalatan® obat tetes mata, larutan.

Nama Generik: Latanoprost  
Nama Dagang: Xalatan®  
Tanggal Berlaku CDS: 25 Februari 2022  
Menggantikan: Tidak Ada  
Disetujui oleh BPOM: 2 Februari 2023

## 2. Deskripsi produk

Botol (5 ml), aplikator pipet (ujung pipet), sungkup ulir, sungkup luar antiperusakan dari bahan polietilen. Setiap botol berisi 2,5 ml larutan obat tetes mata yang setara dengan sekitar 80 tetes larutan obat.

## 3. Apa kandungan obat ini?

1 ml larutan mengandung Latanoprost 50 mikrogram.

## 4. Kekuatan obat

50 mikrogram/mL

## 5. Apa kegunaan obat ini?

Xalatan® digunakan untuk mengobati kondisi yang dikenal sebagai glaukoma sudut terbuka, glaukoma sudut tertutup kronik; dan hipertensi okular pada orang dewasa yang intoleran atau respon tidak adekuat terhadap pengobatan sebelumnya.

## 6. Berapa banyak dan seberapa sering Anda seharusnya menggunakan obat ini? Apa yang harus dilakukan jika ada dosis yang terlewat?

Gunakan obat ini tepat sesuai anjuran dokter atau apoteker Anda. Tanyakan kepada dokter atau apoteker jika Anda merasa tidak yakin.

Dosis yang dianjurkan untuk dewasa (termasuk lansia) adalah satu tetes sekali sehari pada mata yang sakit. Waktu terbaik untuk melakukannya adalah pada malam hari.

Jangan menggunakan Xalatan® lebih dari sekali sehari, karena efektivitas pengobatannya dapat menurun jika Anda menggunakannya lebih sering.

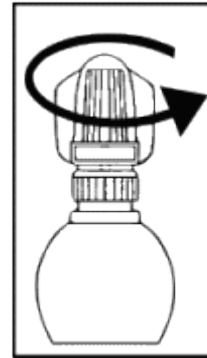
Gunakan Xalatan® sesuai arahan dokter Anda hingga dokter memberi tahu Anda untuk menghentikannya.

### Pengguna lensa kontak

Jika Anda memakai lensa kontak, Anda harus melepaskannya sebelum menggunakan Xalatan®. Setelah menggunakan Xalatan® Anda harus menunggu selama 15 menit sebelum memasang lensa kontak Anda kembali.

### Petunjuk penggunaan

1. Cuci kedua tangan Anda dan duduklah atau berdirilah dengan nyaman.
2. Putar penutup luarnya hingga terlepas (dapat dibuang).



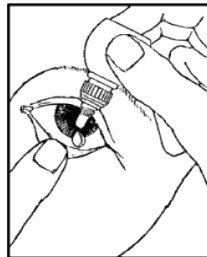
**Gambar 1**

3. Buka sungkup pelindung dalam. Sungkup pelindung harus tetap disimpan.



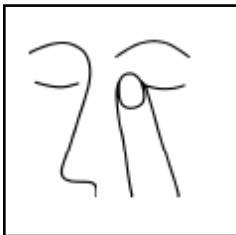
**Gambar 2**

4. Gunakan jari Anda untuk menarik kelopak mata bawah dengan lembut pada mata yang sakit.
5. Dekatkan ujung botol, tetapi jangan sampai menyentuh mata Anda.
6. Pencet botol perlahan sehingga hanya satu tetes yang masuk ke dalam mata Anda, lalu lepaskan kelopak mata bawah.



**Gambar 3**

7. Setelah menggunakan Xalatan®, tekan sudut mata Anda di dekat hidung menggunakan satu jari (gambar 4) selama 1 menit.



**Gambar 4**

8. Ulangi pada mata yang lainnya jika dokter memerintahkan Anda untuk melakukannya.
9. Pasang kembali sungkup pelindung dalam pada botol.

### Jika Anda menggunakan Xalatan® bersama obat tetes mata lainnya

Tunggu minimal 5 menit setelah menggunakan Xalatan® dan lanjutkan dengan menggunakan obat tetes mata lainnya.

Nama Generik: Latanoprost  
Nama Dagang: Xalatan®  
Tanggal Berlaku CDS: 25 Februari 2022  
Menggantikan: Tidak Ada  
Disetujui oleh BPOM: 2 Februari 2023

## **Jika Anda lupa menggunakan Xalatan®**

Lanjutkan dengan dosis normal pada waktu yang semestinya. Jangan menggunakan dosis ganda untuk mengejar dosis yang terlewatkan. Jika Anda merasa ragu, konsultasikan dengan dokter atau apoteker Anda.

## **7. Kapan seharusnya Anda tidak menggunakan obat ini?**

### **Jangan menggunakan Xalatan®**

Jika Anda alergi (hipersensitif) terhadap Latanoprost atau bahan-bahan lainnya dalam obat ini.

## **8. Apa yang harus dipertimbangkan saat menggunakan obat ini?**

### **Peringatan dan tindakan pencegahan**

Konsultasikan dengan dokter atau apoteker Anda sebelum menggunakan Xalatan® jika Anda merasa mengalami kondisi berikut ini:

- Jika Anda menderita mata kering
- Jika Anda mengalami asma berat atau asma yang tidak terkontrol dengan baik
- Jika Anda menggunakan lensa kontak. Anda tetap dapat menggunakan Xalatan®, tetapi ikuti petunjuk untuk pengguna lensa kontak di Bagian 6
- Jika Anda pernah menderita atau saat ini menderita infeksi virus pada mata yang disebabkan oleh virus herpes simpleks (HSV)

## **9. Apa saja obat lain atau makanan yang harus dihindari selama menggunakan obat ini?**

Xalatan® dapat berinteraksi dengan obat-obatan lain. Harap memberi tahu dokter Anda, atau apoteker jika Anda sedang menggunakan atau telah menggunakan obat-obatan lain termasuk obat-obatan (atau obat tetes mata) yang diperoleh tanpa resep dokter. Secara khusus, konsultasikan dengan dokter atau apoteker Anda jika Anda mengetahui bahwa Anda sedang menggunakan prostaglandin, analog prostaglandin, atau turunan prostaglandin.

## **10. Apakah Obat tersebut aman bagi ibu hamil dan menyusui?**

Anda tidak boleh menggunakan Xalatan® jika Anda sedang hamil atau menyusui kecuali jika dokter Anda menganggapnya perlu. Jika Anda hamil atau sedang menyusui, menduga bahwa diri Anda sedang hamil, atau berencana untuk hamil, mintalah saran dokter Anda sebelum menggunakan obat ini.

## **11. Apakah pasien diizinkan mengemudi dan mengoperasikan mesin saat menggunakan obat ini?**

Saat Anda menggunakan Xalatan® Anda mungkin akan mengalami penglihatan kabur untuk beberapa saat. Jika Anda mengalami hal ini, **jangan mengemudi** atau menggunakan peralatan atau mesin apa pun hingga penglihatan Anda jelas kembali.

### **Xalatan® mengandung Benzalkonium klorida dan bufer fosfat**

Obat ini mengandung benzalkonium klorida sebanyak 0,2 mg/ml.

Nama Generik: Latanoprost  
Nama Dagang: Xalatan®  
Tanggal Berlaku CDS: 25 Februari 2022  
Menggantikan: Tidak Ada  
Disetujui oleh BPOM: 2 Februari 2023

Benzalkonium klorida dapat diserap oleh lensa kontak lunak. Anda harus melepaskan lensa kontak sebelum menggunakan obat ini dan memasangnya kembali 15 menit sesudahnya.

Benzalkonium klorida juga dapat menyebabkan iritasi mata, khususnya jika Anda menderita mata kering atau kelainan pada kornea (lapisan bening di bagian depan mata). Jika Anda merasakan sensasi mata yang tidak normal, sensasi tersengat atau nyeri pada mata setelah menggunakan obat ini, konsultasikan dengan dokter Anda.

Obat ini mengandung 6,3 mg fosfat dalam setiap mililiter yang setara dengan 0,2 mg per tetes.

Jika Anda menderita kerusakan berat pada lapisan bening di bagian depan mata (kornea), dalam kasus yang sangat jarang terjadi, fosfat dapat menyebabkan bercak keruh pada kornea akibat penumpukan kalsium selama pengobatan.

## 12. Apa saja potensi efek yang tidak diinginkan dari penggunaan obat ini?

Seperti obat-obatan lainnya, obat ini dapat menimbulkan efek samping, sekali pun tidak semua orang mengalaminya.

Berikut ini adalah efek samping yang diketahui dari penggunaan Xalatan®:

**Umum** (dapat dialami hingga 1 di antara 10 orang):

- Perubahan bertahap pada warna mata Anda dengan meningkatnya kadar pigmen coklat dalam bagian mata Anda yang berwarna yang disebut sebagai iris. Jika Anda memiliki mata dengan warna campuran (biru-cokelat, abu-abu-cokelat, kuning-cokelat, atau hijau-cokelat) semakin besar kemungkinan Anda mengalami perubahan ini dibandingkan jika Anda memiliki mata dengan satu warna (biru, abu-abu, hijau, atau cokelat). Perubahan apa pun pada warna mata Anda mungkin membutuhkan waktu hingga bertahun-tahun, meskipun biasanya akan terlihat setelah pengobatan berjalan 8 bulan. Perubahan warna mata bisa bersifat permanen dan akan semakin terlihat jika Anda menggunakan Xalatan® hanya pada satu mata. Tampaknya tidak ada masalah yang berhubungan dengan perubahan warna mata. Perubahan warna mata tidak akan berlanjut setelah pengobatan dengan Xalatan® dihentikan.
- Kemerahan pada mata.
- Iritasi mata (rasa panas, sensasi pasir dalam mata, gatal, sensasi tersengat, atau seperti ada benda asing di dalam mata). Jika Anda mengalami iritasi mata yang cukup berat sehingga membuat mata Anda sangat berair, atau membuat Anda berpikir untuk menghentikan obat ini, konsultasikan dengan dokter, apoteker, atau perawat Anda secepatnya (dalam waktu seminggu). Mungkin pengobatan Anda perlu ditinjau untuk memastikan Anda tetap menerima pengobatan yang sesuai untuk kondisi Anda.
- Perubahan bertahap pada bulu mata pada sisi mata yang diobati dan rambut-rambut halus di sekeliling mata yang diobati, terlihat terutama pada orang keturunan Jepang. Perubahan ini melibatkan peningkatan intensitas warna (kegelapan), panjang, ketebalan, dan jumlah bulu mata Anda.
- Peradangan kelopak mata (blefaritis), nyeri mata, mata kering, merah, atau gatal (konjungtivitis).

**Tidak umum** (dapat dialami hingga 1 di antara 100 orang):

Nama Generik: Latanoprost  
Nama Dagang: Xalatan®  
Tanggal Berlaku CDS: 25 Februari 2022  
Menggantikan: Tidak Ada  
Disetujui oleh BPOM: 2 Februari 2023

- Sensitivitas terhadap cahaya (fotofobia), pembengkakan kelopak mata, peradangan atau iritasi permukaan mata (keratitis), peradangan pada bagian mata yang berwarna (uveitis), pembengkakan retina (edema makular).
- Ruam kulit.
- Nyeri dada (angina), merasakan irama jantung (palpitasi).
- Asma, sesak napas (dispnea).
- Nyeri dada.
- Sakit kepala, pusing.
- Nyeri otot, nyeri sendi.
- Mual.

**Jarang** (dapat dialami hingga 1 di antara 1000 orang):

- Peradangan iris (iritis), gejala pembengkakan atau tergoresnya/rusaknya permukaan mata,
- Gatal-gatal parah pada kulit.
- Muntah

**Frekuensi tidak diketahui (tidak dapat diperkirakan dari data yang tersedia):**

- Iritasi atau disrupsi pada permukaan mata, penglihatan kabur, arah bulu mata yang tidak beraturan atau bertambahnya barisan bulu mata, jaringan parut pada permukaan mata, area berisi cairan dalam bagian mata yang berwarna (kista iris).
- Reaksi kulit pada kelopak mata, menggelapnya kulit pada kelopak mata.
- Memburuknya asma, serangan asma akut.
- Munculnya infeksi virus pada mata yang disebabkan oleh virus herpes simpleks (HSV).
- Memburuknya angina pada pasien yang juga menderita penyakit jantung, mata terlihat cekung (peningkatan kedalaman sulkus mata).

Dalam kasus yang sangat jarang terjadi, sebagian pasien dengan kerusakan berat pada lapisan bening di bagian depan mata (kornea) mengalami kemunculan bercak keruh pada kornea akibat penumpukan kalsium selama pengobatan.

### **Melaporkan efek samping**

Jika Anda mengalami efek samping apa pun, konsultasikan dengan dokter, apoteker, atau perawat Anda. Termasuk setiap kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Dengan melaporkan efek samping, Anda bisa membantu memberikan informasi lebih lanjut mengenai keamanan obat ini.

### **13. Tanda-tanda dan gejala-gejala overdosis**

Jika Anda meneteskan terlalu banyak obat pada mata Anda, Anda mungkin akan mengalami iritasi ringan dan mata Anda dapat berair dan berubah kemerahan. Kondisi ini akan mereda, tetapi jika Anda khawatir silakan menghubungi dokter Anda untuk meminta saran.

Hubungi dokter Anda sesegera mungkin jika Anda tanpa sengaja menelan Xalatan®.

### **14. Apa yang harus dilakukan jika Anda menggunakan lebih dari dosis yang dianjurkan?**

Nama Generik: Latanoprost  
Nama Dagang: Xalatan®  
Tanggal Berlaku CDS: 25 Februari 2022  
Menggantikan: Tidak Ada  
Disetujui oleh BPOM: 2 Februari 2023

Jika terlihat tanda-tanda dan gejala-gejala overdosis, segera hubungi dokter Anda atau langsung datang ke unit gawat darurat di rumah sakit terdekat. Tunjukkan kepada mereka kemasan Xalatan®.

### **15. Bagaimana cara menyimpan obat ini?**

- Jauhkan obat ini dari pandangan dan jangkauan anak-anak.
- Jangan gunakan obat ini setelah melewati tanggal kedaluwarsa yang tertera pada kemasan luar dan label botol setelah tulisan EXP. Tanggal kedaluwarsa mengacu pada tanggal terakhir di bulan tersebut.
- Simpan botol yang belum dibuka di lemari pendingin pada suhu 2 °C hingga 8 °C (36 °F hingga 46 °F). Jauhkan dari cahaya.
- Setelah dibuka, obat harus digunakan dalam waktu 4 minggu dan dapat disimpan pada suhu ruang hingga 25 °C.

Jangan buang obat melalui saluran pembuangan air atau bersama sampah rumah tangga. Tanyakan kepada apoteker mengenai cara membuang obat yang sudah tidak digunakan lagi. Langkah-langkah ini akan membantu melindungi lingkungan.

### **16. Nomor Izin Edar**

Xalatan® Obat Tetes Mata 0,005%; Dus, botol plastik 2,5 ml No. Reg: DKI0186101046A1

### **17. Nama produsen/importir/Pemegang Hak Pemasaran**

#### **Diproduksi oleh:**

Pfizer Manufacturing Belgium NV/SA, Puurs, Belgium

#### **Diimpor oleh:**

PT Pfizer Indonesia  
Jakarta Indonesia

### **18. Tanggal revisi**

12/2022

### **19. Peringatan khusus**

**HARUS DENGAN RESEP DOKTER**