



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

**Public Assessment Report (PAR)**

**Synocid 40 mg/vial powder for injection**

**Omeprazole 40 mg**

**A4-101448**

**Aurora Pharmaceuticals Nigeria Limited**

This report reflects the scientific assessment for the approval of Synocid. The product was licenced on July 2025

## **PART 1: ABSTRACT**

Synocid containing Omeprazole sodium, manufactured at Kamla Lifesciences Limited, Palghar, Maharashtra, India, was granted marketing authorization by NAFDAC for the treatment of gastric and duodenal ulcers on 30 July 2025.

Synocid is indicated for the treatment of gastric and duodenal ulcers.

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 Synocid 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 Synocid have been shown in part 2 of this report. The Summary of Product characteristics (SmPC) and the approved labeling have been presented in part 3 and part 4 respectively.

Scientific discussion on the quality, non-clinical and clinical aspects of Synocid has been presented in Part 5 of this report.

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

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

## **PART 2: ACCEPTED PRESENTATIONS**

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Synocid 40 mg/vial powder for injection	Omeprazole sodium 42.54 mg equivalent to omeprazole 40 mg	Dry powder for injection A white to almost white hygroscopic powder	USP type-1 clear glass vial with bromo butyl rubber stopper and sealed with aluminium foil	1x1 vial + 10 mL WFI

## **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

COMPONENT: CARTON
DIMENSION: 70 x 30 x 105 mm
COLOUR: CMYK
GSM: 320 gsm TTC Cyber XL
COATING: DRIP OFF-UV

Size: L- 70 x W- 30 x H- 105 mm

The diagram shows a secondary label for Synocid 40 mg/vial powder for injection. The label is rectangular with a height of 105 mm and a width of 70 mm. It features a white background with orange and red accents. The top section is orange with the word "IDONAS" in white. Below this, the text reads "OMEPRAZOLE SODIUM FOR INJECTION 40 MG" and "SYNOCID" in large red letters. Underneath, it says "For I.V. Use Only (Lyophilized)". A red circle with "40 mg" is at the bottom right. The label also includes detailed information such as composition, storage instructions, and a caution. A table at the top right of the label provides technical specifications for the component carton.

## PART 5: SCIENTIFIC DISCUSSION

### 5.1. About the Product

#### 5.1.1 Name of the product

Synocid 40 mg/vial powder for injection.

#### 5.1.2 Therapeutic indication

Synocid fs indicated as an alternative to oral therapy for the treatment of duodenal ulcers and gastric ulcers. It is also used in the prevention of relapse of duodenal ulcers and gastric ulcers.

### **5.1.3 Applicant**

Aurora Pharmaceuticals Nigeria Limited  
RSQ 086 Layin Sarki Maraban Road, Kaduna, Kaduna State, Nigeria.

### **5.1.4 Pharmaceutical form**

Dry powder for injection  
A white to almost white hygroscopic powder

### **5.1.5 Storage**

Store at a temperature not exceeding 30°C.

Protect from light.

### **5.1.6 Shelf life**

36 Months

### **5.1.7 Product presentation**

Synocid is presented as 1 x 1 Vial + 10mL WFI in USP type-1 clear glass vial with bromo butyl rubber stopper and sealed with aluminium foil.

## **5.2 Drug Substance**

### **5.2.1 Manufacturer**

The active ingredient, omeprazole sodium (sterile lyophilized powder) is manufactured by Mac Chem Products (India) Private Limited, 304, Town Centre, Andheri - Kurla Road, Andheri (East), Mumbai – 400 059, 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**

There are no other ingredients used in the formulation of Synocid.

## **5.4 Drug Product**

### 5.4.1 Drug product manufacturer

Kamla Lifesciences Limited, Plot no. G-84/1, Tarapur M.I.D.C, Boisar-401 506, Tal. & Dist. Palghar, Maharashtra, India.

### 5.4.2 Pharmaceutical development

The objective of the development was to manufacture a generic which is stable and bioequivalent to the reference product, Meprasil injection (Omeprazole, 40 mg/vial), manufactured by Gland Pharma Limited, Hyderabad, India. The manufacturing method used was dry and steam sterilization and depyrogenation of vials. All the manufacturing processes were validated.

### 5.4.3 Specification

The finished product specification is based on in-house. The finished product specifications include identification by HPLC, constituted solution (completeness of solution and clarity of solution), uniformity of weight, uniformity of dosage unit (by weight variation), colour of solution, pH, bacterial endotoxins, sterility, particulate matter, water, reconstitution time, related substances 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. Do not freeze' have been accepted.

### 5.6 Conclusion

Based on the assessment of data on quality, bioequivalence, safety and efficacy, the benefit–risk profile of Synocid was acceptable for the following indication 'for the treatment of duodenal ulcers and gastric ulcers and for the prevention of relapse of duodenal ulcers, and gastric ulcers', and is included in the list of approved medicinal products by NAFDAC.

## PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Aurora Pharmaceuticals Nigeria Limited, RSQ 086 Layin Sarki Maraban Road, Kaduna, Kaduna State submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Synocid.

The following are the steps for the registration of Synocid

September 2024	Date of receipt of application
April 2025	Date of conclusion of assessment
April 2025	Date of inspection

30 July 2025	Date of issuance of Marketing Authorization
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**PART 7: STEPS TAKEN FOLLOWING REGISTRATION**

No action or steps have been taken following marketing authorization of Synocid