

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Thiamine Hydrochloride 50 mg/ml solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 50 mg thiamine hydrochloride.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection. Clear, colourless solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Thiamine deficiency conditions where oral therapy is not possible. Treatment of Wernicke's encephalopathy associated with Alcohol addiction and/or alcohol withdrawal syndrome and prevention of Wernicke-Korsakoff syndrome. For the treatment of peripheral neuropathy (dry beriberi) and heart failure (wet beriberi) due to thiamine malabsorption. For the treatment of anorexia – refeeding syndrome.

4.2 Posology and method of administration

Posology

In the administration of thiamine, the condition of the patient and the extent of the disease need to be taken into consideration. A nutritional therapist should be consulted if uncertain. Thiamine is able to be administered via intramuscular and slow intravenous injection.

Treatment of Wernicke's encephalopathy 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 intramuscular or intravenous route 1 time/day for 5 days or until there is no further improvement.

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

In the outpatient detoxification setting, the administration of a course of thiamine 250 mg intramuscularly for 5 days has been recommended over oral therapy. 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.

Beriberi

Treatment: 10 mg to 25 mg/day by intramuscular injection or 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.

Malabsorption due to gastrectomy

The standard recommendation for postoperative supplementation for thiamine in symptomatic patients is 50–100 mg/day iv or im for 7-14 days and then 10 mg/day orally until complete recovery of neurologic symptoms.

The standard recommendation for daily oral supplementation after surgery in asymptomatic patients is 50- 100 mg/day.

Patients with a history of bariatric surgery who present with any signs of gastrointestinal distress should receive thiamine preventively.

Thiamine administration of 100 mg iv or im daily, or enterally if tolerated, has been suggested for any patient with more than 3-4 week of emesis.

Anorexia – refeeding syndrome

It is recommended that thiamine supplementation (100-300 mg/day) is given during the first 3 days in within the intensive care unit for all patients with suspected thiamine deficiency to prevent neurological adverse effects from too rapid glucose delivery.

Paediatric population

No data are available.

4.3 Contraindications

Hypersensitivity to thiamine hydrochloride or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

Intramuscular or intravenous injection of thiamine may cause hypersensitivity reactions including anaphylactic shock. Facilities for treating anaphylaxis (including resuscitation facilities) should be available when parenteral thiamine is administered.

4.5 Interaction with other medicinal products and other forms of interaction

The thiamine antagonist's thiosemicarbazone, ifosfamide, other fluoropyrimidines (e.g. capecitabine) and 5-fluorouracil can neutralise the effect of thiamine. Diuretics, e.g. furosemide may increase urinary thiamine excretion.

Patients using any of these treatments may need their thiamine dose adjusted.

Thiamine could give false positive results for urobilinogen determination by the Ehrlich's reaction. High doses of thiamine may interfere with spectrophotometric assays of theophylline plasma concentration.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited data from the use of high levels of thiamine (>50 mg/day) in pregnant women.

However, there are no known risks, when thiamine is used during pregnancy at recommended daily intake levels. As a precautionary measure, it is preferable to avoid the use of thiamine during pregnancy.

Breastfeeding

Thiamine is excreted in human milk. At recommended daily intake levels, no effects on the breastfed newborns /infants are anticipated. However, there is insufficient information on the levels and possible effects of excretion of thiamine in human milk after administration of high levels of thiamine (>50 mg/day). A risk to the suckling child cannot be excluded.

Fertility

There are no data on possible effects on fertility after administration of high doses of thiamine (>50 mg/day).

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. However, given the nature of the product, no effects are anticipated.

4.8 Undesirable effects

The frequencies of adverse events are ranked according to the following:

Very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/10,000$), not known (cannot be estimated from the available data).

General disorders and administration site conditions:

Not known: Local irritation at the injection site

Immune system disorders:

Not known: Anaphylaxis

Skin and subcutaneous tissue disorders:

Not known: Exanthem, pruritus, urticaria

Vascular disorders:

Not known: Acute blood pressure decrease

Respiratory, thoracic, and mediastinal disorders

Not known: Dyspnoea

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Parenteral administration of large doses may give anaphylactic reactions.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: vitamins, ATC code: A11DA01

The medicinal product is a vitamin product used for injection of high doses of vitamin B1. Thiamine is phosphorylated in the body to the biological active thiamindiphosphate. Thiamindiphosphate is acting as coenzyme to several enzymes,

which are important for reactions e.g., involving energy transfers and for the normal function of the nerve system and the muscles.

5.2 Pharmacokinetic properties

The elimination half-life is approximately 1-4 hours. Excess thiamine is excreted in the urine.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium phosphate dodecahydrate

Thiomalic Acid

Sodium hydroxide solution (for pH adjustment)

Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

2 years

Chemical and physical in-use stability data has been demonstrated for 4 hours at 25°C.

From a microbiological point of view the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would not normally be more than 24 hours at 2-8°C, unless dilution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Store in original package in order to protect from light. Do not store above 25°C. Do not freeze. This product should be used immediately upon dilution.

6.5 Nature and contents of container

Colourless glass ampoules (type I): 6 x 5 ml, 10 x 5ml Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Pemberton Laboratories (UK) Limited
5 The Heights,
Weybridge, KT13 0NY,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 55469/0002

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

09/09/2024

10 DATE OF REVISION OF THE TEXT

09/09/2024