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

## Public Assessment Report (PAR)

Fexomal 75 mg/ mL injection

Alpha beta Arteether injection

A4-101461

Fexona Pharmaceutical Company Limited

This report reflects the scientific assessment for the approval of Alpha beta Arteether injection**.** The product was licenced in August 2025.

## PART 1: ABSTRACT

Fexomal injection, manufactured at Zee Laboratories Limited, Paonta Sahib, India, was granted marketing authorization by NAFDAC for the treatment of malaria on 27 August 2025.

Fexomal injection is indicated for the treatment of chloroquine resistant plasmodium falciparum malaria and cerebral malaria cases.

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 Fexomal injection 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 Alpha beta Arteether injection 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 Alpha beta Arteether injection has been presented in Part 5 of this report.

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

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

## PART 2: ACCEPTED PRESENTATIONS

| Product Name | Active Ingredients | Pharmaceutical Form/Description | Packaging | Pack size |
|---|---|---|---|---|
| Fexomal injection | Alpha - beta Arteether | Liquid<br><br>Yellow colour oily solution filled in amber glass ampoule | amber glass ampoule | 3 ampoules x 1 mL |

## PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

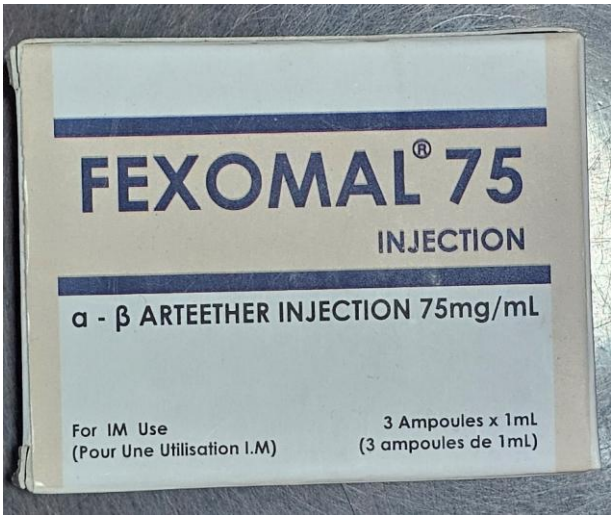
See: https://greenbook.nafdac.gov.ng/

## PART 4: LABELLING

Commented [N1]: Applicant is requested to include the photo of the primary (i.e the ampoule) and the secondary (i.e the outer carton) labels in part 4

Primary label


Secondary label



## PART 5: SCIENTIFIC DISCUSSION

### 5.1. About the Product

#### 5.1.1 Name of the product

Fexomal Injection

#### 5.1.2 Therapeutic indication

Fexomal injection is indicated in the treatment of chloroquine resistant plasmodium falciparum malaria and cerebral malaria cases.

#### 5.1.3 Manufacturer/applicant

Manufactured by Zee Laboratories Limited, 47, Industrial Area, Paonta Sahib-173025, India. The local representative is Fexona Pharmaceutical Company Limited, 19, Akinlawon Street, Ijesha Surulere, Lagos, Nigeria.

#### 5.1.4 Pharmaceutical form

Liquid

Yellow colour oily solution. Available as 3 ampoules x 1mL

#### 5.1.5 Storage

Store below $30^0$C. Protect from light and moisture.

#### 5.1.6 Shelf life

36 months

#### 5.1.7 Product presentation

Fexomal injection is a yellow colour oily solution filled in 1 mL amber glass ampoule, in 3 ampoules x 1 mL per pack.

### 5.2 Drug Substance

#### 5.2.1 Manufacturer

The active pharmaceutical ingredient is manufactured by Triveni Interchem Private Limited, 134, Panchatantra, Char Rasta, G.I.D.C., Vapi - 396195, Gujarat, India.

The API specifications are pharmacopeial 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

Ethyl Oleate, benzyl alcohol, butylated hydroxy, toluene butylated, hydroxy anisole and propyl gallate.

### 5.4 Drug Product

#### 5.4.1 Drug product manufacturer

Zee Laboratories Limited. Behind 47, Industrial Area, Paonta Sahib-173025, India.

### 5.4.2 Pharmaceutical development

The objective is to develop a safe, effective, and stable parenteral formulation of Fexomal injection that delivers the required therapeutic activity against chloroquine resistant plasmodium falciparum malaria and cerebral malaria cases.

The manufacturing method used involved, yield optimization and suitability of scale – up to commercial production. All the manufacturing processes were validated.

### 5.4.3 Specification

The finished product specification is based on pharmacopoeia. The finished product specification includes description Description, Identification, extractable volume, Particulate matter, BET, sterility test, 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 'Store below 30°C. Protect from light. Store in the original package'. Have been accepted.

### 5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of Fexomal injection was acceptable for the following indication: 'for the treatment chloroquine resistant plasmodium falciparum malaria and cerebral malaria cases and is included in the list of approved medicinal products by NAFDAC.

## PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Fexona Pharmaceutical Company Limited, 19, Akinlawon Street, Ijesha Surulere, Lagos, Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Fexomal injection.

The following are the steps for the registration of Fexomal injection

| | |
|---|---|
| December 2023 | Date of receipt of application |
| April 2025 | Date of conclusion of assessment |
| June 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 Fexomal injection.