

## **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 of thiamine hydrochloride.

For a full list of excipients, see section 6.1.

### **3 PHARMACEUTICAL FORM**

Tablet

A white, biconvex round uncoated tablet, 7.2 mm (approx) in diameter with 'VB<sub>1</sub> 50' engraved on one side.

### **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 II diabetes mellitus

## 4.2 Posology and method of administration

### Posology

#### Adults and adolescents from 12 years of age:

Mild chronic deficiency: 50- 100 mg daily

Severe deficiency: 200-300 mg daily, in divided doses

Not recommended for children under 12 years

Method of administration: Oral administration

## 4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1

## 4.4 Special warnings and precautions for use

### **Important information about the ingredients of Thiamine Hydrochloride 100 mg**

#### **Tablets**

#### Sodium

This medicine contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

## 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.

Furosemide may increase urinary loss of thiamine and prolonged use of furosemide therapy may induce thiamine deficiency.  
Excessive alcohol intake induces thiamine deficiency.

#### **4.6 Fertility, pregnancy and lactation**

***Pregnancy:***

There are no or limited amount of data from the use of *thiamine hydrochloride* in *pregnant women*.

As a precautionary measure, it is preferable to avoid the use of *Thiamine Hydrochloride* during pregnancy.

***Breast feeding:***

*Thiamine* is excreted in human milk. A risk to the suckling child cannot be excluded  
A decision must be made whether to discontinue breast-feeding or to  
discontinue/abstain from Thiamine Hydrochloride therapy taking into account the  
benefit of breast feeding for the child and the benefit of therapy for the woman.

***Fertility:***

There is no data of relevance available.

#### **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 website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

## **4.9 Overdose**

Overdose with this route of administration is unlikely. Thiamine is not stored to any appreciable extent in the body and amounts in excess of the body's requirements are excreted in the urine unchanged or as metabolites.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Vitamin B1, Plain

ATC code: A11DA01.

Thiamine diphosphate (also known as thiamine pyrophosphate), the coenzymatic form of thiamine, is involved in two main types of metabolic reactions: oxidative decarboxylation of  $\alpha$ -ketoacids (involved in energy production) and transketolation reaction of the pentose phosphate pathway (involved in carbohydrate metabolism). Therefore, the principal physiological role of thiamine is as a coenzyme in carbohydrate metabolism, where thiamine diphosphate is required for several stages in the breakdown of glucose to provide energy.

Apart from its metabolic role as a coenzyme, thiamine plays an important role in nerve transmission.

Early stages of thiamine deficiency may be accompanied by non-specific symptoms that may be overlooked or easily misinterpreted. Early signs of thiamine deficiency (including subclinical deficiency) include anorexia, irritability and weight loss; later features include headache, weakness, tachycardia and peripheral neuropathy.

Advanced deficiency is characterised by deterioration of cardiovascular system (wet

beri-beri) and the nervous system (dry beri-beri, Wernicke's encephalopathy and Korsakoff's psychosis). The Wernicke-Korsakoff syndrome may be associated with a genetic variant of transketolase, which requires a higher than normal concentration of thiamine for activity. Signs of wet beri-beri include enlarged heart with normal sinus rhythm (usually tachycardia), and peripheral oedema. Signs of dry beri-beri include mental confusion, anorexia, muscle weakness and wasting, ataxia and ophthalmoplegia.

## 5.2 Pharmacokinetic properties

Bioavailability: After oral administration of 50 mg thiamine hydrochloride,  $C_{max}$  for thiamine was reached after 53 min and the concentration was 179% of its initial value. The relative bioavailability of thiamine was 5.3%.

Absorption: Thiamine is well absorbed from the gastrointestinal tract after oral doses, which mostly occurs mainly in the jejunum and ileum by both active transport and passive diffusion. Some lipophilic derivatives of thiamine are better absorbed than thiamine itself. The rate, but not the extent, of absorption from the gastrointestinal tract is decreased when thiamine hydrochloride is administered with food.

Distribution: Thiamine is quickly converted to the diphosphate at cellular level. It is widely distributed to most body tissues, and appears in breast milk. Thiamine is transported in the plasma bound to albumin, and stored in the heart, liver, kidneys and brain. Estimated protein binding is 90-94%. Only small amounts are stored and excess amounts are excreted in the urine.

Metabolism: Thiamine is phosphorylated to the active coenzyme, thiamine diphosphate, which functions as cocarboxylase for transketolose reaction in carbohydrate metabolism.

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**

Maize Starch  
Povidone K30  
Sodium Starch Glycollate (Type A)  
Talc  
Magnesium stearate

## **6.2 Incompatibilities**

Not Applicable

## **6.3 Shelf life**

36 Months

## **6.4 Special precautions for storage**

Do not store above 25°C.  
Store in the original container in order to protect from light and moisture.  
Keep the container tightly closed.

## **6.5 Nature and contents of container**

HDPE container, HDPE lid with Aluminium foil seal liner: 100 tablets

## **6.6 Special precautions for disposal**

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

## **7 MARKETING AUTHORISATION HOLDER**

Activase Pharmaceuticals Limited  
11 Boumpoulinas,

P.C. 1060, Nicosia  
Cyprus

**8      MARKETING AUTHORISATION NUMBER(S)**

PL 28444/0169

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

09/12/2022

**10     DATE OF REVISION OF THE TEXT**

12/08/2024