

# Dibencozide

Cozin®  
Vitamins

1 mg Capsule  
3 mg Capsule

R<sub>x</sub>

**PRODUCT DESCRIPTION:**

Dibencozide 1 mg:  
White to reddish crystalline powder with dark red specks, encapsulated in EGC #4, scarlet cap and gray body.  
Dibencozide 3 mg:  
White to reddish crystalline powder with dark red specks, encapsulated in EGC #2, scarlet cap and scarlet body.

**FORMULATION:**

Each capsule contains:  
Dibencozide ..... 1 mg  
Dibencozide ..... 3 mg

**PHARMACODYNAMICS:**

Dibencozide is one of the active forms of Vitamin B12. Dibencozide increases the protein "efficiency coefficient" for example, the proportion of "bound nitrogen" for protein fabrication in the system evaluated to "consumed nitrogen" with food ingestion. The initial sign of effectiveness is manifested by a marked increase in appetite. Thus, dibencozide facilitates optimum utilization of dietary protein intake, contributes to the formation and repair of body tissues and stimulates appetite.

**PHARMACOKINETICS:**

Vitamin B12 substances bind to intrinsic factor, a glycoprotein secreted by the gastric mucosa, and are then actively absorbed from the gastrointestinal tract. Absorption is impaired in patients with an absence of intrinsic factor, with a malabsorption syndrome or with disease or abnormality of the gut, or after gastrectomy. Absorption from the gastrointestinal tract can also occur by passive diffusion; little of the vitamin present in food is absorbed in this manner although the process becomes increasingly important with larger amounts such as those used therapeutically. After intranasal dosage, peak plasma concentrations of cyanocobalamin have been reached in 1 to 2 hours. The bioavailability of the intranasal preparation is about 7 to 11% of that by intramuscular injection.

**INDICATIONS:**

Premature babies, low birth weight, retarded growth, poor appetite in infants, children and adults, adjuvant to treatment of tuberculosis and other chronic ailment, convalescence from acute infection or surgery, faulty nutrition in older people.

**DOSAGE AND ADMINISTRATION:**

**DIBENCOZIDE 1 mg Capsule:**

| Age Group                    | Dosage                                                                                                   |
|------------------------------|----------------------------------------------------------------------------------------------------------|
| Premature babies and infants | 1 capsule daily (The capsule may be opened and the odorless, tasteless powder mixed with milk or juice). |
| Children and adolescents     | 2 to 3 capsules daily.                                                                                   |
| Adult                        | 3 capsules daily.                                                                                        |

Or as prescribed by the physician.

**DIBENCOZIDE 3 mg Capsule:**

| Age Group | Dosage               |
|-----------|----------------------|
| Adults    | One capsule per day. |

Or as prescribed by the physician.

**CONTRAINDICATION / PRECAUTION / WARNING:**

Precaution: Pregnancy and Breastfeeding- Not enough is known about the use of Dibencozide during pregnancy and breastfeeding. Stay on the safe side and avoid use, GI conditions such as ileal disease or surgical removal part of the intestine can reduce the amount of Vitamin B12 including dibencozide that is absorbed from the intestine.

**DRUG INTERACTIONS:**

Absorption of vitamin B12 from the gastrointestinal tract may be reduced by Neomycin, Amino salicylic acid, Histamine H2 antagonist, Omeprazole and Colchicines. Serum concentration may be decreased by use of oral contraceptives. Many of these interactions are unlikely to be of clinical significance but should be taken into account when performing assays for blood concentration. Parenteral chloramphenicol may attenuate the effect of Vitamin B12 in anemia.

**ADVERSE DRUG REACTIONS:**

All drugs are subject to side effects and it may vary from individual to individual. Use the drug exactly as prescribed by your doctor and in case of any symptoms of adverse reactions, stop using the drug immediately and consult a doctor. No major adverse reactions have been associated with the use of dibencozide capsules.  
Minor side effects include nausea, vomiting, diarrhea, acidity, headache, stomach upset and other GI disorders. Inform your doctor in case any such symptoms become chronic and troublesome.  
Stop using the drug immediately and seek for immediate medical help in case of any symptoms of allergic reactions such as rashes, hives and inflammation.

**OVERDOSE AND TREATMENT:**

It is unlikely that an overdose will occur if the prescribed dose is followed correctly. However stop this medication and ask your doctor if you are feeling unwell or if overdose is suspected.

**STORAGE CONDITION:**

Store at temperature not exceeding 30°C

**PACKING AVAILABLE:**

Alu/Alu strip pack x 10's (Box of 100's)

**INSTRUCTION AND SPECIAL PRECAUTION FOR HANDLING AND DISPOSAL:**

No special handling and disposal required.

**CAUTION STATEMENT:**

Food, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

**ADVERSE REPORTING STATEMENT:**

For suspected adverse drug reaction, report to FDA: [www.fda.gov.ph](http://www.fda.gov.ph).

Seek medical attention immediately at the first sign of adverse drug reaction.

**REGISTRATION NUMBER:** Dibencozide 1 mg Capsule (COZIN): DRP-6559-03  
Dibencozide 3 mg Capsule (COZIN): DRP-6558-04

**DATE OF FIRST AUTHORIZATION / RENEWAL OF AUTHORIZATION:** 18 NOVEMBER 2022

**DATE OF REVISION OF PACKAGE INSERT:** 15 MAY 2024

Manufactured by:  
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