# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Tyvera 50 mg Tablets

Thiamine Hydrochloride 50 mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 mg thiamine hydrochloride.

Excipients with known effect:

Each tablet contains 121.5 mg lactose monohydrate.
Each tablet contains 5.0 mg sucrose.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet

White uncoated tablets, 8mm in diameter, one side scored, the other marked T/50.

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

Posology

Adults, the Elderly and Children over three years:

Mild chronic deficiency: 50mg daily

Severe deficiency: 100mg three times daily.

Paediatric population

Not recommended for children under three years.

Method of administration:

Oral

## 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**

This medicinal product contains lactose monohydrate.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

This medicinal product contains sucrose.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Sodium

This medicine contains less than 1 mmol sodium (23 mg) 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.

## 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; Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

## 4.9 Overdose

Overdose has not been reported.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

ATC Code: A11DA01

Pharmacotheraputic Group: Vitamin B1, Plain

Thiamine is an essential co-enzyme for carbohydrate metabolism.

## 5.2 Pharmacokinetic properties

Absorption

Thiamine is well absorbed from the gastrointestinal tract following oral administration, although the absorption of large doses is limited.

Distribution

It is widely distributed to most body tissues and appears in breast milk.

Biotransformation

Within the cell, thiamine is mostly present as the diphosphate.

Elimination

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

Sucrose

Sodium starch glycolate

Talc

Magnesium stearate

### 6.2 Incompatibilities

None known

### 6.3 Shelf life

2 years

### 6.4 Special precautions for storage

Do not store above 25$^{o}$C; store in the original package.

### 6.5 Nature and contents of container

Pack of 100 tablets in a polypropylene bottle with a polyethylene cap or in a polyethylene bottle with a polypropylene cap.

### 6.6 Special precautions for disposal

None

## 7 MARKETING AUTHORISATION HOLDER

Accord Healthcare Limited
Sage House
319 Pinner Road
North Harrow
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## 8 MARKETING AUTHORISATION NUMBER(S)

PL 20075/0715

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

03/02/2025

## 10 DATE OF REVISION OF THE TEXT

03/02/2025