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

Public Assessment Report (PAR)

Ketamine 50 mg/mL injection

Ketamine hydrochloride 50mg

A4-101508

Grace Drugs & Healthcare Limited

This report reflects the scientific assessment for the approval of Ketamine injection. The product was licensed in August 2025

PART 1: ABSTRACT

Ketamine hydrochloride, manufactured at Vital Healthcare Private Limited, Satpur, Santacruz (W), Mumbai, was granted marketing authorization by NAFDAC for its use as an anesthetic on 27 August 2025.

Ketamine injection is indicated in children and adults as an anaesthetic agent for short diagnostic and surgical procedures which do not require skeletal muscle relaxation.

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 Ketamine 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 Ketamine 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 Ketamine injection has been presented in Part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Ketamine injection 50 mg/mL	Ketamine hydrochloride BP	Solution for injection or infusion A clear colourless solution.	Type-I amber vials plugged with grey butyl plug.	1 x 10 mL vial

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

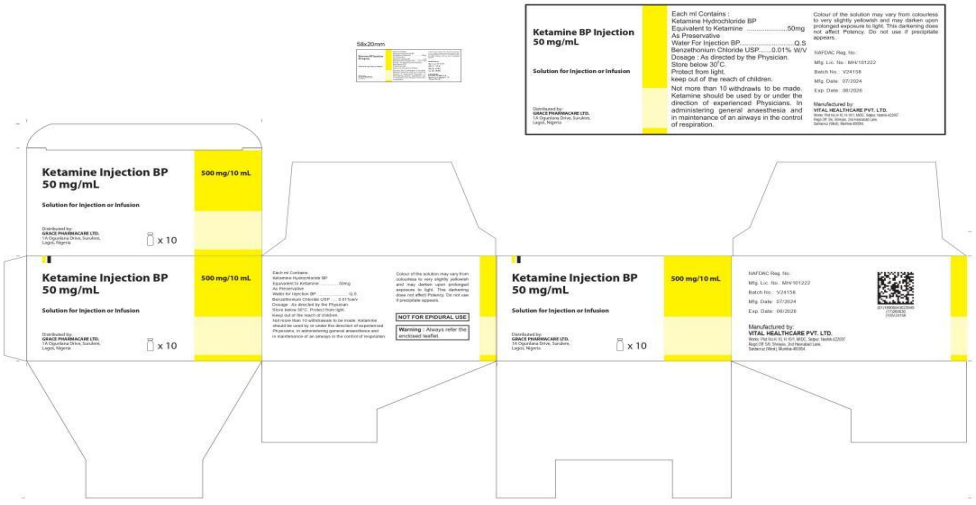
Refer to the NAFDAC Greenbook URL below for the SmPC

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

Ketamine injection 50 mg/mL

5.1.2 Therapeutic indication

Ketamine injection is indicated in children and adults as an anaesthetic agent for short diagnostic and surgical procedures which do not require skeletal muscle relaxation.

5.1.3 Manufacturer/applicant

Grace Drugs & Healthcare Limited. 1A, Ogunlana drive, Surulere, Lagos, Nigeria.

5.1.4 Pharmaceutical form

Solution for injection or infusion

A clear colourless solution filled in 10 ml USP Type-I amber vial plugged with grey butyl plug.

5.1.5 Storage

Do not store above 30°C. Protect from light.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Ketamine injection is a clear colourless solution filled in 10 mL USP Type-I amber vial plugged with grey butyl plug.

5.2 Drug Substance

5.2.1 Manufacturer

Ketamine hydrochloride injection is manufactured by Supriya Lifescience Limited**.** A-5/2, Lote Parshuram Industrial Area, M.I.DCc Taluka – Khed, District – Ratnagiri, Maharashtra, 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 Ketamine injection are Benzethonium chloride USP, Disodium EDTA BP and water for injection (WFI) BP, all being pharmacopoeial 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

The Ketamine injection is manufactured by Vital Healthcare Private Limited, Plot No. H/10, H10/1, M.I.D.C., Satpur, Nashik-422007. Regd. Office: 5/6, Shreyas, 2nd Hasnabad Lane, Santacruz (W), Mumbai, India.

5.4.2 Pharmaceutical development

The objective is to design and establish a quality, safe, and effective medicine that is therapeutically equivalent to the reference product (Ketalar, manufactured by Pfizer Inc.), while ensuring consistent performance, stability and required therapeutic activity as an anaesthetic.

5.4.3 Specification

The finished product specification is based on British Pharmacopoeia monograph. The finished product specifications include identification by IR & TLC, acidity pH, related substances, assay, extractable volume, particulate matter, bacterial endotoxin test and test for sterility. 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 'Do not store above 30°C, protect from light' have been accepted.

5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of Ketamine injection 50 mg/mL was acceptable for the following indication: 'indicated in children and adults as an aesthetic agent for short diagnostic and surgical procedures which do not require skeletal muscle relaxation' and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Grace Drugs & Healthcare Limited. 1A, Ogunlana drive, Surulere, Lagos, Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Ketamine injection 50 mg/mL.

The following are the steps for the registration of Ketamine injection

May 2025	Date of receipt of application
April 2025	Date of conclusion of assessment
May 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 Ketamine injection 50 mg/mL.