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

Public Assessment Report (PAR)

Mexen Pentazocine 30 mg/ mL injection

Pentazocine 30 mg/ mL

A4-101440

Mexzen Nigeria Limited

This report reflects the scientific assessment for the approval of Mexen Pentazocine injection. The product was licenced in July 2025.

PART 1: ABSTRACT

Mexen containing pentazocine, manufactured at Merit Organics Limited, Gujarat, India, was granted marketing authorization by NAFDAC for the relief of moderate to severe pain on 30 July 2025. Mexen Pentazocine is indicated for the relief of moderate to severe pain.

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 Mexen Pentazocine 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 Mexen Pentazocine 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 Mexen Pentazocine has been presented in part 5 of this report.

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

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

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Mexen Pentazocine injection 30 mg/ mL	Pentazocine 30 mg/mL	A colorless or almost colorless solution packed in an amber glass ampoule	10 x 1mL glass ampoules containing transparent liquid are placed in transparent tray and packed in a printed mono carton	10 x 1mL

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

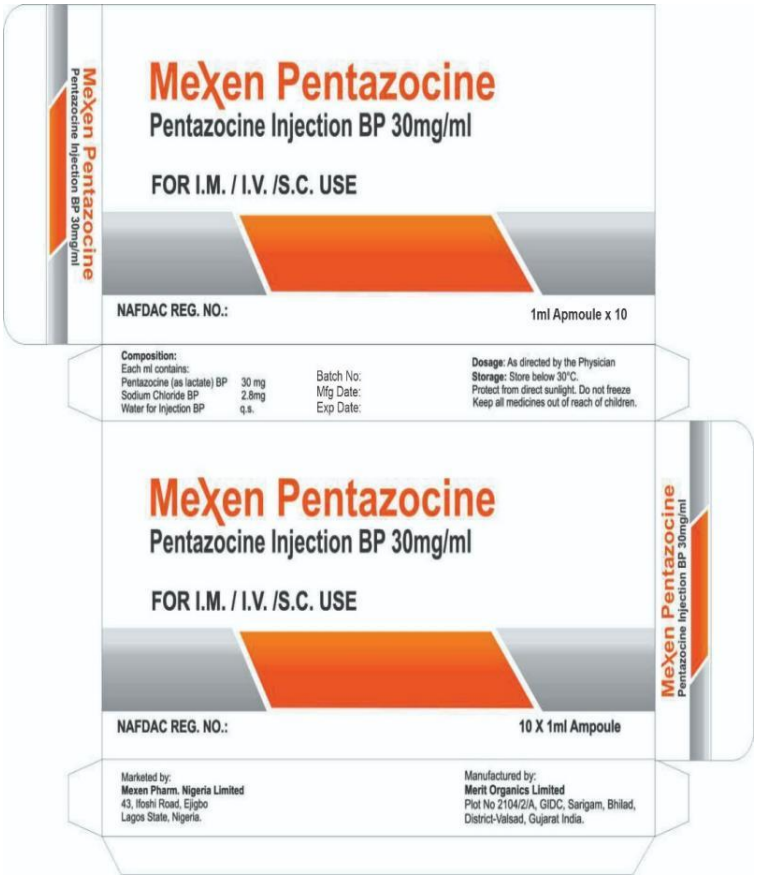
Refer to the NAFDAC Greenbook URL below for the SmPC

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

Mexen pentazocine injection 30 mg/ mL

5.1.2 Therapeutic indication

Mexen Pentazocine injection is used for the relief of moderate to severe pain.

5.1.3 Applicant

Mexzen Nigeria Limited, 43, Ifoshi Road, Pipeline Bus-stop, Ejigbo, Lagos State, Nigeria

5.1.4 Pharmaceutical form

A colorless or almost colorless solution packed in a glass ampoule.

5.1.5 Storage

Do no store above 30ºC. Store in the original packaging. Protect from light. Store at a temperature not exceeding 30ºC.

5.1.6 Shelf life

36 Months

5.1.7 Product presentation

Mexen Pentazocine injection is presented as 10 x 1 mL in a glass ampoule containing colorless or almost colorless solution. They are placed in transparent tray and packed in a printed mono carton.

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, pentazocine is manufactured by Aquatic Formulations India Limited, 1209,1210,1211, Cabin B, 12th Floor, Universal Majestic, P.L.Lokhande Marg, Chembur Mumbai, Mumbai City MH 400043 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

Other ingredients used in the formulation of Mexen Pentazocine injection include sodium chloride, lactic acid and water for injection all being controlled by pharmacopoeia. None of the excipients are derived from human or animal origin.

5.4 Drug Product

5.4.1 Drug product manufacturer

Merit Organic Limited, 2104/2/A, G.I.D.C, Sarigam, Bhilad-396 155, 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, Fortwin (Pentazocine lactate injection), manufactured by Ranbaxy Private Limited, 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 BP monograph. The finished product specifications include identification by IR & TLC, average net volume, extractable volume, pH, bacterial endotoxin test, sterility, particulate matter, 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, protect from light’ have been accepted.

5.6 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of Mexen Pentazocine was acceptable for the following indication 'for the relief of moderate to severe pain’, and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Mexzen Nigeria Limited, 43, Ifoshi Road, Pipeline Bus-stop, Ejigbo, Lagos State, Nigeria submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Mexen Pentazocine injection.

The following are the steps for the registration of Mezen Pentazocine

September 2024	Date of receipt of application
June 2025	Date of conclusion of assessment
March 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 Mexen Pentazocine injection