



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

Public Assessment Report (PAR)

Meropenem for injection

Meropenem 1 gram

A4-101445

Malven Medics International Company Limited, Nigeria.

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

PART 1: ABSTRACT

Meropenem for injection containing meropenem, manufactured at Swiss Parenteral Limited, (Unit II) Ahmedabad, Gujarat, India, was granted marketing authorization by NAFDAC for the treatment of bacterial susceptible infections on 30 July 2025.

Meropenem is indicated for the treatment of severe pneumonia, including hospital and ventilator-associated pneumonia, complicated urinary tract infections, complicated skin and soft tissue infection in adults and children aged 3 months and older.

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 Meropenem 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 Meropenem 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 Meropenem has been presented in part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Meropenem for injection 1 gram	Meropenem 1gram	Powder for injection White to yellowish white powder	Plain glass Vial (USP Type-I) and 20 mm approved colored flip off seal with 20 mm grey butyl rubber stopper along with 50 mL of 0.9% sodium chloride solution in the diluent chamber.	1 vial + 2 x 10 mL WFI.

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

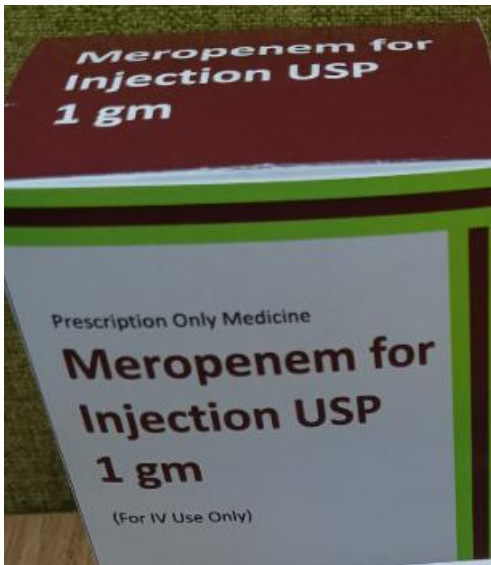
See: <https://greenbook.nafdac.gov.ng/>

PART 4: LABELLING

Primary label



Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Meropenem 1gm powder for injection.

5.1.2 Therapeutic indication

Meropenem for injection is indicated for the treatment of severe pneumonia, including hospital and ventilator-associated pneumonia, complicated urinary tract infections, complicated skin and soft tissue infections. Meropenem may be used in the treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.

5.1.3 Manufacturer/applicant

Malven Medics International Company Limited., 4 Ligali Street, Ogudu, Lagos State, Nigeria.

5.1.4 Pharmaceutical form

Powder for injection

White to yellowish white powder

5.1.5 Storage

Do not store above 30°C.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Meropenem for injection is presented in plain glass vial (USP Type-I) and 20 mm approved colored flip off seal with 20 mm grey butyl rubber stopper along with 50 mL of 0.9% sodium chloride solution in the diluent chamber.

5.2 Drug Substance

5.2.1 Manufacturer

The sterile mixture of Meropenem and Sodium carbonate is manufactured by M/s Vartika Chemicals & Pharmaceuticals (Private) Limited, G1-567-550, RIICO Industrial Area, Khushkhera, Bhiwadi – 301019 Dist. Bhiwadi (Rajasthan), India.

The API specifications are pharmacopoeial and USP 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 ingredient used in the formulation of Meropenem for injection aside the active anhydrous Meropenem sodium carbonate.

5.4 Drug Product

5.4.1 Drug product manufacturer

Swiss Parenterals Limited (Unit II), Plot No. 402, 412-414 Kerala Industrial Estate, G.I.D.C, Nr, Bavla, Dist. Ahmedabad-382 220. Gujarat, 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, reference product Merrem IV, 1 gram, by PFIZER INC. The manufacturing method used was dry and steam sterilization.

5.4.3 Specification

The finished product specification is based on USP pharmacopoeia. The finished product specifications include average filled weight, uniformity of dosage unit, pH, identification A by HPLC, loss on drying, Bacterial Endotoxins, sterility, particulate matter, content of sodium, organic impurities 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 have been accepted.

5.5 Conclusion

Based on the assessment of data on quality, safety and efficacy, the benefit–risk profile of Meropenem for injection was acceptable for the following indication: severe pneumonia, including hospital and ventilator-associated pneumonia, complicated urinary tract infections, complicated skin and soft tissue infections. Meropenem may be used in the treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above, and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The manufacturer, Swiss Parenterals Limited (Unit II), Plot No. 402, 412-414 Kerala Industrial Estate, G.I.D.C, Nr, Bavla, Dist. Ahmedabad-382 220. Gujarat, India, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Meropenem for injection.

The following are the steps for the registration of Meropenem for injection.

September 2024	Date of receipt of application
May 2025	Date of conclusion of assessment
July 2025	Date of inspection
30 July 2025	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Meropenem for injection.