

**Agog Pharma Ltd.**

(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauripada, Vasai (E), Dist. Thane - 401 208, INDIA.  
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<b>Brand Name : VITA-100 TABLETS</b>		2021
<b>Generic Name : Thiamine Tablets BP 100 mg</b>		
<b>Module 1</b>	Administrative Information and Product Information	<b>Confidential</b>
<b>1.5</b>	Product Informationw	

## 1.5 PRODUCT INFORMATION

### 1.5.1 Prescribing information (Summary of products characteristics)

#### SUMMARY PRODUCT CHARACTERISTICS

#### 1. Name of drug product:

VITA-100 TABLETS (Thiamine Tablets BP 100 mg)

#### 2. Qualitative and Quantitative Composition:

Each uncoated tablet contains: Thiamine Hydrochloride Tablets BP 100 mg.

#### 3. Pharmaceutical form:

White, circular, flat uncoated tablets having break line on one side and plain on the other side of each tablet.

#### 4. Clinical particulars:

##### 4.1 Therapeutic Indications:

**Thiamine**, also known as **thiamin** or **vitamin B<sub>1</sub>**, is a vitamin found in food and manufactured as a dietary supplement and medication. Food sources of thiamine include whole grains, legumes, and some meats and fish. Grain processing removes much of the thiamine content, so in many countries cereals and flours are enriched with thiamine. Supplements and medications are available to treat and prevent thiamine deficiency and disorders that result from it, including beriberi and Wernicke encephalopathy. Other uses include the treatment of maple syrup urine disease and Leigh syndrome. They are typically taken by mouth, but may also be given by intravenous or intramuscular injection.

Thiamine supplements are generally well tolerated. Allergic reactions, including anaphylaxis, may occur when repeated doses are given by injection. Thiamine is in the B complex family. It is an essential micronutrient, which cannot be made in the body. Thiamine is required for metabolism including that of glucose, amino acids, and lipids.



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## 4.2 Posology and Method of Administration:

Thiamine is a prescription and over-the-counter (OTC) vitamin, also called vitamin B1. Vitamin B1 is found in many foods including yeast, cereal grains, beans, nuts, and meat. It is often used in combination with other B vitamins.

Thiamine is taken for conditions related to low levels of thiamine, including beriberi and inflammation of the nerves (neuritis) associated with pellagra or pregnancy. Thiamine is also used for digestive problems including poor appetite, ulcerative colitis, and ongoing diarrhea.

Thiamine is also used for AIDS and boosting the immune system, diabetic pain, heart disease, alcoholism, aging, a type of brain damage called cerebellar syndrome, canker sores, vision problems such as cataracts and glaucoma, motion sickness, and improving athletic performance. Other uses include preventing cervical cancer and progression of kidney disease in patients with type 2 diabetes.

Some people use thiamine for maintaining a positive mental attitude; enhancing learning abilities; increasing energy; fighting stress; and preventing memory loss, including Alzheimer's disease.

Healthcare providers give thiamine shots for a memory disorder called Wernicke's encephalopathy syndrome, other thiamine deficiency syndromes in critically ill people, alcohol withdrawal, and coma.

Thiamine is available under the following different brand names: vitamin B1.

Dosages of Thiamine:

Adults and Pediatric Dosages

Tablets

- 50 mg
- 100 mg
- 250 mg

Capsule

- 50 mg

Injectable solution

- 100 mg/ml



## Dosage Considerations – Should be Given as Follows:

### Recommended Daily Average

#### Adults:

- Males: 1.2 mg/day
- Females: 1.1 mg/day
- Pregnancy/Lactation: 1.4 mg/day

#### Pediatric:

- Infants 0-6 months: 0.2 mg/day
- Infants 6-12 months: 0.3 mg/day
- Children 1-3 years old: 0.5 mg/day
- Children 3-8 years old: 0.6 mg/day
- Children 8-13 years old: 0.9 mg/day
- Children 13-18 years old: 1.2 mg/day (male), 1 mg/day (female)

#### Deficiency

- 10-50 mg/day orally in divided doses

#### Beriberi

##### Adults

- Intramuscularly: 5-30 g three times daily (if critically ill); then 5-30 mg three times daily for 1 month
- Duration dependent on persistence of symptoms

##### Pediatric

- 10-25 mg intravenously/intramuscularly per day (if critically ill) or 10-50 mg dose orally per day for at least 2 weeks, then 5-10 mg/day orally for 1 month
- Duration dependent on persistence of symptoms

#### Wernicke Encephalopathy

- 100 mg intravenously; then 50-100 mg/day intramuscularly or intravenously until consuming regular balanced diet

#### Thiamin Deficiency

- 1 tablet or capsule/day
- Need for thiamin increased when carbohydrate content of diet is high



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Method of administration: Oral.

#### **4.3 Contraindications:**

- Hypersensitivity

Effects of Drug Abuse

- No information available

Short-Term Effects

- See "What Are Side Effects Associated with Using Thiamine?"

Long-Term Effects

- See "What Are Side Effects Associated with Using Thiamine?"

#### **4.4 Warning**

- This medication contains thiamine. Do not take vitamin B1 if you are allergic to thiamine or any ingredients contained in this drug.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately.

#### **4.5 Pregnancy and Lactation**

- Thiamine (injectable) is generally acceptable during pregnancy
- Controlled studies in pregnant women show no evidence of fetal risk
- Only use thiamine in doses exceeding the recommended daily average during pregnancy with caution if benefits outweigh risks
- Animal studies show risk and human studies are not available, or neither animal nor human studies were done
- Thiamine is safe to use while breastfeeding





## **5. Pharmacological properties:**

### **5.1 Pharmacokinetic Properties:**

Thiamine deficiency is associated with traditional rice preparation methods, including the use of nonparboiled polished rice (from which the thiamine-rich bran has been removed), and may be particularly common in nursing mothers and their infants because of increased dietary thiamine requirements of pregnancy and lactation. Although the accepted cause of thiamine deficiency is dietary inadequacy, to our knowledge, pharmacokinetics of oral thiamine absorption have not been studied in Asian populations at risk of beriberi. Available pharmacokinetic data have assessed thiamine-replete whites.

### **5.2 Pharmacodynamic Properties:**

Thiamine is a vitamin with antioxidant, erythropoietic, cognition-and mood-modulatory, antiatherosclerotic, putative ergogenic, and detoxification activities. Thiamine has been found to protect against lead-induced lipid peroxidation in rat liver and kidney. Thiamine deficiency results in selective neuronal death in animal models. The neuronal death is associated with increased free radical production, suggesting that oxidative stress may play an important early role in brain damage associated with thiamine deficiency. Thiamine plays a key role in intracellular glucose metabolism and it is thought that thiamine inhibits the effect of glucose and insulin on arterial smooth muscle cell proliferation. Inhibition of endothelial cell proliferation may also promote atherosclerosis. Endothelial cells in culture have been found to have a decreased proliferative rate and delayed migration in response to hyperglycemic conditions. Thiamine has been shown to inhibit this effect of glucose on endothelial cells.

## **6. Pharmaceutical particulars:**

### **6.1 List of Excipients:**

Di Basic Calcium Phosphate	BP
Maize starch	BP
Methyl Paraben sodium	BP
Propyl Paraben sodium	BP
Purified talc	BP
Sodium Starch Glycolate	BP
Colloidal silicon dioxide	BP
Magnesium stearate	BP



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**6.2 Incompatibilities:**

None Reported

**6.3 Shelf-Life:**

36 months from the date of manufacture.

**6.4 Special Precautions for Storage:**

Store under normal storage conditions (15°C to 30°C). Protect from light.

**6.5 Nature and Contents of Container:**

50 tablets packed in a primary packaging material of Poly Bag having dimension 3 X 4.5 inches & such Poly Bag is packed in a 50 ml HDPE Jar.

**6.6 Special precautions for disposal:**

None reported.

**7. Registrant:**

**AGOG PHARMA LTD.**

Plot No. 33, Sector II,  
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**8. Manufacturer:**

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**9. Date of revision of the text: 07/10/2022**