SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Thiamine Hydrochloride 50 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 mg Thiamine Hydrochloride.

Excipient(s) with known effect:
Each tablet contains 85.00 mg lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

White to off white, circular biconvex uncoated tablets embossed with “THT” and “50” separated by break line on one side and plain on other side.
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of thiamine deficiency

4.2 Posology and method of administration

Adults, the Elderly and Children over three years:

Mild chronic deficiency: 50 mg daily

Severe deficiency: 100 mg three times daily.

Not recommended for children under three years.

Route of administration: oral

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

This medicinal 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 antagonist's 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:
Hypersensitivity reactions have been reported (mainly after parenteral administration).
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 at www.mhra.gov.uk/yellowcard.

4.9 Overdose

Overdose has not been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: A11DA01

Pharmacotheraputic Group: Vitamin B_1, Plain

Thiamine is an essential co-enzyme for carbohydrate metabolism.

5.2 Pharmacokinetic properties

Thiamine is well absorbed from the gastrointestinal tract following oral administration, although the absorption of large doses is limited. It is widely distributed to most body tissues and appears in breast milk. Within the cell, thiamine is mostly present as the diphosphate.
Thiamine is not stored to any appreciable extent in the body; amounts in excess of the body's requirements are excreted in the urine as unchanged thiamine or metabolites.

5.3 Preclinical safety data

No relevant data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Maize Starch
Pregelatinised Starch
Magnesium Stearate
Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.
HDPE containers: Discard 100 days after first opening the container.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Pack of 100's and 250's tablets in white opaque HDPE bottle with white polypropylene child resistant cap containing a polyester coil and desiccant container.
Pack of 28's tablets in blisters of Aluminium-PVC/PVDC
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Flamingo Pharma UK Ltd.
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8 MARKETING AUTHORISATION NUMBER(S)

PL 43461/0037

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

03/07/2018

10 DATE OF REVISION OF THE TEXT

20/03/2019