

70mm x 140mm

Thiamine Injection BP 100 mg/2 ml

Composition:

Each 2 ml contains:
Thiamine Hydrochloride BP 100 mg
Water for Injection Q.S.

DESCRIPTION

Thiamine hydrochloride injection, BP is a sterile solution of thiamine hydrochloride in Water for Injection for intramuscular (IM) or slow intravenous (IV) administration.

Thiamine hydrochloride, or vitamin B1, occurs as white crystals or crystalline powder that usually has a slight characteristic odor. Freely soluble in water; soluble in glycerin; slightly soluble in alcohol; insoluble in ether and benzene. Thiamine is rapidly destroyed in neutral or alkaline solutions but is stable in the dry state. It is reasonably stable to heat in acid solution.

The chemical name of thiamine hydrochloride is thiazolium,3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methylchloride, monohydrochloride.

CLINICAL PHARMACOLOGY

The water soluble vitamins are widely distributed in both plants and animals. They are absorbed in man by both diffusion and active transport mechanisms. These vitamins are structurally diverse (derivatives of sugar, pyridine, purines, pyrimidine, organic acid complexes and nucleotide complex) and act as coenzymes, as oxidation-reduction agents, possibly as mitochondrial agents. Metabolism is rapid, and the excess is excreted in the urine.

INDICATIONS AND USAGE

Thiamine hydrochloride injection is effective for the treatment of thiamine deficiency or beriberi whether of the dry (major symptoms related to the nervous system) or wet (major symptoms related to the cardiovascular system) variety. Thiamine hydrochloride injection should be used where rapid restoration of thiamine is necessary, as in Wernicke's encephalopathy, infantile beriberi with acute collapse, cardiovascular disease due to thiamine deficiency, or neuritis of pregnancy if vomiting is severe. It is also indicated when giving IV dextrose to individuals with marginal thiamine status to avoid precipitation of heart failure.

Thiamine hydrochloride injection is also indicated in patients with established thiamine deficiency who cannot take thiamine orally due to coexisting severe anorexia, nausea, vomiting, or malabsorption. Thiamine hydrochloride injection is not usually indicated for conditions of decreased oral intake or decreased gastrointestinal absorption, because multiple vitamins should usually be given.

CONTRAINDICATIONS

A history of sensitivity to thiamine or to any of the ingredients in this drug is a contraindication.

WARNINGS

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration. Serious hypersensitivity/anaphylactic reactions can occur, especially after repeated administration. Deaths have resulted from IV or IM administration of thiamine (see **ADVERSE REACTIONS**).

PRECAUTIONS

General

Simple vitamin B1 deficiency is rare. Multiple vitamin deficiencies should be suspected in any case of dietary inadequacy.

Information for Patients

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.

Usage in Pregnancy

Pregnancy Category A

Studies in pregnant women have not shown that thiamine hydrochloride 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 however, thiamine hydrochloride 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 hydrochloride is administered to a nursing mother.

ADVERSE REACTIONS

An occasional individual may develop a hypersensitivity or life threatening anaphylactic reaction to thiamine, especially after repeated injection. Collapse and death have been reported. A feeling of warmth, pruritus, urticaria, weakness, sweating, nausea, restlessness, tightness of the throat, angioneurotic edema, cyanosis, pulmonary edema, and hemorrhage into the gastrointestinal tract have also been reported. Some tenderness and induration may follow IM use.

DOSAGE AND ADMINISTRATION

"Wet" beriberi with myocardial failure must be treated as an emergency cardiac condition, and thiamine must be administered slowly by the IV route in this situation (see **WARNINGS**).

In the treatment of beriberi, 10 mg to 20 mg of thiamine hydrochloride are given IM 3 times daily for as long as 2 weeks. (See **WARNINGS** regarding repeated injection of thiamine.) An oral therapeutic multivitamin preparation containing 5 mg to 10 mg thiamine, administered daily for one month, is recommended to achieve body tissue saturation.

Infantile beriberi that is mild may respond to oral therapy, but if collapse occurs, doses of 25 mg may cautiously be given IV.

Storage : Store in a cool and dry place, protect from light.

Presentation: 10 x 2 ml Amp pack in an tray along with insert.

Manufactured in India by :



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