

# Tribees<sup>®</sup> Forte (Tablets)



23300

Ref. No: B2123300/22.02

Thiamine Nitrate (Vitamin B<sub>1</sub>)  
Pyridoxine Hydrochloride (Vitamin B<sub>6</sub>)  
Cyanocobalamin (Vitamin B<sub>12</sub>)

## PRESENTATION:

**Tribees<sup>®</sup> Forte Tablets:** Crimson red, circular, biconvex film coated tablet embossed 'COSMOS' on one side and plain on the other side.

Each film coated tablet contains:

Thiamine Nitrate (Vitamin B <sub>1</sub> )	200mg
Pyridoxine Hydrochloride (Vitamin B <sub>6</sub> )	50mg
Cyanocobalamin (Vitamin B <sub>12</sub> )	1000 $\mu$ g
Lactose and other excipients	

## CLINICAL PHARMACOLOGY:

Thiamine is a water-soluble vitamin, although some of its derivatives have greater lipophilicity. It is an essential coenzyme for carbohydrate metabolism in the form of the diphosphate (thiamine pyrophosphate, cocarboxylase).

Pyridoxine, a water-soluble vitamin, is involved principally in amino acid metabolism, but is also involved in carbohydrate and fat metabolism.

Cyanocobalamin (Vitamin B<sub>12</sub>), a water-soluble vitamin, occurs in the body mainly as methylcobalamin (mecobalamin) and as adenosylcobalamin (cobamamide) and hydroxocobalamin. Mecobalamin and cobamamide act as coenzymes in nucleic acid synthesis. Mecobalamin is also closely involved with folic acid in several important metabolic pathways.

## Pharmacokinetics:

Small amounts of **thiamine** are well absorbed from the gastrointestinal tract following oral administration, but the absorption of doses larger than about 5mg is limited. It is widely distributed to most body tissues, and appears in breast milk. Within the cell thiamine is mostly present as the diphosphate. Thiamine is not stored to any appreciable extent in the body and amounts in excess of the body's requirements are excreted in the urine as unchanged thiamine or as metabolites.

**Pyridoxine**, pyridoxal, and pyridoxamine are readily absorbed from the gastrointestinal tract following oral administration and are converted to the active forms pyridoxal phosphate and pyridoxamine phosphate. They are stored mainly in the liver where there is oxidation to 4-pyridoxic acid and other inactive metabolites which are excreted in the urine. As the dose increases, proportionally greater amounts are excreted unchanged in the urine.

**Cyanocobalamin (Vitamin B<sub>12</sub>)** 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. Vitamin B<sub>12</sub> 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 B<sub>12</sub> is stored in the liver, excreted in the bile, and undergoes extensive enterohepatic recycling; part of a dose is excreted in the urine, most of it in the first 8 hours; urinary excretion, however, accounts for only a small fraction in the reduction of total body stores acquired by dietary means. Vitamin B<sub>12</sub> diffuses across the placenta and also appears in breast milk.

## USES:

Tribees<sup>®</sup> Forte Tablets are used as an:

Adjuvant in the treatment of the following:

- Neuritic pain: acute or chronic neuritis and polyneuritis
- Neuralgia
- Toxic damages of the nerve tissue: alcoholism, diabetic polyneuropathy, drug intoxication.

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## **DOSAGE AND ADMINISTRATION:**

1-2 tablets daily.

## **CONTRA-INDICATIONS AND WARNINGS:**

### **Adverse Effects:**

Adverse Effects seldom occur following administration of thiamine, but hypersensitivity reactions have occurred, mainly after parenteral administration. These reactions have ranged in severity from very mild, to very rarely, fatal anaphylactic shock. Long-term administration of large doses of pyridoxine is associated with the development of severe peripheral neuropathies. Cyanocobalamin or hydroxocobalamin should, if possible, not be given to patients with suspected vitamin B<sub>12</sub> deficiency without first confirming the diagnosis. Regular monitoring of the blood is advisable. Use of doses greater than 10 micrograms daily may produce a haematological response in patients with folate deficiency; indiscriminate use may mask the precise diagnosis.

### **Interactions:**

Pyridoxine reduces the effects of levodopa but this does not occur if a dopa decarboxylase inhibitor is also given. Pyridoxine reduces the activity of alretamine. It has also been reported to decrease serum concentrations of phenobarbital and phenytoin. Many drugs may increase the requirements for pyridoxine; such drugs include hydralazine, isoniazid, penicillamine, and oral contraceptives.

Absorption of cyanocobalamin (vitamin B<sub>12</sub>) from the gastrointestinal tract may be reduced by neomycin, amino-salicylic acid, histamine H<sub>2</sub>-antagonists, and colchicine. Serum concentrations may be decreased by concurrent administration 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 concentrations. Parenteral chloramphenicol may attenuate the effect the effect of vitamin B<sub>12</sub> in anaemia.

### **Pregnancy and Lactation:**

The usual precautions should be observed when administering drugs during pregnancy, especially in the first trimester. In high doses, pyridoxine may interfere with prolactin release and should only be used with caution in nursing mothers.

## **PHARMACEUTICAL PRECAUTIONS:**

Store in a dry place below 30°C. Protect from light. Keep all medicines out of the reach of children.

## **LEGAL CATEGORY:**

Prescription Only Medicine (POM)

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