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

Public Assessment Report (PAR)

Ganfort eye drop

Bimatoprost/timolol maleate 0.3 mg/ 5 mg

A4-101504

Pharaon Healthcare Nigeria Limited

This report reflects the scientific assessment for the approval of Ganfort eye drop**.** The product was licenced in August 2025.

PART 1: ABSTRACT

Ganfort a fixed dose combination of bimatoprost and timolol, manufactured at Allergan Pharmaceuticals, Westport County Mayo, Ireland was granted marketing authorization by NAFDAC for the treatment of intraocular pressure in adults on 27 August 2025.

Ganfort is indicated for the reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.

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 Ganfort 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 Ganfort 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 and clinical aspects of Ganfort has been presented in part 5 of this report.

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

No action or steps have been taken following the marketing authorization of Ganfort.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Ganfort eye drop	bimatoprost / timolol 0.3 mg/5 mg/mL	eyedrop Colourless to slightly yellow solution	Clear, single-dose low density polyethylene (LDPE) containers with a twist-off tab	1 x 3 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

Ganfort a fixed dose combination of bimatoprost and timolol 0.3 mg/5 mg/mL eye drop.

5.1.2 Therapeutic indication

Ganfort is indicated for the reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.

5.1.3 Manufacturer/applicant

Manufactured by Allergan Pharmaceuticals, Westport County Mayo, Ireland. Loal representative is Pharaon Healthcare Nigeria Limited, 36, Turnbull Road, Ikoyi, Lagos Nigeria.

5.1.4 Pharmaceutical form

Ophthalmic solution

Colourless to slightly yellow solution

5.1.5 Storage

Do not store above 30°C

5.1.6 Shelf life

24 months

5.1.7 Product presentation

Clear, single-dose low density polyethylene (LDPE) containers with a twist-off tab.

5.2 Drug Substance

5.2.1 Manufacturer

Piramal Healthcare (Canada) Limited, 110 Industrial Parkway North, Aurora, Ontario, Canada.

The API specifications include tests for description, identification (IR and HPLC), assay, related compounds, water content, residual solvents, residue on ignition, optical rotation, bacterial endotoxin and microbial enumeration test.

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 Ganfort include benzalkonium chloride, citric acid monohydrate, dibasic sodium phosphate heptahydrate, sodium chloride, hydrochloric acid, sodium hydroxide and purified water all being controlled by acceptable specifications.

5.4 Drug Product

5.4.1 Drug product manufacturer

Allergan Pharmaceuticals Ireland, Castlebar Road, Westport, County Mayo, Ireland

5.4.2 Pharmaceutical development

The development pharmaceutics of the combination product (Ganfort) is based on the chemistry of the approved Lumigan® and generic timolol 0.5% ophthalmic solution. The formulation development goal was to formulate 0.03% w/v bimatoprost and 0.5% w/v timolol into a safe, effective and stable ophthalmic solution.

5.4.3 Specification

The finished product specification is based on pharmacopoeial and in-house methods. The finished product specifications include identification, description, pH, sterility, osmolarity, particulate matter, 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 at 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’ have been accepted.

5.5 Conclusion

Based on the assessment of data on quality, safety and efficacy, the benefit–risk profile of Ganfort was acceptable for the following indication: 'reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The manufacturer, Allergan Pharmaceuticals Ireland, Castlebar Road, Westport, County Mayo, Ireland, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Ganfort.

The following are the steps for the registration of Ganfort

April 2025	Date of receipt of application
June 2025	Date of conclusion of assessment
July 2025	Date of inspection
27 August 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Ganfort.