

## THIAMINE HYDROCHLORIDE INJECTION, USP (Vitamin B1)

### *Therapeutic Category: Vitamin*

**Pharmacology:** In the body, thiamine combines with adenosine triphosphate (ATP) to form thiamine pyrophosphate, also known as cocarboxylase, a coenzyme. Its role in carbohydrate metabolism is the decarboxylation of pyruvic acid and alpha-ketoacids to acetaldehyde and carbon dioxide. Increased levels of pyruvic acid in the blood indicate a vitamin B1 deficiency. The normal mean whole-blood level of bound thiamine is 28 µg/L and those of free thiamine are 6.5 to 11.4 µg/L.

Thiamine requirement is directly related to the carbohydrate content of the diet. The minimum daily requirement is estimated to be 0.33 mg/4200 kJ (1000 kcal). Absorption is an active process. The total amount of large doses which can be absorbed is 4 to 8 mg. Body stores are approximately 30 mg with a 1 mg daily turnover. When the body tissues are saturated with thiamine, it is excreted in the urine as pyrimidine. As the intake of thiamine is further increased, thiamine appears unchanged in the urine in amounts exceeding 100 µg/24 hours.

Vitamin B1 depletion can occur after approximately 3 weeks of total absence of thiamine in the diet. Patients receiving dialysis may require supplementation.

**Indications:** Prophylaxis and treatment of thiamine deficiency including beri-beri and Wernicke's encephalopathy. Parenteral administration is indicated when the oral route is not feasible, as in anorexia, nausea, vomiting, or preoperative and postoperative conditions. It is also indicated when gastrointestinal absorption is impaired as in the "malabsorption syndrome" (steatorrhea).

**Contraindications:** Thiamine allergy.

**Precautions:** Serious sensitivity reactions can occur. Deaths have resulted from IV use. An intradermal test dose is recommended prior to administration in patients suspected of being sensitive to the drug.

Simple thiamine deficiency is rare. Multiple vitamin deficiencies should be suspected in any case of dietary inadequacy. The patient should be advised as to proper dietary habits during treatment so that relapses will be less likely to occur with reduction in dosage or cessation of injection therapy.

**Pregnancy:** Studies in pregnant women have not shown that thiamine HCl increases the risk of fetal abnormalities if administered during pregnancy. If the drug is used during pregnancy, the possibility of fetal harm appears remote. Because studies cannot rule out the possibility of

harm, thiamine should be used during pregnancy only if clearly needed.

**Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when thiamine is administered to nursing women.

**Adverse Effects:** Some tenderness and induration may follow intramuscular use. Feeling of warmth, pruritus, urticaria, weakness, sweating, nausea, restlessness, tightness of the throat, angioneurotic edema, cyanosis, pulmonary edema, hemorrhage into the gastrointestinal tract, collapse and death have been reported.

**Dosage:** Wernicke's encephalopathy and high output cardiac failure secondary to beri-beri must be treated as emergencies. Critically ill patients or those with malabsorption syndromes should also be treated by the IV or IM route. In the treatment of beri-beri, 10 to 20 mg of thiamine may be given intramuscularly 3 times daily for 2 weeks. Dosage should then be reduced depending on patient response, followed by oral therapy.

In Wernicke's encephalopathy, 100 mg IV is given initially followed by 50 to 100 mg IM or IV daily until the patient is eating a well balanced diet. IV dextrose solutions increase thiamine requirements and thiamine should be given parenterally before administering these solutions to the patient with Wernicke's. Following clinical improvement and consumption of a regular diet, oral therapy may be instituted.

**Availability:** Each mL contains thiamine HCl 100 mg, monothioglycerol 0.5%, chlorbutanol 0.5%, sodium hydroxide to adjust pH and Water for Injection. In multidose vials of 10 mL. Latex-free stopper.

Store at room temperature (15°-30°C). Protect from light.

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