



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

Public Assessment Report (PAR)

Xolamol ophthalmic solution

Dorzolamide hydrochloride/timolol maleate 2%/0.5% w/v

A4-102359

Assene-Laborex Limited

This report reflects the scientific assessment for the approval of Xolamol ophthalmic solution. The product was licenced in July 2026.

PART 1: ABSTRACT

Xolamol ophthalmic solution containing dorzolamide hydrochloride and timolol maleate, manufactured at Jamjoon Pharmaceutical Company, Jeddah, Makkah Province, Saudi Arabia, was granted marketing authorization by NAFDAC for the treatment of glaucoma on 28 July 2026.

Xolamol is indicated for the treatment of elevated intraocular pressure in patients with open-angle 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 xolamol 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 xolamol 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 xolamol have been presented in Part 5 of this report.

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

No action or steps have been taken following the marketing authorization of xolamol ophthalmic solution.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Xolamol ophthalmic solution	Dorzolamide hydrochloride/d timolol maleate 2%w/v/0.5% w/v	Ophthalmic solution Clear, colourless, slightly viscous solution, free from particulate matter, filled in a 5 mL opaque plastic bottle	5 mL opaque plastic (HDPE) bottle with a transparent plastic (LDPE) nozzle and HDPE cap	1 x 5 mL

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

Xolamol ophthalmic solution

5.1.2 Therapeutic indication

Xolamol ophthalmic solution is indicated for the treatment of elevated intraocular pressure in patients with open-angle glaucoma.

5.1.3 Applicant

Assene-Laborex Limited, 7c Creek Road Apapa, Lagos.

5.1.4 Pharmaceutical form

Ophthalmic solution

A clear, colourless, slightly viscous solution, free from particulate matter.

5.1.5 Storage

Do not store above 30°C, store in the original packaging.

5.1.6 Shelf life

24 months

5.1.7 Product presentation

5 mL opaque plastic (HDPE) bottle with a transparent plastic (LDPE) nozzle and HDPE cap.

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredients, dorzolamide hydrochloride & timolol maleate, are manufactured by Hetero Drugs Limited, Survey Nos. 123, 214 & 255, Bonthapally Mandal, Sangareddy District, Telangana, India, and FDC Limited, Plot Nos. 19 & 20/2, Maharashtra Industrial Development Corporation Industrial Area, Village Dhatay, Roha – 402166, District Raigad, Maharashtra State, India, respectively.

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 xolamol ophthalmic solution include: benzalkonium chloride, sodium citrate, mannitol, hydroxyethylcellulose, sodium hydroxide and 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

Jamjoom Pharmaceutical Company, Plot No. ME1:3, Phase 5, Industrial City, Post Office Box 6267, Jeddah 21442, Saudi Arabia.

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development is to manufacture a generic which is stable, delivers the intended performance, and is safe in terms of efficacy to the reference product, Cosopt® ophthalmic solution, currently licensed by Merck Sharp & Dohme.

The manufacturing method used was dissolution, filtration and sterilization. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on in-house standard. The finished product specifications include identification, particulate matter, sterility, pH, osmolarity, assay, individual unspecified impurity, and total impurities. The test procedures have been adequately validated.

5.4.4 Stability

Stability studies have been conducted at 30°C/75%RH as long-term storage conditions and for six months at accelerated conditions in the packaging intended for marketing of 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 24 months and ‘Do not store above 30°C, store in the original packaging’ have been accepted.

5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of xolamol ophthalmic solution was acceptable for the following indication: ‘for the treatment of elevated intraocular pressure in patients with open-angle glaucoma’ and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Assene-Laborex Limited, 7c Creek Road Apapa, Lagos, submitted an application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of xolamol ophthalmic solution.

The following are the steps for the registration of xolamol ophthalmic solution

September 2024	Date of receipt of application
September 2025	Date of conclusion of assessment
February 2025	Date of inspection
28 July 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Xolamol ophthalmic solution.