DIACOBAL capsules (Mecobalamin 500 mcg)

1. Name of the medicinal product
DIACOBAL capsules (Mecobalamin 500 mcg)

2. Qualitative and quantitative composition
Each capsules contains Mecobalamin 500mcg

For the full list of excipients see section 6.1.

3. Pharmaceutical form

Capsules

Orange opaque hard gelatin capsule of size '1' containing white to off-white pinkish powder with fine dark red crystals.

4. Clinical particulars
4.1 Therapeutic indications

For the treatment of nerve pain, numbness, tingling, burning sensation, loss of feeling and paralysis due to diabetes-related peripheral neuropathies such as diabetic nerve damage and polyneuritis (inflammation of multiple nerves).

4.2 Posology and method of administration

Adult: Oral administration 1 capsule 3 times a day (1500 mcg of Mecobalamin). For best absorption, take before meals. The dosage should be adjusted according to age of patient and severity of symptoms.

4.3 Contraindications
Mecobalamin is contraindicated in those hypersensitive to any component of a vitamin B12 containing product.

4.4 Special warnings and precautions for use

Mecobalamin should if possible not be given to patients without first confirming the diagnosis. Regular monitoring of the blood is advisable. In patients with folate deficiency, use of doses greater than 10 mcg daily may produce a haematological response; indiscriminate use may mask the precise diagnosis.

4.5 Interaction with other medicinal products and other forms of interaction

Absorption of Vitamin B12 from the gastrointestinal tract may be reduced by neomycin, aminosalicylic acid, histamine H2-antagonists, and colchicines. Serum concentrations may be decreased by concurrent use of oral contraceptives.

4.6 Pregnancy and lactation

If you are pregnant or breastfeeding, please consult your doctor or healthcare professional before taking this product.

4.7 Effects on ability to drive and use machines

There are no reports of vitamin B12 effects on ability to drive and use machine.

4.8 Undesirable effects

Gastrointestinal	:	Symptoms eg, anorexia, nausea or diarrheas may occur infrequently.
Dermatological	:	Skin rash may occur rarely.
Others	:	Headache, sweating, hot sensation and hypersensitivity to Mecobalamin or any component of the capsule. Prolonged use of larger doses of Mecobalamin is not recommended to patients whose occupation requires handling of mercury or its compounds.

4.9 Overdose

There are no reports of vitamin B12 overdosage in the literature.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Vitamin B12 in the form of Mecobalamin is a cofactor in the methionine synthase reaction. The enzyme converts homocysteine to methionine. Methionine is a precursor of S-adenosylmethionine (SAMe). SAMe is the principal transmethylating agent and is involved in, among many other things, the synthesis of myelin basic protein. Abnormal myelin basic protein resulting in defective myelination, is thought to be responsible for many of the neurological effects of B12 deficiency.

B12 deficiency results in decreased formation of thymidylic acid and purine nucleotides, precursors of DNA synthesis and which are necessary for normal cell division.

Mecobalamin acts to repair damaged nerve tissue in nerve disorder eg, axonal degeneration and demyelination.

5.2 Pharmacokinetic properties

Single-Dose Administration: After oral administration of single dose of 500 mcg and 1500 mcg of Mecobalamin to healthy adult subjects, dose-related peak plasma concentrations were both achieved after 3 hrs. From 40-80% of the cumulative amount of total B12 recovered in the urine by 24 hrs after oral administration were excreted within the first 8 hrs.

Repeated-Dose Administration: The percentage of increase in the plasma concentration of total B12 were determined in healthy subjects given an oral daily dose of 1500 mcg of Mecobalamin for 12 consecutive weeks. The changes in the plasma level were also measured in the same patients for a period of the first 4 weeks after the last administration.

The plasma concentration increased for the 4 weeks after administration, reaching twice as high as the initial concentration. Therefore, it was followed by a gradual increase up to about 280% of that before administration at 12th week of the dosing, and then declined. But it was maintained at approximately 180% of the level before dosing 4 weeks after the last administration.

Vitamin B12 is extensively bound to specific plasma proteins called transcobalamins; transcobalamin II appears to be involved in the rapid transport of the cobalamins to tissues. Vitamin B12 is stored in the liver and is secreted in the bile and reabsorbed via the enterohepatic circulation. Some of the B12 secreted in the bile is excreted in the faeces. Also, oral B12 that is not absorbed is excreted in the faeces. Reabsorption of B12 via the enterohepatic circulation requires the intrinsic factor. If the

circulating level of B12 exceeds the B12 binding capacity of the blood, the excess is excreted in the urine.

5.3 Preclinical safety data

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6. Pharmaceutical particulars

6.1 List of excipients

Dibasic Calcium Phosphate Anhydrous, Microcrystalline Cellulose, Sodium Starch Glycolate, Colloidal Anhydrous Silica and Magnesium Stearate.

6.2 Incompatibilities

None

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container

Alu-Amber PVC strip. Each strip contains 10 capsules. 10 x 10 capsules are packed into pre-printed outer carton together with a piece of package insert.

6.6 Special precautions for disposal and other handling

Not applicable

7. Marketing authorisation holder

Plot 61, Bayan Lepas Industrial Park Phase 4,
Lintang Bayan Lepas 1, 11900 Bayan Lepas,
Pulau Pinang, Malaysia

8. Marketing authorisation number(s)

9. Date of first authorisation/renewal of the authorisation

10. Date of revision of the text

6th May 2026