



New Zealand Data Sheet

APO-THIAMINE

Thiamine hydrochloride 10mg, 25mg and 50mg Tablets BP

Presentation

APO-THIAMINE 10mg tablets are white, round, 5.5mm in diameter, biconvex. Each tablet contains 10mg thiamine hydrochloride and typically weighs 55mg.

APO-THIAMINE 25mg tablets are white, round, 7mm in diameter, flat with beveled edges. Each tablet contains 25mg thiamine hydrochloride and typically weighs 100mg.

APO-THIAMINE 50mg tablets are white, round, 8mm in diameter, biconvex, engraved with "APO" on one side and "THI" over "50" on the other side. Each tablet contains 50mg thiamine hydrochloride and typically weighs 200mg.

Uses

Actions

Thiamine hydrochloride (vitamin B₁) is a water-soluble vitamin. It is an essential co-enzyme for carbohydrate metabolism in the form of the diphosphate (thiamine pyrophosphate, cocarboxylase). 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 vitamin B₁ deficiency.

Thiamine deficiency can occur when dietary intake is inadequate (after approximately 3 weeks of total absence of the vitamin from the diet). Deficiency may occur in alcoholics and food faddist or in special clinical situations such as haemodialysis, chronic peritoneal dialysis, or after administration of glucose to a vitamin B₁ depleted patient. Requirements may be increased due to burns, chronic fever, gastrectomy, intestinal disease, liver disease and hyperthyroidism. Deficiency of vitamin B₁ eventually leads to beriberi or Wernicke's encephalopathy. The cardiovascular and/or nervous system may be affected.

Cardiovascular involvement is manifested by high output, biventricular heart failure and oedema. CNS symptoms include peripheral neuropathy and an encephalopathy syndrome characterised by nystagmus, ophthalmoplegia, fever, ataxia and progressive mental deterioration which may ultimately result in coma and death.

Pharmacokinetics

Small amounts of thiamine are absorbed from the gastrointestinal tract mainly from the duodenum by both active and passive processes. However absorption of doses greater than 5mg is limited.

It is widely distributed to most body tissue and appears in breast milk. Body stores (as the phosphorylated form) are approximately 30mg with a 1mg daily turnover. Storage is mainly in skeletal muscles, heart, liver, kidneys and brain.

Amounts of thiamine in excess of the body's requirements are excreted in the urine as either unchanged thiamine or as metabolites. Thiamine is metabolised in the liver.

It is transformed by phosphorylation into active co-enzyme thiamine pyrophosphate. Dephosphorylation can occur in the kidneys and probably other organs and excess quantities of the free vitamin and the pyrimidine are excreted in the urine. The urinary excretion is depends in part on the urine volume and during diuresis large amounts of thiamine may be lost. Small quantities are excreted in the sweat.

Indications

Prophylaxis and treatment of vitamin B₁ deficiency states including beriberi and Wernicke's encephalopathy.

Dosage and Administration

In preventing vitamin deficiencies adequate dietary intake is preferred over supplementation whenever possible. An adequate human diet in most circumstances is one containing between 0.8 and 1.5mg vitamin B₁ daily.

The usual adult dose to treat deficiency is 5-30mg either as a single or in divided doses.

In severe thiamine deficiency including treatment of beriberi doses of up to 300mg daily in three divided doses may be given. Even higher daily doses may be given in Wernicke's encephalopathy although the intravenous route is usually chosen under these circumstances.

Contraindications

Hypersensitivity to vitamin B₁.

Warnings and Precautions

Serious sensitivity reactions can occur with deaths having resulted from I.V. use.

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

Use in Pregnancy and Lactation

No adverse effects have been reported with the intake of normal daily requirements during pregnancy.

Although thiamine appears in breast milk, no adverse effects have been reported with intake of normal daily requirements during lactation.

Adverse Effects

Feeling of warmth, pruritus, urticaria, weakness, sweating, nausea, restlessness, tightness of the throat, angioneurotic oedema, cyanosis, pulmonary oedema, haemorrhage into the gastrointestinal tract, collapse and death have been rarely reported mainly following repeated I.V. administration.

Interactions

None have been reported.

Overdosage

Overdosage has not been reported and intake in excess of the body's requirements is excreted in the urine. Should overdosage occur and adverse reactions result, treatment should be supportive and symptomatic. Fluid intake should be maintained.

Pharmaceutical Precautions

Store below 30°C. Protect from heat, light and moisture.
Keep container tightly closed.



APO-THIAMINE

Thiamine hydrochloride 10mg, 25mg and 50mg Tablets BP

Medicine Classification

General Sale Medicine

Package Quantities

APO-THIAMINE 50mg - Bottles of 100.

APO-THIAMINE 10mg and APO-THIAMINE 25mg are currently not marketed.

Further Information

Tablets contain lactose.

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