



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

Public Assessment Report (PAR)

Swidar tablets

(Pyrimethamine/sulfadoxine, 25 mg/500 mg)

A4-6639

Swiss Pharma Nigeria Limited, Nigeria

This report reflects the scientific assessment for the approval of Swidar tablets. The product was licenced on August 2022.

PART 1: ABSTRACT

Swidar is a fixed dose combination of pyrimethamine/sulfadoxine, 25 mg/500 mg. It is manufactured by Swiss Pharma Nigeria Limited, Agege, Lagos, Nigeria.

Swidar tablets is indicated for intermittent preventive treatment (IPTp) of malaria due to *Plasmodium falciparum* for all women in second and third trimester of pregnancy as part of antenatal care (ANC), in areas of moderate-to-high malaria transmission in Africa.

For details on the uses of this product and for side effects and warnings, see the summary of product characteristics.

The marketing authorization of Swidar by NAFDAC is based on reliance pathway in which there was an abridged review of module 1 to module 5 of submitted Common Technical Document (CTD) dossier to ascertain the quality, safety, efficacy and sameness of Swidar prequalified by WHO.

All accepted presentations of Swidar have been shown in part 2 of this report. The approved Summary of Product characteristics (SmPC) and the approved labelling have been presented in part 3 and part 4 respectively.

Scientific discussion on the quality, nonclinical and clinical aspects of Swidar has been presented in part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Swidar tablets	Pyrimethamine/ sulfadoxine 25 mg/500 mg	Tablet White, round and debossed tablet with 'SWIDAR Swipha' on one side and scored on the other side.	Blister packed in a secondary pack	1 x 3 tablets 10 x 3 tablets 50 x 3 tablets

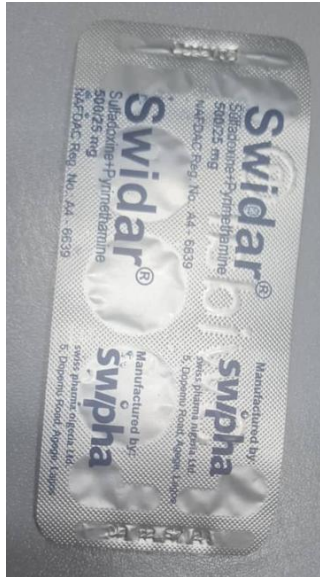
PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

<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

Swidar, a fixed dose combination of pyrimethamine/sulfadoxine, 25 mg/500 mg.

5.1.2 Therapeutic indication

Swidar is indicated for intermittent preventive treatment (IPTp) of malaria due to *Plasmodium falciparum* for all women in second and third trimester of pregnancy as part of antenatal care (ANC), in areas of moderate-to-high malaria transmission in Africa.

5.1.3 Manufacturer/applicant

Swiss Pharma Nigeria Limited, 5, Dopemu Road, Agege, Ikeja, Lagos, Nigeria is both the manufacturer and the applicant.

5.1.4 Pharmaceutical form

Tablet

White, round and debossed tablet with 'SWIDAR Swipha' on one side and scored on the other side.

5.1.5 Storage

Do not store above 30°C.

5.1.6 Shelf life

24 months

5.1.7 Product presentation

Swidar is supplied in a transparent PVC sealed with an aluminum foil. Available as 1 blister card of 3 tablets per box, 10 blister cards of 3 tablets each per box. 50 blister cards of 3 tablets each per box.

5.2 Drug Substance

5.2.1 Manufacturer

The two active pharmaceutical ingredients are manufactured by the same manufacturer, Anuh Pharma Ltd Block – Ab-3 E-17/3, 17/4 & E-18, M.I.D.C, Tarapur, Boisar, Taluka Palgher, Dist. Thane-401506, India.

The API specifications are pharmacopoeial and in-house 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.

5.4 Drug Product

5.4.1 Drug product manufacturer

Swiss Pharma Nigeria Limited, 5, Dopemu Road, Agege, Ikeja, Lagos, Nigeria.

5.4.2 Pharmaceutical development

The objective of the development was to manufacture a generic which is stable and bioequivalent to the reference product, reference product G-Cospetm 500/25 mg, by Guilin Pharmaceutical Co., Limited, China. The manufacturing method used was wet granulation.

5.4.3 Specification

The finished product specification is based on Ph. Int, in-house. 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 24 months has been accepted.

5.5 Assessment of bioequivalence

The following bioequivalence study has been performed in 2021 according to internationally accepted guidelines.

A comparative, randomized, single-dose, two-treatment, two-period, two-sequence crossover open label bioequivalence study on healthy subjects was adopted to evaluate the bioequivalence of the test product Swidar (Sulfadoxine / pyrimethamine) 500 mg/25 mg immediate release tablet and the reference product G-Cospetm 500 mg/25 mg immediate release tablet, after oral administration to healthy male and non-pregnant female adults under fasting conditions.

The primary objective of this study was to assess the bioequivalence between the test product and the reference product based on C_{max} (maximum measured plasma concentration over the time span specified. Determined directly from the plasma concentration-time curve) and AUC_{0→72h} (the area under the plasma concentration versus time curve, from time (0) to the last measurable concentration (72hr), as calculated by the linear trapezoidal method) for sulfadoxine and pyrimethamine in healthy volunteers.

The secondary objectives are to describe the T_{max} (Time of the maximum measured plasma concentration) and assess the safety and tolerability profile of both test and reference products.

The washout period was 45 days.

For C_{max} and AUC_{0→72h}, point estimates and the 90% Confidence Intervals for sulfadoxine transformed ratios (Treatment A/Treatment B) were within the accepted limits of 80.00 % - 125.00%, indicating a similar rate and extent of absorption.

For C_{max} and AUC_{0→72h}, point estimates and the 90% Confidence Intervals for pyrimethamine transformed ratios (Treatment A/Treatment B) were within the accepted limits of 80.00 % - 125.00%, indicating a similar rate and extent of absorption.

Therefore, the bioequivalence of Swidar (Sulfadoxine / Pyrimethamine) by Swiss Pharma Nigeria Ltd., Nigeria with G-Cospetm by Guilin Pharmaceutical Co., Ltd., China can be concluded.

5.6 Conclusion

Based on the assessment of data on quality, bioequivalence, safety and efficacy, the benefit–risk profile of Swidar was acceptable for the following indication: 'intermittent preventive treatment (IPTp) of malaria due to Plasmodium falciparum for all women in second and third trimester of pregnancy', and is included in the list of approved medicinal products by NAFDAC.

PART 7: STEPS TAKEN FOR REGISTRATION

The manufacturer, Swiss Pharma Nigeria Limited, 5, Dopemu Road, Agege, Ikeja, Lagos State, Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Swidar.

The following are the steps for the registration of Swidar

March 2022	Date of receipt of application
July 2022	Date of inspection
25 August 2022	Date of issuance of Marketing Authorization

PART 8: STEPS TAKEN FOLLOWING REGISTRATION

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