



National Agency for Food & Drug Administration & Control (NAFDAC)

NAFDAC Public Assessment Report (NAPAR)

Latanoprost 0.005 w/v eye drops

Latanoprost 0.005 w/v

A4-102226

Wild Eagle Healthcare Limited

This report reflects the scientific assessment for the approval of Latanoprost eye drops. The product was licenced in June 2026.

PART 1: ABSTRACT

Latanoprost eye drop, manufactured at Scott-Edil Pharmacia Limited, Baddi, Solan (H.P.), India, was granted marketing authorization by NAFDAC for the treatment of treatment of glaucoma on 30 June 2026.

Latanoprost eye drop is indicated for treatment of glaucoma.

For details on the uses of this product and for side effects and warnings, see the summary of product characteristics (SmPC), which can be found in the NAFDAC Greenbook.

The marketing authorization of Latanoprost by NAFDAC is based on the review of the Common Technical Document (CTD) dossier submitted to ascertain the quality, safety, and efficacy.

All accepted presentations of Latanoprost have been shown in part 2 of this report. The summary of product characteristics (SmPC) and the approved labelling have been presented in part 3 and part 4 respectively.

Scientific discussion on the quality, non-clinical and clinical aspects of Latanoprost has been presented in part 5 of this report.

The detailed steps taken to approve Latanoprost by NAFDAC have been presented in part 6 of this report.

No action or steps have been taken following the marketing authorization of Latanoprost eye drop.

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Latanoprost eye drop	Latanoprost 0.005 w/v/	Eye drop Colourless eye drop packed in 2.5 mL plastic bottle	2.5 mL pet bottle Available as 1 x 2.5 mL	1 x 2.5 mL bottle

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

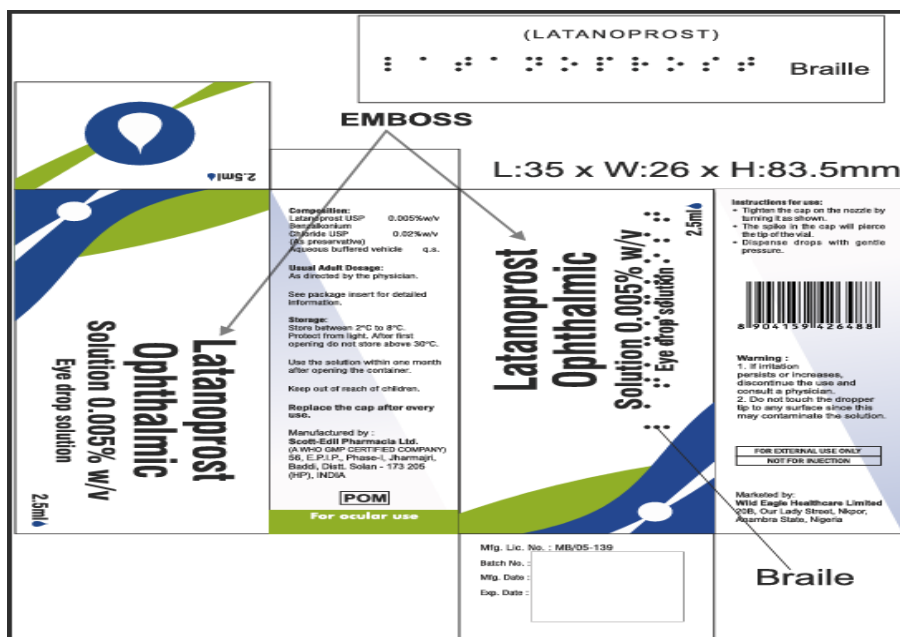
See: <https://greenbook.nafdac.gov.ng/>

PART 4: LABELLING

Primary label



Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Latanoprost 0.005 w/v Eye Drop

5.1.2 Therapeutic indication

Latanoprost eye drop is indicated for treatment of glaucoma.

5.1.3 Applicant

Wild Eagle Healthcare Limited, No 20b Our Lady Street, Nkpor Anambra State Nigeria.

5.1.4 Pharmaceutical form

Eye drop

Colourless eye drop packed in 2.5 mL plastic bottle.

5.1.5 Storage

Store between 2° to 8°C. Protect from light.

After first opening the bottle, do not store above 25°C and use within four weeks.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Colourless eye drop packed in 2.5 mL plastic bottle

5.2 Drug Substance

5.2.1 Manufacturer

Latanoprost is manufactured by Flax Laboratories Private Limited, B-29/1, MIDC Mahad, Birvadi village, Dist:-Raigad, Maharashtra, India-402301.

The API specifications are pharmacopoeial based.

Stability testing was conducted according to the requirements of NAFDAC. The proposed re-test period is justified based on the stability results when the API is stored in line with the storage statement.

5.3 Other ingredients

Other ingredients used in the formulation of latanoprost eye drops include sodium chloride, sodium dihydrogen phosphate, disodium hydrogen phosphate, hydroxypropyl betadex, benzalkonium chloride solution, water for injection all being pharmacopoeial controlled. None of the excipients are derived from human or animal origin.

5.4 Drug Product

5.4.1 Drug product manufacturer

Scott-Edil Pharmacia Ltd, 56, EPIP, Phase-I Jharmajri, Baddi, Distt. Solan (H.P.), 173205 India.

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development is to manufacture a generic which is stable, deliver the intended performance, safe and bioequivalent in terms of efficacy to the reference product, Xalatan, manufactured by Pfizer.

The manufacturing method employed was the aseptic solution compounding method, involving material dispensing and verification, dissolution of ingredients in water for injection, in-process quality control, pH adjustment, and before release for aseptic filling.

5.4.3 Specification

The finished product specification is based on pharmacopoeial. The finished product specifications include description, identification (by hplc), average fill volume, pH (between 6.4 to 7.0), particulate matter, sterility test & assay. The test procedures have been adequately validated.

5.4.4 Stability

Stability studies have been conducted at 30°C/75%RH at long-term storage conditions and for six months at accelerated conditions in the packaging intended for marketing the product. The product proved to be quite stable in these conditions, with no apparent negative trend. Based on the data submitted, the proposed shelf life of 36 months and 'Store between 2° to 8°C. Protect from light. After first opening the vial: do not store above 25°C and use within four weeks' have been accepted.

5.6 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of Latanoprost eye drop was acceptable for the following indication: 'treatment of glaucoma', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Wild Eagle Healthcare Limited, No. 20b Our Lady Street, Nkpor Anambra State Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Latanoprost eye drop.

The following are the steps for registration

October 2025	Date of receipt of application
June 2025	Date of conclusion of assessment
May 2026	Date of inspection
30 June 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Latanoprost eye drop.