



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

NAFDAC Public Assessment Report (NAPAR)

Fluconazole 200 mg capsules

Fluconazole 200 mg

A4-102071

Jeksam Pharmaceutical Company Limited

This report reflects the scientific assessment for the approval of Fluconazole 200 mg capsules. The product was licenced in April 2026.

PART 1: ABSTRACT

Fluconazole capsules, manufactured at AR Lifesciences, Gandhinagar, Gujarat, India, was granted marketing authorization by NAFDAC for the treatment of susceptible fungal infections on 28 April 2026.

Fluconazole is indicated for the treatment of susceptible fungal infections, including candidiasis and cryptococcal meningitis.

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 fluconazole capsules 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 fluconazole 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 fluconazole capsules have been presented in part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Fluconazole 200 mg capsules	Fluconazole 200 mg	Hard gelatin capsule Hard gelatin capsules with an opaque red cap and opaque white body. They contained white powder.	Aluminum foil blister cards, each containing 10 capsules. Available in cartons of 1 x 10 capsules.	1 x 10 capsules

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

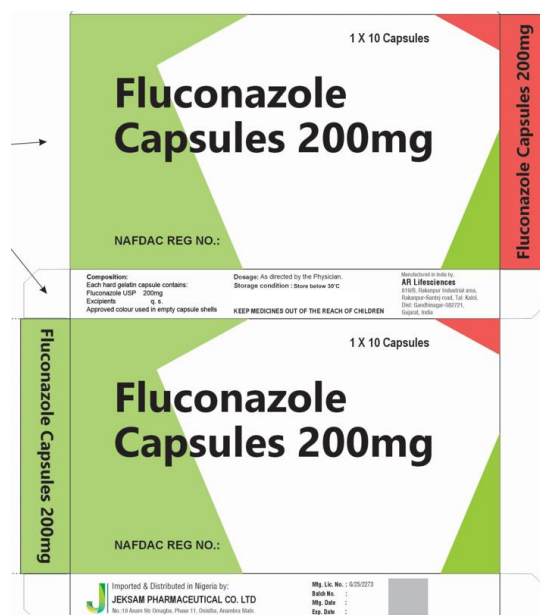
See: <https://greenbook.nafdac.gov.ng/>

PART 4: LABELLING

Primary label



Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Fluconazole 200 mg capsules

5.1.2 Therapeutic indication

Fluconazole capsule is indicated for the treatment of susceptible fungal infections, including candidiasis and cryptococcal meningitis.

5.1.3 Applicant

Jeksam Pharmaceutical Company Limited, No. 19 Anam Street, Omagba, Phase II, Onitsha, Anambra State.

5.1.4 Pharmaceutical form

Hard gelatin capsule

Hard gelatin capsules with an opaque red cap and opaque white body. They contained white powder.

5.1.5 Storage

Do not store above 30°C, protect from light and moisture.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Aluminum foil blister cards, each containing 10 capsules. Available in cartons of 1 x 10 capsules

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, fluconazole, is manufactured by Endoc Pharma, Plot Nos. 4 to 7, Survey No. 53, behind Saurashtra Paper Board Mill, Shapar-Veraval Industrial Area, Shapar, Taluka: Kotada Sanghani, District Rajkot, Gujarat, India.

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 fluconazole capsules include maize starch, dibasic calcium phosphate, sodium lauryl sulphate, aerosil, talcum and empty hard gelatin capsule size '2' red/white, all being pharmacopoeial controlled except the latter, which is in-house controlled.

None of the excipients are derived from human or animal origin.

5.4 Drug Product

5.4.1 Drug product manufacturer

AR Lifesciences 819/b Rakanpur Industrial Area, Taluka Kalol, District Gandhinagar, Gujarat, 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 Diflucan® 200 mg capsules currently licensed by Pfizer Australia Proprietary Limited.

The manufacturing method used was granulation, blending, and capsule filling. Comparative dissolution profile was conducted in line with ICH M9 guidelines between the reference product, Diflucan® 200 mg capsules (Pfizer Australia Proprietary Limited) and fluconazole 200 mg capsules. The profile in the three BCS media is similar.

5.4.3 Specification

The finished product specification is based on the USP monograph. The finished product specifications include identification, assay, dissolution and impurities. The test procedures have been adequately validated.

5.4.4 Stability

Stability studies have been conducted at 30°C/75% RH 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 'Do not store above 30°C, protect from light and moisture' have been accepted.

5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of fluconazole capsule was acceptable for the following indication: 'for the treatment of susceptible fungal infections, including candidiasis and cryptococcal meningitis' and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Jeksam Pharmaceutical Company Limited, No. 19 Anam Street, Omagba, Phase II, Onitsha, Anambra State, submitted an application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of fluconazole capsules.

The following are the steps for registration

August 2025	Date of receipt of application
April 2026	Date of conclusion of assessment
March 2026	Date of inspection
28 April 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

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