# New Zealand Data Sheet

## 1 PRODUCT NAME

**THIAMINE STEROP** 100 mg/2 mL Solution for Injection

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 mL injection in ampoule contains 100 mg of thiamine hydrochloride
For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Solution for injection for intravenous use.
The pH of the solution is 2.5 to 4.5.
Aqueous, clear, colourless to slightly yellow solution, visible particle free

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Thiamine hydrochloride 100 mg in 2 mL Injection is used for the prevention and treatment of vitamin B1 deficiency, when oral administration of thiamine is not acceptable or possible.

### 4.2 Dose and method of administration

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

Thiamine hydrochloride 100 mg in 2 mL Injection is administered by slow IV injection over a period of over 30 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 (see section 4.4).

Thiamine Deficiency

In critically ill thiamine deficient adults and in patients with malabsorption syndromes, the usual IV dosage of thiamine hydrochloride is 5 to 100 mg three times daily.

Beriberi

Treatment: 10 mg to 25 mg/day by slow intravenous infusion for 2 weeks. IV doses of 100 mg/day or even higher may be needed in severe cases, for example 500 mg three times a day could be used.

Treatment of Wernicke ' s encephalopathy (WE) associated with Alcohol addiction and/or alcohol withdrawal syndrome and prevention of Wernicke-Korsakoff syndrome

Treatment: 500 mg by intravenous route 3 times/day for at least 2 days (up to 1000 mg/dose during the first 12 hours may be used). In case of favourable response the treatment can be continued with 250 mg by intravenous route 1 time/day for 5 days or until there is no further improvement.

When administering intravenously thiamine should be diluted with 50 mL to 100 mL of physiological saline and administered over 30 minutes duration. This product should be used immediately upon dilution.

Clinical experience indicates that patients with WE may benefit from continued treatment for more than 2 weeks. In alcoholics without WE, oral thiamine administration is as effective as parenteral administration after 5 days.

Use in Infants and Children

Critically ill children who are thiamine deficient receive a usual IV dose of thiamine hydrochloride of 10-25 mg daily.

Compatibility

Thiamine hydrochloride 100 mg in 2 mL Injection 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

Hypersensitivity

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.

Multiple Vitamin Deficiencies

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.

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 Interaction with other medicines and other forms of interaction

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.

Please see Section 6.2 Incompatibilities.

## 4.6 Fertility, pregnancy and lactation

### 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.

### Breastfeeding

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.

### Fertility

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

## 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 Undesirable effects

Adverse reactions reported as possibly associated to thiamine are presented in the following table by MedDRA System Organ Class (SOC), Preferred Term and frequency. The following frequency categories are used:

Very common (>1/10);
Common (>1/100, 1/1,000, 1/10,000);
Uncommon (>1/1,000, 1/10,000);
Rare (>1/10,000);
Very rare (<1/10,000), including isolated reports.

Post-marketing adverse reactions are reported voluntarily from a population with an unknown rate of exposure. Therefore, it is not possible to estimate the true incidence of adverse reactions, and the frequency is "unknown".

**Tabulated summary of adverse reactions**

| System Organ Class (SOC) | Frequency | Undesirable Effect |
|---|---|---|
| Immune system disorders | Rare | Anaphylactic reactions [a] |
| | Not Known | Hypersensitivity (see description of selected adverse reactions) |
| Metabolic and Nutritional Disorders | Very rare | Fatty degeneration of the liver resulting in hyaline necrosis and ascites |
| Vascular disorders | Rare | Chronic pigment purpura |
| Skin and subcutaneous tissue disorders | Rare | Contact dermatitis |
| | Not Known | Pruritis, urticaria and rash |

[a] *These reactions can be preceded by sneezing or transient pruritus*

**Description of selected adverse reactions**

Hypersensitivity

Serious hypersensitivity reactions to thiamine have been reported following parenteral administration. 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 [see Section 4.4 Special warnings and precautions for use].

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://pophealth.my.site.com/carmreportnz/s/

## 4.9 Overdose

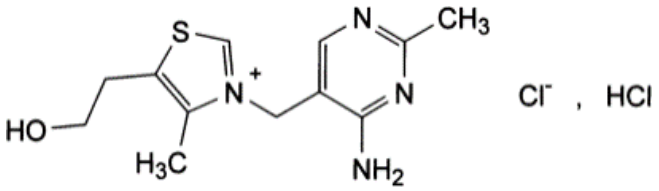
In animals, very large parenteral doses have produced neuromuscular and ganglionic blockade. Parenteral doses of 100 mg to 500 mg, as single or repeated doses have been administered without toxic effects. In cases of overdose, withdraw thiamine and give supportive treatment for symptoms and respiratory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

For risk assessment and advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Physicochemical properties

**Chemical structure**




**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, slightly soluble in ethanol 96%.

## 5.2 Pharmacodynamic properties

**Mechanism of action**

In humans, an exogenous source of thiamine (or Vitamin B1) 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.

## 5.3 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. 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. 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 administration.

In patients with severe or life-threatening thiamine deficiency, rapid repletion with high dose of thiamine is achieved with parenteral administration (see section 4.2).

**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.

### 5.4 Preclinical safety data

**Genotoxicity**
No data available.

**Carcinogenicity**
No data available.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Thiamine Sterop contains sodium hydroxide and 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.

Please see Section 4.5 Interactions with other medicines and other forms of interactions.

### 6.3 Shelf life

12 months

### 6.4 Special precautions for storage

Store below 25°C. Protect from Light.

### 6.5 Nature and contents of container

**Container type:**
Type I colourless glass ampoule.

**Pack sizes:**
Thiamine Hydrochloride 100mg/2 ml injection has below mentioned pack size;
10 × 2 mL ampoule per carton.

### 6.6 Special precautions for disposal

No special requirements.
Any unused medicine or waste material should be disposed of in accordance with local requirements.

## 7 MEDICINE SCHEDULE

General Sale Medicine

## 8 SPONSOR

BNM Group
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Browns Bay
Auckland 0753

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## 9 DATE OF FIRST APPROVAL

03 July 2025

## 10 DATE OF REVISION OF TEXT