BAUSCH+LOMB
PART #/ SPEC: Trim Size (LxW) 22" x 5": 9739700 (L-500346 Pre-folded to 11"x5") / 9739800 (folded to 0.9375" x5")
DESCRIPTION: Insert Vyzulta Thailand JS504
SPECIAL INSTRUCTIONS: • DIELINE DOES NOT PRINT • PRINT PER SPECIFICATION • BARCODES VERIFIED
COLORS: BLACK PMS 186
PRINTED BARCODES MUST BE VERIFIED READABLE AND ACCURATE BY VENDOR TO THE HUMAN READABLE INDICATED ON ARTWORK.
BAUSCH+LOMB, 8500 HIDDEN RIVER PARKWAY, TAMPA, FL 33637 - 813-866-2485

เอกสารกำกับยาภาษาอังกฤษ

BAUSCH+LOMB

VYZULTA® 0.024%

FULL PRESCRIBING INFORMATION: CONTENTS

1. NAME OF THE MEDICINAL PRODUCT

VYZULTA 0.24 mg/mL topical ophthalmic solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL of solution contains 0.24 mg of latanoprostene bunod. For the full list of excipients, see section 6.1.

3. Pharmaceutical Form: Sterile topical ophthalmic solution

Clear and colorless to slightly yellow solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indication: VYZULTA (Latanoprostene bunod ophthalmic solution) 0.024% is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension (see section 5.1).

4.2 Posology and method of administration

Posology

Use in adults, including the elderly

The recommended dosage is one drop in the conjunctival sac of the affected eye(s) once daily in the evening. Do not administer VYZULTA (Latanoprostene bunod ophthalmic solution), 0.024% more than once daily since it has been shown that more frequent administration of prostaglandin analogs may lessen the intraocular pressure lowering effect.

Special populations

Pediatric Use

Use in pediatric patients aged 16 years and younger is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use.

Geriatric Use

No overall clinical differences in safety or effectiveness have been observed between elderly and other adult patients.

Method of administration

For ocular use.

Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye, surrounding structures, fingers, or any other surface in order to avoid contamination of the solution by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

Advise patients that if they develop a new ocular condition (e.g., trauma or infection), experience a sudden decrease in visual acuity, have ocular surgery, or develop any ocular reactions, particularly conjunctivitis and eyelid reactions, they should immediately seek their physician's advice concerning the continued use of VYZULTA.

If VYZULTA is to be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure, administer each drug product at least five (5) minutes apart.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warning and precautions for use

1. Pigmentation

VYZULTA (Latanoprostene bunod ophthalmic solution), 0.024% may cause changes to pigmented tissues. The most frequently reported changes with prostaglandin analogs have been increased pigmentation of the iris and periorbital tissue (eyelid).

Pigmentation is expected to increase as long as latanoprostene bunod ophthalmic solution is administered. The pigmentation change is due to increased melanin content in the melanocytes rather than to an increase in the number of melanocytes. After discontinuation of VYZULTA, pigmentation of the iris is likely to be permanent, while pigmentation of the periorbital tissue and eyelash changes are likely to be reversible in most patients. Patients who receive prostaglandin analogs, including VYZULTA, should be informed of the possibility of increased pigmentation, including permanent changes. The long-term effects of increased pigmentation are not known.

Iris color change may not be noticeable for several months to years. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery of the iris and the entire iris or parts of the iris become more brownish. Neither nevi nor freckles of the iris appear to be affected by treatment. While treatment with VYZULTA (Latanoprostene bunod ophthalmic solution), 0.024% can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.

Patients should be advised about the potential for increased brown pigmentation of the iris, which may be permanent. Patients should also be informed about the possibility of eyelid skin darkening, which is usually reversible after discontinuation of VYZULTA.

2. Eyelash Changes

VYZULTA may gradually change eyelashes and vellus hair in the treated eye. These changes include increased length, thickness, and the number of lashes or hairs. Eyelash changes are usually reversible upon discontinuation of treatment. Patients should also be informed of the possibility of eyelash and vellus hair changes in the treated eye during treatment with VYZULTA.

3. Intraocular Inflammation

VYZULTA should be used with caution in patients with a history of intraocular inflammation (iritis/uveitis) and should generally not be used in patients with active intraocular inflammation as it may exacerbate this condition.

4. Macular Edema

Macular edema, including cystoid macular edema, has been reported during treatment with prostaglandin analogs. VYZULTA should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

5. Bacterial Keratitis

There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface.

6. Use with Contact Lens

Contact lenses should be removed prior to the administration of VYZULTA because this product contains benzalkonium chloride. Lenses may be reinserted 15 minutes after administration.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no available human data for the use of VYZULTA during pregnancy to inform any drug associated risks. The background risk of major birth defects and miscarriage for the indicated population is unknown. However, the background risk in the U.S. general population of major birth defects is 2 to 4%, and of miscarriage is 15 to 20%, of clinically recognized pregnancies. Studies in animal have however shown reproductive toxicity (see section 5.3)

Breast-feeding

There are no data on the presence of VYZULTA in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for VYZULTA, and any potential adverse effects on the breastfed infant from VYZULTA.

Fertility

There are no available Fertility data for the use of VYZULTA (see section 5.3).

4.7 Effects on ability to drive and use machines

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

Summary of the safety profile

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

VYZULTA was evaluated in 811 patients in 2 controlled clinical trials of up to 12 months duration. The most common ocular adverse reactions observed in patients treated with latanoprostene bunod were: conjunctival hyperemia (6%), eye irritation (4%), eye pain (3%), and instillation site pain (2%).

Tabulated summary of adverse reactions

The adverse reactions listed in the table below were observed in clinical studies. They are ranked according to system organ class and classified according to the following convention: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000), very rare (<1/10,000) or not known (cannot be estimated from the available data). Within each frequency grouping, adverse reactions are presented in decreasing order of seriousness.

System organ class	Frequency	Adverse reactions
Eye disorders	Common	Eye pain
		Instillation site pain
		Eye irritation
		Conjunctival hyperemia
	Uncommon	Eye inflammation
		Macular oedema
		Bacterial keratitis
		Punctate keratitis
		Ocular hyperaemia
		Vision blurred
		Foreign body sensation in eyes
		Eyelash changes
		Conjunctival irritation
		Conjunctival oedema
		Iris hyperpigmentation
		Blepharal hyperpigmentation

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

4.9 Overdose

No overdose evaluation was conducted with latanoprostene bunod. Apart from ocular irritation and conjunctival or episcleral hyperemia, no other ocular side effects of latanoprost administered at high doses are known. If overdosage with VYZULTA occurs, treatment should be symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Ophthalmologicals; Antiglaucoma preparations and miotics, prostaglandin analogue, ATC code: S01EE06.

Mechanism of Action

Latanoprostene bunod is thought to lower intraocular pressure by increasing outflow of aqueous humor through both the trabecular meshwork and uveoscleral routes. Intraocular pressure is a major modifiable risk factor for glaucoma progression. Reduction of intraocular pressure reduces risk of glaucomatous visual field loss.

Pharmacodynamics effect

Reduction of the intraocular pressure starts approximately 1 to 3 hours after the first administration with the maximum effect reached after 11-13 hours in eyes with elevated intraocular pressure.

Clinical efficacy

In clinical studies up to 12 months duration, patients with open-angle glaucoma or ocular hypertension with average baseline intraocular pressures (IOPs) of 26.7 mmHg, the IOP-lowering effect of VYZULTA (latanoprostene bunod ophthalmic solution) 0.024% once daily (in the evening) was up to 7 to 9 mmHg.

5.2 Pharmacokinetic Properties

Absorption

The systemic exposure of latanoprostene bunod and its metabolites latanoprost acid and butanediol mononitrate were evaluated in one study with 22 healthy subjects after topical ocular administration of VYZULTA 0.024% once daily (one drop bilaterally in the morning) for 28 days. There were no quantifiable plasma concentrations of latanoprostene bunod (lower limit of quantitation, LLOQ, of 10.0 pg/mL) or butanediol mononitrate (LLOQ of 200 pg/mL) post-dose on Day 1 and Day 28. The mean maximal plasma concentrations (Cmax) of latanoprost acid (LLOQ of 30 pg/mL) were 59.1 pg/mL and 51.1 pg/mL on Day 1 and Day 28, respectively. The mean time of maximal plasma concentration (Tmax) for latanoprost acid was approximately 5 minutes post-administration on both Day 1 and Day 28.

Distribution

There were no ocular distribution studies performed in humans.

Metabolism

After topical ocular administration, latanoprostene bunod is rapidly metabolized in the eye to latanoprost acid (active moiety), an F2α prostaglandin analog, and butanediol mononitrate. After latanoprost acid reaches the systemic circulation, it is primarily metabolized by the liver to the 1,2-dinor and 1,2,3,4-tetranor metabolites via fatty acid β-oxidation.

Butanediol mononitrate is metabolized to 1,4-butanediol and nitric oxide. The metabolite 1,4-butanediol is further oxidized to succinic acid and enters the tricarboxylic acid (TCA) cycle.

Elimination

The elimination of latanoprost acid from human plasma is rapid as latanoprost acid plasma concentration dropped below the LLOQ (30 pg/mL) in the majority of subjects by 15 minutes following ocular administration of VYZULTA 0.024% in humans.

5.3 Preclinical Safety Data

Latanoprostene bunod was not mutagenic in bacteria and did not induce micronuclei formation in the *in vivo* rat bone marrow micronucleus assay. Chromosomal aberrations were observed *in vitro* with human lymphocytes in the absence of metabolic activation.

Latanoprostene bunod has not been tested for carcinogenic activity in long-term animal studies. Latanoprost acid is a main metabolite of latanoprostene bunod. Exposure of rats and mice to latanoprost acid, resulting from oral dosing with latanoprost in lifetime rodent bioassays, was not carcinogenic.

Fertility studies have not been conducted with latanoprostene bunod. The potential to impact fertility can be partially characterized by exposure to latanoprost acid, a common metabolite of both latanoprostene bunod and latanoprost. Latanoprost acid has not been found to have any effect on male or female fertility in animal studies.

Latanoprostene bunod has caused miscarriages, abortion, and fetal harm in rabbits. Latanoprostene bunod was shown to be abortifacient and teratogenic when administered intravenously (IV) to pregnant rabbits at exposures ≥ 0.28 times the clinical dose. Doses ≥ 20 mcg/kg/day (23 times the clinical dose) produced 100% embryofetal lethality. Structural abnormalities observed in rabbit fetuses included anomalies of the great vessels and aortic arch vessels, domed head, sternebral and vertebral skeletal anomalies, limb hyperextension and malrotation, abdominal distension and edema. Latanoprostene bunod was not teratogenic in the rat when administered IV at 150 mcg/kg/day (87 times the clinical dose).

Embryofetal studies were conducted in pregnant rabbits administered latanoprostene bunod daily by intravenous injection on gestation days 7 through 19, to target the period of organogenesis. The doses administered ranged from 0.24 to 80 mcg/kg/day. Abortion occurred at doses ≥ 0.24 mcg/kg/day latanoprostene bunod (0.28 times the clinical dose, on a body surface area basis, assuming 100% absorption). Embryofetal lethality (resorption) was increased in latanoprostene bunod treatment groups, as evidenced by increases in early resorptions at doses ≥ 0.24 mcg/kg/day and late resorptions at doses ≥ 6 mcg/kg/day (approximately 7 times the clinical dose). No fetuses survived in any rabbit pregnancy at doses of 20 mcg/kg/day (23 times the clinical dose) or greater.

Latanoprostene bunod produced structural abnormalities at doses ≥ 0.24 mcg/kg/day (0.28 times the clinical dose). Malformations included anomalies of sternum, coarctation of the aorta with pulmonary trunk dilation, retroesophageal subclavian artery with absent brachiocephalic artery, domed head, forepaw hyperextension and hindlimb malrotation, abdominal distention/edema, and missing/fused caudal vertebrae.

An embryofetal study was conducted in pregnant rats administered latanoprostene bunod daily by intravenous injection on gestation days 7 through 17, to target the period of organogenesis. The doses administered ranged from 150 to 1500 mcg/kg/day. Maternal toxicity was produced at 1500 mcg/kg/day (870 times the clinical dose, on a body surface area basis, assuming 100% absorption), as evidenced by reduced maternal weight gain. Embryofetal lethality (resorption and fetal death) and structural anomalies were produced at doses ≥ 300 mcg/kg/day (174 times the clinical dose). Malformations included anomalies of the sternum, domed head, forepaw hyperextension and hindlimb malrotation, vertebral anomalies and delayed ossification of distal limb bones. A no observed adverse effect level (NOAEL) was established at 150 mcg/kg/day (87 times the clinical dose) in this study.

A 9-month toxicology study administered topical ocular doses of latanoprostene bunod to one eye of cynomolgus monkeys: control (vehicle only), one drop of 0.024% bid, one drop of 0.04% bid and two drops of 0.04% per dose, bid. The systemic exposures are equivalent to 4.2-fold, 7.9-fold, and 13.5-fold the clinical dose, respectively, on a body surface area basis (assuming 100% absorption). Microscopic evaluation of the lungs after 9 months observed pleural/subpleural chronic fibrosis/inflammation in the 0.04% dose male groups, with increasing incidence and severity compared to controls. Lung toxicity was not observed at the 0.024% dose.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Preservative: benzalkonium chloride 0.2 mg/mL

Inactive ingredients: Polysorbate 80, Glycerin, Citric acid, Sodium citrate, EDTA, Water for injection

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

2 years for 2.5 mL fill size

3 years for 5 mL fill size

6.4 Special precautions for storage

Unopened bottle should be stored refrigerated at 2° to 8°C (36° to 46°F). Once a bottle is opened it may be stored at 2° to 25°C (36° to 77°F) for 8 weeks. During shipment, bottles may be maintained at temperatures up to 40°C (104°F) for a period not exceeding 14 days.

Protect from light. Protect from freezing.

6.5 Nature and contents of container

2.5 mL and 5 mL are supplied in low density polyethylene bottles with dropper tips and turquoise caps. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7. MARKETING AUTHORIZATION HOLDER

Manufactured by:

Bausch & Lomb Incorporated

8500 Hidden River Parkway, Tampa, FL 33637 USA

© 2021 Bausch & Lomb Incorporated or its affiliates

Imported by:

Bausch & Lomb (Thailand) Ltd.

Bangkok, Thailand

8. MARKETING AUTHORIZATION NUMBERS: 1C 15048/64 (NC)

9. DATE OF AUTHORIZATION/RENEWAL OF THE AUTHORIZATION: 18 June 2021

10. DATE OF REVISION OF THE TEXT Jul 2021

VYZULTA is a trademark of Bausch & Lomb Incorporated or its affiliates.

REGULATORY MUST ANSWER QUESTIONS BELOW BEFORE ARTWORK CAN BE FINALIZED:

DO PROPOSED CHANGES REQUIRE HEALTH AUTHORITY APPROVAL PRIOR TO IMPLEMENTATION WITH COMMERCIAL PRODUCT?

NO ☒ YES ☐

IF YES, PROVIDE TYPE OF FILING/VARIATION REQUIRED, STATUS OF FILING AND OTHER DETAILS IN THE COMMENT BOX BELOW.

COMMENTS:

6/3/2020
9/1/2021 RC
9/7/2021 RC
9/9/2021 RC - Thia PIL added
9/15/2021 RC
9/22/2021 RC
9/24/2021 RC
10/1/2021 RC
10/4/2021 RC

Quality Approval :

Chutima Thaksinayon
Digitally signed by Chutima Thaksinayon
DN: cn=Chutima Thaksinayon, o=Bausch and Lomb (Thailand) Ltd., ou=QA, email=Chutima.Thaksinayon@bausch.com, c=TH
Date: 2021.10.05 16:17:35 +07'00'

Marketing Approval :

WIPRONRAT ADJIMATERA
Digitally signed by WIPRONRAT ADJIMATERA
Date: 2021.10.06 15:44:01 +07'00'

Regulatory Approval :

Saengsai, Benya
Digitally signed by Saengsai, Benya
DN: dc=com, dc=bausch, dc=blasia, ou=THA, ou=Users, cn=Saengsai, Benya
Date: 2021.10.06 16:15:44 +07'00'

ลาทาโนพรอสทีน บูโนด
0.24 มิลลิกรัม/มิลลิลิตร
ชนิดน้ำยาหยอดตา
ชื่อการค้า VYZULTA® (ไวซัลต้า®)

1. ยานี้คือยาอะไร

1.1. ยานี้มีชื่อว่าอะไร

- ยานี้มีชื่อว่า ลาทาโนพรอสทีน บูโนด (Latanoprostene bunod) มีตัวยา 0.24 มิลลิกรัม/มิลลิลิตร

1.2. ยานี้ใช้เพื่ออะไร

- ยานี้ใช้สำหรับลดความดันลูกตา ในผู้ป่วยโรคต้อหินชนิดมุมเปิด หรือผู้ที่มีความดันลูกตาสูง

2. ข้อควรรู้ก่อนใช้ยา

2.1. ห้ามใช้ยานี้เมื่อไหร่

⊗ เคยแพ้ยานี้ หรือ ส่วนประกอบของยานี้

2.2. ข้อควรระวังเมื่อใช้ยานี้

- **ให้ปรึกษาแพทย์หรือเภสัชกรในกรณีต่อไปนี้**
  - ผู้ที่มีประวัติด้านตาหรือกำลังมีปัญหาด้านตา
  - หญิงตั้งท้องหรือให้นมลูก
  - เด็กอายุต่ำกว่า 16 ปี
- **ให้ถอดเลนส์สัมผัสก่อนหยอดยา**

3. วิธีใช้ยา

3.1. ขนาดและวิธีใช้

- **ควรใช้ยาตามคำแนะนำของแพทย์หรือเภสัชกรเท่านั้น** เพราะขนาดและระยะเวลาในการใช้ยานี้ ขึ้นกับชนิดและความรุนแรงของโรค
- ล้างมือให้สะอาด เปิดฝาครอบขวดยา ออก วางบนพื้นราบที่สะอาดโดยให้ฝาหงายขึ้น และไม่ให้ขอบฝาสัมผัสกับมือ
- นอนหงาย หรือนั่งเงยหน้าขึ้น
- ใช้มือข้างที่ถนัดถือขวดยา แล้วหยอดยา 1 หยด บริเวณถุงเยื่อบุตา ข้างที่เป็น วันละครั้ง ในตอนเย็น หรือตามคำสั่งของแพทย์
- ระวังไม่ให้ปลายหลอดสัมผัสกับตา ขนตา เปลือกตา มือ หรือสิ่งใดๆ
- ถ้าต้องใช้ยาหยอดตา 2 ชนิดขึ้นไป ควรเว้นระยะห่างในการหยอดยาแต่ละชนิดประมาณ 5 นาที
- ถ้ายาอีกชนิดเป็นยาป้ายตา ให้ใช้ยาหยอดตาก่อน และรอประมาณ 10 นาที จึงใช้ยาป้ายตา

3.2. หากลืมหยอดยาควรทำอย่างไร

- ปรึกษาแพทย์หรือเภสัชกรเมื่อลืมใช้ยานี้

3.3. ถ้าใช้ยานี้เกินขนาดที่แนะนำควรทำอย่างไร

- ให้สังเกตอาการอย่างใกล้ชิด หากมีอาการผิดปกติที่รุนแรง ให้รีบนำส่งโรงพยาบาลทันที และนำยาไปด้วย

4. ข้อควรปฏิบัติระหว่างใช้ยา

- การใช้ยาหยอดตาอาจทำให้ตาพร่า ดังนั้น ไม่ควรขับรถหรือทำงานที่เสี่ยงต่ออันตราย จนกว่าตาจะมองเห็นได้ชัดเจนตามปกติ

5. อันตรายที่อาจเกิดจากยา

5.1. อาการที่ต้องหยุดยาแล้วรีบไปพบแพทย์ทันที

- ลมพิษ บวมที่ใบหน้า เปลือกตา ริมฝีปาก
- หน้ามืด เป็นลม แน่นหน้าอก หายใจลำบาก
- ผื่นแดง ตุ่มพอง ผิวหนังหลุดลอก มีจ้ำตามผิวหนังหรือเลือดออกผิดปกติ

"ให้หยุดยาแล้วรีบไปพบแพทย์ทันที"

5.2. อาการที่ไม่จำเป็นต้องหยุดยา แต่ถ้ามีอาการรุนแรง ให้ไปพบแพทย์ทันที

- เม็ดสีของม่านตาเข้มขึ้น
- ขนตายาวขึ้น หนาขึ้น และมีปริมาณมากขึ้น
- การอักเสบของตา
- อาการบวมน้ำที่จอประสาทตา
- ตาบวม ปวดตา ตาอักเสบ ติดเชื้อ การมองเห็นผิดปกติ ภาวะเลือดคั่งของเส้นเลือดที่เยื่อบุตา
- การระคายเคืองตา
- อาการปวดตา
- ปวดบริเวณที่ปลูกถ่าย

"ไม่จำเป็นต้องหยุดยา แต่ถ้ามีอาการรุนแรง ให้ไปพบแพทย์"

6. ควรเก็บยานี้อย่างไร

- เก็บในบรรจุภัณฑ์เดิมตามที่ได้รับมา ป้องกันแสง
- กรณีที่ยังไม่เปิดขวดยา ให้เก็บในตู้เย็นช่องธรรมดา ที่อุณหภูมิ 2 - 8 องศาเซลเซียส
- กรณีที่เปิดขวดยา ให้เก็บยาที่อุณหภูมิ 2 - 25 องศาเซลเซียส ได้นาน 8 สัปดาห์
- ห้ามแช่แข็ง
- เก็บยาให้พ้นมือเด็ก

7. ลักษณะและส่วนประกอบของยานี้

- **ลักษณะยา:** น้ำยาปราศจากเชื้อสำหรับหยอดตา
- **ตัวยาสำคัญ**: ลาทาโนพรอสทีน บูโนด
- **ส่วนประกอบอื่นๆ** ได้แก่ benzalkonium chloride, polysorbate 80, glycerin, edetate disodium dihydrate, sodium citrate dihydrate, citric acid และ water for injection

ผู้ผลิต: บอช แอนด์ ลอมบ์ อินคอร์เปอเรต สหรัฐอเมริกา

ผู้รับอนุญาต: บริษัท บอช แอนด์ ลอมบ์ (ประเทศไทย) จำกัด กรุงเทพมหานคร

เอกสารนี้ปรับปรุงครั้งล่าสุดเมื่อ มี.ค. 2564

ศึกษาข้อมูลยาเพิ่มเติมทางเว็บไซต์ของ อย.
http://www.fda.moph.go.th/sites/oss/Pages/Main.aspx
http://ndi.fda.moph.go.th

เอกสารนี้เป็นข้อมูลโดยย่อ หากมีข้อสงสัย ให้ปรึกษาแพทย์หรือเภสัชกร

3742

9739700 (11"x5")
9739800 (0.937"x5")
Trim Size (LxW) 22" x 5"

Digitally signed by Karagate Kominta
Date: 2021.10.06 19:21:00 +07'00'

BAUSCH+LOMB
PART #/ SPEC: Trim Size (LxW) 22" x 5": 9739700 (L-500346 Pre-folded to 11"x5") / 9739800 (folded to 0.937"x5")
DESCRIPTION: Insert Vyzulta Thailand J5504
SPECIAL INSTRUCTIONS: • DIELINE DOES NOT PRINT
COLORS: BLACK PMS 186 • PRINT PER SPECIFICATION • BARCODES VERIFIED
PRINTED BARCODES MUST BE VERIFIED READABLE AND ACCURATE BY VENDOR TO THE HUMAN READABLE INDICATED ON ARTWORK.
BAUSCH+LOMB, 8500 HIDDEN RIVER PARKWAY, TAMPA, FL 33637 - 813-866-2485