SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Thiamine Hydrochloride 50mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Thiamine Hydrochloride 50mg Tablets are a thiamine (vitamin B1)-containing monovitamin product.

Each tablet contains thiamine hydrochloride, 50mg.

Excipient(s) with known effect:
This product contains lactose monohydrate, see section 4.4.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Round, white or almost white, biconvex tablets embossed with “T50”

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of thiamine deficiencies due to increased dietary requirements, reduced intakes, reduced absorption or increased excretion. Also for treatment of Wernicke-Korsakoff syndrome, beriberi and thiamine deficiency related to chronic alcoholism.

Situations often accompanied by marginal thiamine deficiency and requiring supplementation include but are not limited to:

• Regular heavy drinking / chronic alcohol consumption

- High carbohydrate intakes
- Heavy physical exertion
- Compromised nutritional status
- High dose diuretics
- Type I and Type II diabetes mellitus

4.2 Posology and method of administration

Posology

Treatment:
Adults and adolescents from 12 years of age:

Mild deficiency: 50-100mg per day

Severe deficiency: 200-300mg per day in divided doses

Not recommended for children under 12 years.

Route of Administration
Oral

4.3 Contraindications

Known allergy or hypersensitivity to thiamine or to any of the excipients in Thiamine Hydrochloride 50mg Tablets (see section 6.1).

4.4 Special warnings and precautions for use

This product contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

The thiamine antagonists thiosemicarbazone and 5-fluorouracil can neutralise the effect of thiamine. 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

This product is not intended for use in pregnant or lactating women.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.
However, patients should be cautioned to see how they react before driving or operating machinery.

4.8 Undesirable effects

Gastrointestinal disorders:
Mild gastrointestinal events such as nausea, vomiting, diarrhoea, and abdominal pain have been reported. Frequency not known (cannot be estimated from data).

Immune system disorders:
Allergic and anaphylactic reactions, with symptoms of pruritus, urticaria, itching, hives, angioedema, abdominal pain, respiratory distress, tachycardia, palpitations, and shock have been reported in single cases. Frequency not known (cannot be estimated from data).

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 website www.mhra.gov.uk/yellowcard.

4.9 Overdose

Overdose with this route of administration is unlikely. A suspected overdose should be treated symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vitamin B1, Plain
ATC code: A11DA01.

Thiamine pyrophosphate (TPP), the coenzymatic form of thiamine, is involved in two main types of metabolic reactions: decarboxylation of α-ketoacids (e.g. pyruvate, α-ketoglutarate and branched-chain keto acids) and transketolation (e.g. among hexose and pentose phosphates). Therefore, the principal physiological role of thiamine is as a coenzyme in carbohydrate metabolism, where TPP is required for several stages in the breakdown of glucose to provide energy.

Apart from its metabolic role as a coenzyme, thiamine plays a role in neurotransmitter function and in nerve conduction.

In high doses, thiamine suppresses the transmission of neural stimuli and thus can have an analgesic effect.

Early stages of thiamine deficiency may be accompanied by non-specific symptoms that may be overlooked or easily misinterpreted. The clinical signs of deficiency include anorexia; weight loss; mental changes such as apathy, decrease in short-term memory, confusion and irritability; muscle weakness; and cardiovascular effects such as an enlarged heart.

Cardiac failure, muscle weakness, peripheral and central neuropathy are functional consequences of severe thiamine deficiency. Clinical manifestations of beriberi (severe thiamine deficiency) vary with age. Adults may present with dry (paralytic or nervous), wet (cardiac), or cerebral (Wernicke-Korsakoff syndrome) forms of beriberi.

5.2 Pharmacokinetic properties

Absorption: Thiamine is rapidly absorbed in humans, largely in the proximal small intestine. There are two mechanisms, one by a carrier mediated transport at low physiological concentrations (<2μM), one by passive diffusion at higher concentrations. Absorption is typically high, but intestinal absorption in humans is rate limiting.

Distribution: The average total amount of thiamine in an adult is approximately 30mg. In general the heart has the highest concentration (0.28-0.79mg per 100g), followed by kidney (0.24-0.58mg per 100g), liver (0.20-0.76mg per 100g), and brain (0.14-0.44mg per 100g). In the spinal cord and the brain, the thiamine level is about double that of peripheral nerves. The whole-blood thiamine content varies from 5 to 12μg per 100 ml, 90% of which is in the red cells and leukocytes. Leukocytes have a 10 fold higher concentration than red cells. Thiamine has a high turnover rate in the body and is not stored in large amounts for any period of time in any tissue. When intake is about 60μg per 100g body weight (or 42mg per 70kg) and the total body thiamine reaches 2μg/g (or 140mg per 70kg), a plateau is reached in most tissues.

Thiamine transport across the blood-brain barrier involves two different mechanisms. The saturable mechanism at the blood-brain barrier, however, differs from the energy-dependent mechanism described in the gut, and from the active transport system described in cerebral cortex cells, which may be dependent upon membrane-bound phosphatases.

The immunohistochemical distribution of TTP (thiamine triphosphate) suggests that it has a role in nerve conduction.

Metabolism: Thiamine is quickly converted to the diphosphate and to a smaller extent the triphosphate esters in the tissues. All thiamine in excess of tissue needs, as well as binding and storage capacity, is rapidly excreted in the urine in the free form. Stimulation of nerves causes the release of thiamine or the monophosphate with a concomitant decrease in the triand diphosphates.

Excretion: Thiamine is excreted in the urine. The half-life of thiamine in the body is 10-20 days. In addition to free thiamine and a small amount of thiamine diphosphate, thiochrome, and thiamine disulfide, about 20 metabolites of thiamine have been reported in the urine of rats and humans but only six have been conclusively identified. The relative proportion of metabolites to thiamine excreted increases with decreasing thiamine intake.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline Cellulose
Croscarmellose Sodium
Stearic Acid
Magnesium Stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Blister: 2 years

Pot: 2 years - unopened.

After first opening the pot, medicinal product should be used within 100 days.

6.4 Special precautions for storage

Store below 25°C.

Store in the original package.

For storage conditions after first opening of pots, see section 6.3

6.5 Nature and contents of container

Pot: Polypropylene snap Secure Pot with HDPE/LDPE closure
Blister pack: 250µm PVC/PVDC (white opaque) with 40 gsm aluminium foil (20µm)

28 and 84 tablets in blisters and 100 tablets in pots packaging.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Kent Pharmaceuticals Limited, Connect 38, 1, Dover Place, Ashford, Kent, United Kingdom. TN23 1FB

8 MARKETING AUTHORISATION NUMBER(S)

PL 08215/0182

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