



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

## **Public Assessment Report (PAR)**

### **Ndosol-N eye/ear drops**

### **Betamethasone sodium phosphate/ neomycin sulphate 0.1%/0.5%**

**A4-101510**

**Ndozz Pharmaceutical Nigeria Limited**

This report reflects the scientific assessment for the approval of NDOSOL-N eye/ear drops. The product was licenced in August 2025.

## PART 1: ABSTRACT

Ndosol-N a fixed dose combination of Betamethasone sodium phosphate and Neomycin sulphate, manufactured at Alpa Laboratories Limited, Pigdamber, Indore (MP)-India, was granted marketing authorization by NAFDAC for the treatment of inflammatory conditions and bacterial infection of the eye and outer ear on 27 August 2025.

Ndosol-N eye/ear drops is indicated for short-term treatment of inflammatory conditions of the eye and outer ear where a bacterial infection is also present or suspected.

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 Ndosol-N eye/ear drops 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 Ndosol-N eye/ear drops 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 NDOSOL-N eye/ear drops has been presented in Part 5 of this report.

The detailed steps taken to approve Ndosol-N eye/ear drops by NAFDAC have been presented in Part 6 of this report.

No action or steps have been taken following the marketing authorization of Ndosol-N eye/ear drops.

## PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Ndosol-N eye/ear drops	Betamethasone sodium phosphate /neomycin sulphate 0.1%/0.5%	solution A clear colourless solution filled in 10 mL white plastic container with white sealed screw capped.	10 mL white plastic container with white sealed screw capped.	1x10 mL plastic bottle.

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

Refer to the NAFDAC Greenbook URL below for the SmPC

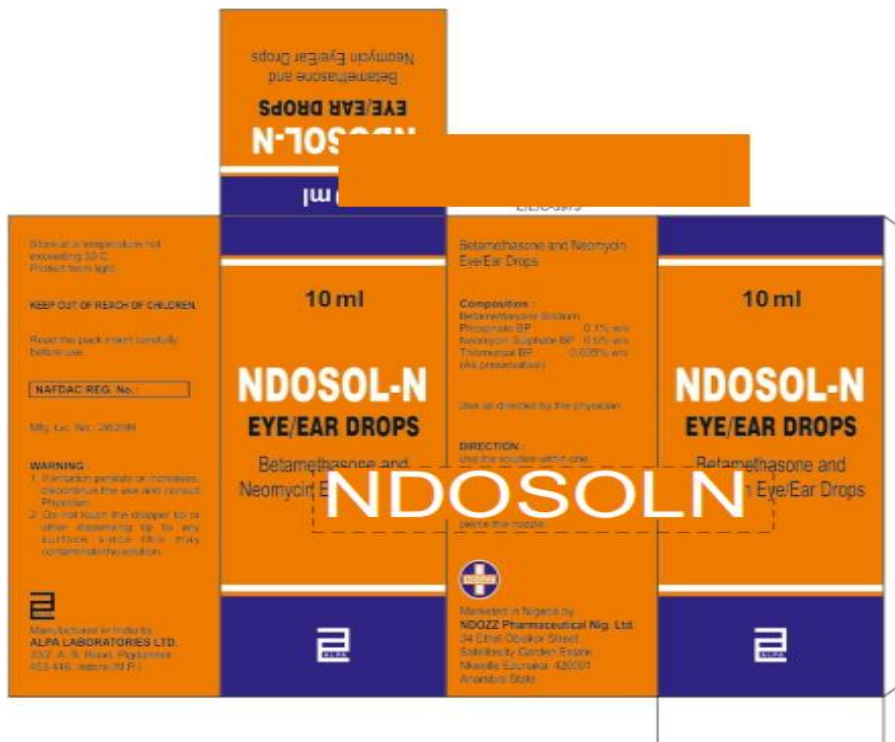
See: <https://greenbook.nafdac.gov.ng/>

### PART 4: LABELLING

#### Primary label



#### Secondary label



## **PART 5: SCIENTIFIC DISCUSSION**

### **5.1. About the Product**

#### **5.1.1 Name of the product**

Ndosol-N eye/ear drops

#### **5.1.2 Therapeutic indication**

Ndosol-N eye/ear drops is indicated for short-term treatment of inflammatory conditions of the eye and outer ear where a bacterial infection is also present or suspected.

#### **5.1.3 Manufacturer/applicant**

Ndozz Pharmaceutical Nigeria Limited, No 34, Ethel Obiakor Street, Satelite City Garden Estate, Nkwelle Ezunaka, Anambra State, Nigeria.

#### **5.1.4 Pharmaceutical form**

Solution

A clear colourless solution filled in 10 mL white plastic container with white sealed screw capped.

#### **5.1.5 Storage**

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

#### **5.1.6 Shelf life**

36 months

#### **5.1.7 Product presentation**

Ndosol-N eye/ear drops is a clear colourless solution filled in 10 mL white plastic container with white sealed screw capped in 1x10 mL plastic bottle per pack.

### **5.2 Drug Substance**

#### **5.2.1 Manufacturer**

Betamethasone Sodium Phosphate BP is manufactured by Anuh Pharma Limited, Plot No. D-5/8 & 5/9, T.T.C. Industrial Area, M.I.D.C., Turbhe, Navi Mumbai- 400703, 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**

Other ingredients used in the formulation of NDOSOL-N eye/ear drops include Di-sodium EDTA BP, Sodium metabisulphite BP, Di-sodium hydrogen phosphate BP, Sodium dihydrogen phosphate BP, Polyethylene glycol 400 BP, Thiomersal BP, Sodium hydroxide BP and water for injection BP, all being controlled by acceptable specifications. None of the excipients are derived from human or animal origin.

## 5.4 Drug Product

### 5.4.1 Drug product manufacturer

Alpa Laboratories Limited. 33/2 A.B Road, Pigdamber, Indore (MP)-India

### 5.4.2 Pharmaceutical development

The objective is to develop a safe, effective, and stable otic and ocular formulation of eye/ear drops that delivers the required therapeutic activity against inflammation and susceptible bacterial infections in eye and ear.

The manufacturing method used involved aseptic process, 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 specifications include description, Identification, particulate matter, pH, sterility (by membrane filtration) 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 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. Store in the original packaging' have been accepted.

## 5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of Ndosol-N eye/ear drops was acceptable for the following indication: 'for short-term treatment of inflammatory conditions of the eye and outer ear where a bacterial infection is also present or suspected' and is included in the list of approved medicinal products by NAFDAC.

## PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, local agent Ndozz pharmaceutical Nigeria limited. No 34 Ethel Obiakor Street, Satellite City Garden Estate, Nkwelle Ezunaka, Anambra State, Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Ndosol-N eye/ear drops.

The following are the steps for the registration of Ndosol-N eye/ear drops

September 2024	Date of receipt of application
August 2024	Date of conclusion of assessment
April 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 Ndosol-N eye/ear drops.