SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Tiacur 25 mg/ml solution for injection
Tiacur 50 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 25 mg thiamine hydrochloride.

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 e.g. malabsorption, anorexia and alcohol addiction.

4.2 Posology and method of administration

Posology

In 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. Tiacur is administered via intramuscular and slow intravenous injection.

Malabsorption
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 the the intensive care unit for all patients with suspected thiamine deficiency to prevent neurological adverse effects from too rapid glucose delivery.

Alcohol addiction- alcohol withdrawal syndrome
For patients who are at risk of Wernicke´s encephalopathy (WE) the dose is 200-250 mg parenterally 3 times daily for 3-5 days. In the outpatient detoxification setting, the administration of a course of im thiamine 200 mg 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.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Intramuscular or intravenous injection of Tiacur may cause hypersensitivity reactions including anafylactic shock.

4.5 Interaction with other medicinal products and other forms of interaction

Loop diuretics, e.g. furosemide that inhibit tubular reabsorption may cause increased excretion of thiamine in long-term therapy and thus, lowering of the thiamine level.

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 Tiacur during pregnancy.

BreastfeedingThiamine 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. A decision must be made wether to discontinue breast-feeding or to discontinue/abstain from Tiacur therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

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

Not relevant.

4.8 Undesirable effects

The frequencies of adverse events are ranked according to the following:
Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥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

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: Dyspnea

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 national reporting system listed in Appendix V*.

4.9 Overdose

Parenteral administration of large doses may give anafylactic reactions.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: vitamins, ATC code: A11DA01

The medicinal product is a vitamin product used for intramuscular 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

There are no preclinical data considered relevant to clinical safety beyond data included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Chlorobutanol hemihydrate
Water for injections
Hydrochloric acid (for pH adjustment)
Sodium hydroxide (for pH adjustment)

6.2 Incompatibilities

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

6.3 Shelf life

2 years

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.

6.5 Nature and contents of container

Colourless glass ampoules (type I): 5 x 2 ml, 10 x 2 ml
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

To be completed nationally

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be completed nationally

10. DATE OF REVISION OF THE TEXT

2015-01-21