



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

### **NAFDAC Public Assessment Report (NAPAR)**

#### **Methylcobalamin/pregabalin 750 mcg/75 mg capsules**

#### **Methylcobalamin /pregabalin 750 mcg/75 mg**

**A4-102063**

**PDP Pharmaceutical Limited**

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| <p>This report reflects the scientific assessment for the approval of Methylcobalamin /pregabalin 750 mcg/ 75 mg capsules. The product was licenced in April 2026.</p> |
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## PART 1: ABSTRACT

Methylcobalamin /pregabalin capsules, manufactured at McW Healthcare Private Limited, Indore, Madhya Pradesh, India, was granted marketing authorization by NAFDAC for the treatment of neuropathic pain on 28 April 2026.

Methylcobalamin/pregabalin capsule is indicated for the treatment of neuropathic 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 methylcobalamin/pregabalin 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 methylcobalamin/pregabalin 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 methylcobalamin/pregabalin have been presented in part 5 of this report.

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

No action or steps have been taken following the marketing authorization of methylcobalamin /pregabalin capsules.

## PART 2: ACCEPTED PRESENTATIONS

| Product name                                       | Active ingredients             | Pharmaceutical form/description                                                                                                     | Packaging                                                                                         | Pack size       |
|----------------------------------------------------|--------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|-----------------|
| Methylcobalamin /pregabalin 750 mcg/75 mg capsules | Methylcobalamin /pregabalin 75 | Hard gelatin capsule<br>Hard gelatin capsules with a pink cap and a transparent colourless body. They contain white and red pellets | Aluminum foil blister cards, each containing 10 capsules. Available in cartons of 3 x 10 capsules | 3 x 10 capsules |

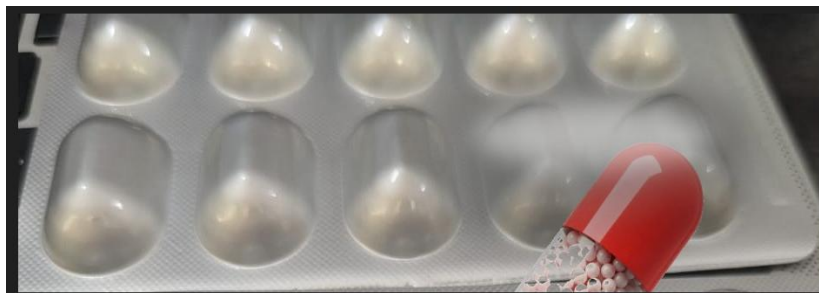
## PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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

Methylcobalamin 750 mcg and pregabalin 75 mg capsules.

#### 5.1.2 Therapeutic indication

Methylcobalamin and pregabalin capsule is indicated for the treatment of neuropathic pain.

### **5.1.3 Applicant**

PDP Pharmaceutical Limited, 7 Sapara Williams Street, Industrial Estate, Ikeja, Lagos.

### **5.1.4 Pharmaceutical form**

Hard gelatin capsule

Hard gelatin capsules with a pink cap and a transparent colourless body. They contain white and red pellets.

### **5.1.5 Storage**

Do not store above 30°C

### **5.1.6 Shelf life**

24 months

### **5.1.7 Product presentation**

Aluminium foil blister cards, each containing 10 capsules. Available in cartons of 3 x 10 capsules.

## **5.2 Drug Substance**

### **5.2.1 Manufacturer**

The active ingredients, methylcobalamin and pregabalin, is manufactured by Concord Drugs Limited, Survey No. 249, Brahmanapally village, Hayatnagar Mandal, Hyderabad, Telangana 501511, India.

The API specifications are in-house.

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 methylcobalamin/pregabalin capsules include empty hard gelatin capsule shells, which is in-house controlled.

None of the excipients are derived from human or animal origin.

## **5.4 Drug Product**

### **5.4.1 Drug product manufacturer**

McW Healthcare Private Limited, 286, 287A, 287B, Sector E, Industrial area, Sanwer Road, Indore (Madhya Pradesh), India.

### **5.4.2 Pharmaceutical development**

The objective of the pharmaceutical development is to manufacture a generic which is stable, delivers the intended performance, and is safe, in terms of efficacy to the reference product Pregeb M 75 mg currently licensed by Torrent Pharma Limited.

The manufacturing method used was sifting, capsule filling, and visual inspection. Comparative dissolution profile was conducted in line with ICH M9 guidelines between the reference product Pregeb

M 75 mg (Torrent Pharma Limited) and methylcobalamin/pregabalin capsules. The profile in the three BCS media is similar.

### 5.4.3 Specification

The finished product specification is based on in-house standard. The finished product specifications include identification, disintegration, and assay. The test procedures have been adequately validated.

### 5.4.4 Stability

Stability studies have been conducted at 30°C/75% RH long-term storage conditions and for six months at accelerated conditions in the packaging intended for marketing 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 24 months and 'Do not store above 30°C' have been accepted.

### 5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of methylcobalamin/pregabalin capsule was acceptable for the following indication: 'for the treatment of neuropathic pain' and is included in the list of approved medicinal products by NAFDAC.

## PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, PDP Pharmaceutical Limited, 7 Sapara Williams Street, Industrial Estate, Ikeja, Lagos, submitted an application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of methylcobalamin/pregabalin capsules.

The following are the steps for registration

|               |                                             |
|---------------|---------------------------------------------|
| February 2025 | Date of receipt of application              |
| March 2026    | Date of conclusion of assessment            |
| March 2026    | Date of inspection                          |
| 28 April 2026 | Date of issuance of Marketing Authorization |

## PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of methylcobalamin/ pregabalin capsules.