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

Public Assessment Report (PAR)

Kaytears 0.3% w/v ophthalmic solution

Hypromellose USP 0.3% w/v

A4-101871

Kayhelt Pharma Limited

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

PART 1: ABSTRACT

Kaytears ophthalmic solution containing hypromellose, manufactured at Ciron Drugs & Pharmaceuticals Private Limited, Tarapur, Maharashtra, India, was granted marketing authorization by NAFDAC for the immediate relief of dry eye conditions on 27 January 2026.

Kaytears ophthalmic solution is indicated for the immediate relief of dry eye conditions caused by environmental or clinical factors.

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 Kaytears ophthalmic solution 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 Kaytears ophthalmic solution 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 Kaytears ophthalmic solution has been presented in Part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Kaytears 0.3% w/v ophthalmic solution	Hypromellose USP 0.3% w/v	Ophthalmic solution (eye drops); a clear, colourless, viscous, liquid, filled in a 10 mL white lupolene bottle.	10 mL white lupolene bottle with nozzle & white dual-resealable cap.	1 x 10 mL

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

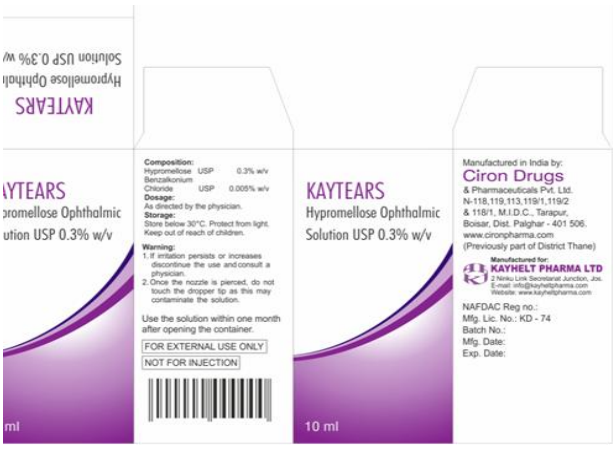
Refer to the NAFDAC Greenbook URL below for the SmPC

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

Kaytears 0.3% w/v ophthalmic solution

5.1.2 Therapeutic indication

Kaytears ophthalmic solution is indicated for the immediate relief of dry eye conditions caused by environmental or clinical factors.

5.1.3 Applicant

Kayhelt Pharma Limited, 2, Ninku link, secretariat Junction, Jos, Plateau State, Nigeria.

5.1.4 Pharmaceutical form

A clear, colourless, viscous liquid, filled in a 10 mL white lupolene bottle.

5.1.5 Storage

Do not store above 30°C. Protect from sunlight.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Kaytears ophthalmic solution is presented as a 10 mL white lupolene bottle with nozzle & white dual-resealable cap containing a clear, colourless, viscous liquid, and packed in a printed mono carton.

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, hypromellose USP, is manufactured by Lotte Fine Chemicals, 129B 4L, Namdong industrial complex, 47, Namdong-daero 79 beon-gil, Namdong–gu, Incheon, Korea

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 Kaytears ophthalmic solution include: benzalkonium chloride USP, sodium chloride USP, potassium chloride USP, calcium chloride USP, magnesium chloride USP, sodium acetate USP, sodium citrate USP, glycerin USP, sodium hydroxide solution (0.1M) USP, hydrochloric acid solution (0.1 N) USP and water for injection USP, 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

Ciron Drugs & Pharmaceuticals Private Limited N-118, 118/1, 119, Midc, Tarapur, Boisar, Palghar - 401506, Maharashtra, India.

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, Benecel® ophthalmic solution, currently licensed by Ashland Limited.

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

5.4.3 Specification

The finished product specification is based on USP monograph and in-house standards. The finished product specifications include identification by chemical tests, sterility, average filled volume, leakage test, acidity (pH) and assay. 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 36 months and 'Do not store above 30°C, protect from sunlight' have been accepted.

5.5 Conclusion

Based on the assessment of data on quality, safety and efficacy, the benefit–risk profile of Kaytears ophthalmic solution was acceptable for the following indication: 'for the immediate relief of dry eye conditions caused by environmental or clinical factors' and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Kayhelt Pharma Limited, 2, Ninku Link, Secretariat Junction, Jos, Plateau State, Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Kaytears ophthalmic solution.

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

May 2025	Date of receipt of application
January 2026	Date of conclusion of assessment
November 2024	Date of inspection
27 January 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

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