Australian Product Information

Thiamine Kabi
Thiamine Hydrochloride 100 mg/ml Solution for Injection

1. Name of the Medicine

Thiamine hydrochloride

2. Qualitative and Quantitative Composition

Each 1 mL Injection contains 100 mg of thiamine hydrochloride.

For the full list of excipients, see Section 6.1 List of Excipients.

3. Pharmaceutical Form

Injection for Intravenous or Intramuscular use. The injection is a clear and colourless to slightly yellow solution.

The pH of the solution is 2.8 to 3.4.

4. Clinical Particulars

4.1 Therapeutic Indications

Thiamine Kabi is used for the prevention and treatment of vitamin B_1 deficiency.

4.2 Dose and Method of Administration

Use in one patient on one occasion only and discard any residue.

Thiamine Kabi is administered by IM injection or slow IV injection over a period of at least 10 minutes.

Due to the potential for serious anaphylactic reactions, parenteral administration of thiamine is only indicated when oral administration of thiamine is not acceptable or possible. Facilities for treating anaphylaxis should be available when administering Thiamine Injection.

Thiamine Deficiency
Simple thiamine deficiency is rare and as a result multiple vitamin deficiencies should be suspected either in those patients exhibiting signs consistent with thiamine deficiency, or those considered to be at risk of developing thiamine deficiency. Consideration should be given to administering other water-soluble vitamins in conjunction with thiamine.

In critically ill thiamine deficient adults and in patients with malabsorption syndromes, the usual IM or IV dosage of thiamine hydrochloride is 5 to 100 mg three times daily. In patients with beriberi, the dose should then be reduced according to response and followed by oral therapy for one month.

In patients with Wernicke's encephalopathy, thiamine hydrochloride therapy is usually initiated with an IV dose of 100 mg over at least 30 minutes, followed by IM or IV doses of 50–100 mg daily until the patient is consuming a regular, well-balanced diet. High carbohydrate diets or IV glucose solutions increase thiamine requirements and may worsen symptoms in thiamine deficient patients. Thiamine should be administered parentally before giving glucose solutions to the patient with Wernicke's encephalopathy.

In alcohol withdrawal syndrome to prevent Wernicke's encephalopathy, 100 mg of thiamine should be given IM or IV followed by 100 mg orally, IM or IV for up to 5 days.

Dietary Supplementation
Dietary Improvement is preferred over supplementation wherever possible. The Australian recommended daily intake (RDI) of thiamine for adults is shown in Table 1 below:

Table 1: Australian RDI of thiamine for adults

Age group	RDI for thiamine
Men 19-64 years	1.1 mg
Men > 64 years	0.9 mg
Women 19-64 years	0.8 mg
Women > 64 years	0.7 mg
Pregnant women	1.0 mg
Lactating women	1.2 mg

Use in Infants and Children
Critically ill children who are thiamine deficient receive a usual IM or IV dose of thiamine hydrochloride of 10-25 mg daily. The Australian recommended daily intake (RDI) of thiamine for children is shown in Table 2 below:

Table 2: Australian RDI of thiamine for children

Age group	RDI for thiamine
Children 2-3 years	0.5 mg
Children 4-7 years	0.7 mg
Boys 8-11 years	0.9 mg
Boys 12-18 years	1.2 mg
Girls 8-11 years	0.8 mg
Girls 12-15 years	1.0 mg
Girls 16-18 years	0.9 mg

Compatibility
Thiamine Kabi is reported to be compatible with 100 mL of diluent; glucose 5%, glucose 10%, sodium chloride 0.9% or compound sodium lactate (Hartmann's solution).

4.3 Contraindications

- Known hypersensitivity to any of the ingredients

4.4 Special Warnings and Precautions for Use

Serious hypersensitivity reactions to thiamine have been reported following parenteral administration [see Section 4.8 Adverse Effects (Undesirable Effects)]. These reactions include feelings of warmth, tingling, pruritus, pain, urticaria, weakness, sweating, nausea, restlessness, tightness of the throat, angioedema, respiratory distress, cyanosis, pulmonary oedema, gastrointestinal bleeding, transient vasodilatation and hypotension, vascular collapse, and death.

A sensitivity history should be obtained from the patient prior to administration of thiamine.

An intradermal diluted test dose of thiamine should be administered to patients with suspected sensitivity (e.g. a history of an allergic response such as itching, sneezing, wheezing or frank anaphylactic shock with a previous injection) before parenteral administration.

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

Intravenous glucose loading may precipitate or worsen the condition of Wernicke's encephalopathy in thiamine-deficient patients: - Thiamine hydrochloride should be administered prior to glucose.

Use in the elderly
Problems in geriatrics have not been documented with intake of normal daily recommended amounts. The elderly may have impaired thiamine status, thereby requiring thiamine supplementation. Information on large doses is not available.

Paediatric use
There is only limited experience with therapy in children and adolescents.

Information on large doses in children over 2 years is not available.

Effects on laboratory tests
Thiamine reportedly causes false-positive results in the urine spot test with Erlich's reagent for urobilinogen and may also interfere with the phosphotungstate method for determination of uric acid concentrations.

Large doses of thiamine have reportedly interfered with the Schack and Waxler spectrophotometric determination of serum theophylline concentrations, giving falsely raised results.

4.5 Interactions with Other Medicines and Other Forms of Interactions

Although the clinical importance is unknown, thiamine reportedly may enhance the effect of neuromuscular blocking agents.

In vitro thiamine hydrochloride at a concentration of 0.1% significantly reduces the activity of Kanamycin sulfate and Streptomycin sulfate at 25 °C.

4.6 Fertility, Pregnancy and Lactation

Effects on fertility
There is no information available on the effects of thiamine injection on fertility.

Use in pregnancy
Exempt from classification in the Australian categorisation system for prescribing medicines in pregnancy.

There is an increasing demand for thiamine throughout pregnancy due to the increased energy requirement plus the amount needed to meet the foetal requirement. Thiamine is required by the newborn for normal growth and development. Problems in humans have not been documented with intake of normal daily recommended amounts.

There is limited information in humans that large doses in the second or third trimester have no apparent effect.

Embryonic and foetal death have been reported in pregnant women who have severe thiamine deficiency as a result of hyperemesis gravidarum.

Use in lactation
There is an increasing metabolic requirement for thiamine to produce milk, and additional thiamine is also needed to compensate for that lost in the milk and also for the increased maternal energy requirement. About 100-200 micrograms of thiamine is distributed daily into the milk of lactating women receiving a normal diet (see Section 5.2 Pharmacokinetics Properties). Problems in humans have not been documented with intake of normal daily recommended amounts.

Information on large doses is not available.

4.7 Effects on Ability to Drive and Use Machines

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 Adverse Effects (Undesirable Effects)

Anaphylactic Reactions: Rare: these reactions can be preceded by sneezing or transient pruritus.

Symptoms and signs of hypersensitivity and other adverse reactions to thiamine may include any one or more of the following: feelings of warmth, tingling, pruritis, pain, urticaria, erythema, scaling of the facial skin, severe rash, weakness, sweating, nausea, vomiting, restlessness, tightness of the throat, angioedema, respiratory distress, cyanosis, pulmonary oedema, dyspnoea, respiratory failure, gastrointestinal bleeding, abdominal pain, precordial pain, palpitations, tachycardia, transient vasodilation and hypotension, shock, vascular collapse, semi-comatose state and death have occurred (see Section 4.4 Special Warnings and Precautions for Use).

Metabolic and Nutritional Disorders: Very rare: fatty degeneration of the liver resulting in hyaline necrosis and ascites.
Skin and Appendages: Common: pain on injection, local irritation. Tenderness and induration have been reported following IM injection.
Rare: Contact dermatitis, chronic pigment purpura.

Reporting suspected adverse effects
Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at http://www.tga.gov.au/reporting-problems.

4.9 Overdose

In animals, very large parenteral doses have produced neuromuscular and ganglionic blockade. Parenteral doses of 100 mg to 500 mg, as single or repeated doses have been administered without toxic effects. In cases of overdose, withdraw thiamine and give supportive treatment for symptoms and respiratory and cardiac function.

For information on the management of overdose please contact the Poison Information Centre on 13 11 26 (Australia).

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Mechanism of action
In humans, an exogenous source of thiamine (or Vitamin B_1) is required for carbohydrate metabolism. Thiamine combines with adenosine triphosphate (ATP) in the liver, kidneys, and leukocytes to form thiamine diphosphate (thiamine pyrophosphate) also known as cocarboxylase. Thiamine diphosphate is a coenzyme in carbohydrate metabolism (in the decarboxylation of pyruvic acid and α-ketoglutaric acids) and in transketolase reactions. Thiamine diphosphate is also a coenzyme in the utilization of pentose in the hexose monophosphate shunt. Even large doses of thiamine have no effect on blood glucose concentrations. Thiamine deficiency leads to decreased transketolase activity in erythrocytes and to increased pyruvic acid concentration in the blood. In the absence of thiamine as thiamine pyrophosphate, pyruvic acid is not converted to acetyl-COA and therefore is unable to enter the usual aerobic oxidative pathway (Krebs citric acid cycle), resulting in accumulation of pyruvic acid and subsequent conversion to lactic acid. In addition, the resultant decreased production of NADH within the Krebs cycle stimulates anaerobic glycolysis and further lactic acid production. Therefore, lactic acidosis may occur in thiamine deficiency.

The normal mean level of thiamine in whole blood is 28 micrograms/L, and of free thiamine is 6.5 to 11.4 micrograms/L.
Thiamine is used in the prevention or treatment of vitamin B1 deficiency syndromes including beriberi, Wernicke's encephalopathy and peripheral neuritis associated with pellagra or neuritis of pregnancy (if associated with severe vomiting). Dietary improvement is preferred over supplementation whenever possible to the administration of vitamin supplements.
Thiamine deficiency results in beriberi and Wernicke's encephalopathy syndrome. Clinical signs of thiamine deficiency become evident after 2-3 weeks of inadequate thiamine intake. The organ systems principally affected by thiamine deficiency are the peripheral nervous system, cardiovascular system and the gastrointestinal tract. Administration of thiamine completely reverses the cardiovascular and gastrointestinal symptoms of thiamine deficiency, however the degree of improvement in neurological symptoms depends on the duration and severity of the lesions. Fatal deficiency can develop as rapidly as within 3-4 weeks in the absence of thiamine intake. Several cases of fatal, acute beriberi developed within 5 weeks in patients receiving thiamine deficient total parenteral nutrition solutions during a US shortage of parenteral multivitamin preparations.

Thiamine supplementation is useful in preventing deficiency in malabsorption syndromes such as alcoholism, cirrhosis and gastrointestinal diseases. Increased thiamine requirements are also associated with pregnancy, increased carbohydrate intake, increased physical activity, hyperthyroidism, infection and hepatic disease. Dietary improvement is preferred over supplementation whenever possible to the administration of vitamin supplements.

Thiamine requirement is directly related to the carbohydrate content of the diet. The minimum daily requirement is estimated to be 0.33 mg/4,200kJ (1,000 kcal). Vitamin B1 depletion can occur after approximately 3 weeks of total absence of thiamine in the diet. Deficiency may occur in alcoholics and food faddists or in special situations such as haemodialysis or chronic peritoneal dialysis. Requirements may be increased due to burns, chronic fever, gastrectomy, intestinal disease, liver disease and hyperthyroidism. Symptoms of deficiency include mental confusion, anorexia, muscle wasting, oedema and heart failure.

Clinical trials
No data available.

5.2 Pharmacokinetic Properties

Absorption
Following oral administration of small doses, thiamine hydrochloride is readily absorbed; however absorption is
an active process and the total amount absorbed after oral administration of a large dose is limited to about 4 - 8 mg.

GI absorption of thiamine is decreased in alcoholics and in patients with cirrhosis or malabsorption. The rate, but not the extent, of GI absorption of thiamine is decreased when the drug is administered with meals.

Thiamine is completely and rapidly absorbed after IM and IV administration. In chronic alcohol mis-users, malnutrition can reduce intestinal thiamine absorption by ~70%, decreasing serum levels from 30 to 98% below the lower level established for normal subjects. Alcohol itself alone can also decrease absorption by 50% in one third of patients who are not malnourished.

Distribution
Thiamine is widely distributed into body tissues, including the brain, liver, heart, kidneys, muscle, cerebrospinal fluid and blood cells. Thiamine is not stored to any appreciable extent in the body. Body stores of thiamine have been estimated to be about 30 mg with about a 1 mg daily turnover. About 100 - 200 micrograms of thiamine is distributed daily into the milk of nursing women receiving a normal diet.

Metabolism
Thiamine is metabolised in the liver in animals. Several urinary metabolites of thiamine have been identified in humans.

Excretion
Little or no unchanged thiamine is excreted in urine following administration of physiologic doses; however, dosages exceeding 30 mg three times daily are not utilised effectively. 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 micrograms / 24 hours.

5.3 Preclinical Safety Data

Genotoxicity
No data available.

Carcinogenicity
No data available.

6. Pharmaceutical Particulars

6.1 List of Excipients

Hydrochloric acid, Sodium hydroxide, Water for injections

6.2 Incompatibilities

Thiamine is unstable in neutral or alkaline solutions; therefore, administration with carbonates, citrates, barbiturates, or copper ions is not recommended. In addition, stability is poor in intravenous solutions containing sodium bisulfite as an antioxidant or preservative; if these solutions must be given, they should be given separately from a thiamine hydrochloride injection.

Oxidation of thiamine hydrochloride results in the formation of the highly blue-coloured and biologically inactive compound – thiochrome.

6.3 Shelf Life

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 Special Precautions for Storage

Store below 25°C. Protect from light.
Keep out of reach of children.

6.5 Nature and Contents of Container

Container type:
Type 1 colourless glass ampoule.

Pack sizes:

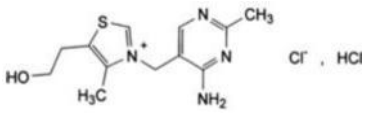
Thiamine Kabi has one pack size:
10 x 1 mL vials per carton

6.6 Special Precautions for Disposal

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 Physicochemical Properties

Chemical structure



Molecular formula: $C_{12}H_{17}ClN_4OS,HCl$

CAS number
67-03-8

Thiamine hydrochloride occurs as a white or almost white, crystalline powder or colourless crystals. It is freely soluble in water, soluble in glycerol, slightly soluble in alcohol.

7. Medicine Schedule (Poisons Standard)

Not scheduled

8. Sponsor

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9. Date of First Approval

28 October 2026

10. Date of Revision

Not Applicable

Summary Table of Changes

Section Changed	Summary of new information
	New registration