Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Metatone Tonic

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Excipient(s) with known effect:

Each 5 ml contains

750 micrograms thiamine hydrochloride
45.6 mg calcium glycerophosphate
45.6 mg potassium glycerophosphate
22.8 mg sodium glycerophosphate
697 micrograms manganese glycerophosphate

0.513mg Amaranth (E123)
1.436g Sucrose
0.455g Glucose syrup
438mg Ethanol

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup.
Clear red syrup.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Metatone Tonic is indicated in the management of convalescence and debility which benefits from the combination of vitamins and minerals for supplementation.

4.2 Posology and method of administration

Adults and children 12 years and over:
Oral. 5 ml to 10 ml syrup (preferably diluted) two or three times daily, before meals.
Maximum daily dose: 30 ml

Children aged 6 to 12 years:
Oral. 5 ml syrup (preferably diluted) two or three times daily, before meals.
Maximum daily dose: 15 ml

Children under 6 years:
Metatone tonic is not suitable for administration to children under six years of age, except under the advice of a physician.

The Elderly:
Normal adult dosage is appropriate

Hepatic/renal Dysfunction:
There is no specific information available relating to the use of Metatone Tonic in renal or hepatic impairment, normal adult dosage is appropriate.

4.3 Contraindications

Metatone Tonic is contra-indicated in individuals with known hypersensitivity to the product or any of its components.

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

4.4 Special warnings and precautions for use

When diluted with water this product should be used within 14 days.

Metatone Tonic contains amaranth (E123), which may cause allergic reactions.

This medicine contains 438 mg of alcohol (ethanol) in each 5 ml per dose which is equivalent to 11% w/v. The amount in 5ml of this medicine is equivalent to 11 ml beer or 5 ml wine.

The alcohol in this preparation is likely to affect children. These effects may include feeling sleepy and changes in behaviour. It may also affect their ability to concentrate and take part in physical activities.
The amount of alcohol in this medicine can affect your ability to drive or use machines. This is because it may affect your judgement and how fast you react.
If you have epilepsy or liver problems, talk to your doctor or pharmacist before taking this medicine.
The amount of alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines. If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine. If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

This medicine contains sucrose 1.436g per 5ml and glucose syrup 0.455g per 5ml. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. This should be taken into account in patients with diabetes mellitus. May be harmful to the teeth.

Metatone contains sodium. This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interactions

None known

4.6 Fertility, pregnancy and lactation

This product should not be used during pregnancy or in women breast feeding children unless considered essential by a physician.

4.7 Effects on ability to drive and use machines

Unlikely to produce an effect.

4.8 Undesirable effects

Metatone contains active substances that have a well-established safety profile with limited adverse events when taken orally at the recommended dosage.

Thiamine does not have adverse effects when given orally. At the concentration used in Metatone Tonic adverse effects due to calcium, potassium, sodium and manganese salts are rare and mainly gastro-intestinal irritation.

The undesirable effects are presented in the table below, by system organ class and by frequency using the following categories: very common (≥ 1/10), common (≥1/100 to 1<1/10), uncommon (≥1/1000 to 1<1/100), rare (≥1/10,000 to

<1/1000), very rare (<1/10,000), not known (cannot be estimated from the available data). The adverse events listed are from spontaneous reporting and therefore frequency categories have not been assigned.

System organ class	Undesirable Effect	Frequency
Immune system disorders	Hypersensitivity	Not known
Gastrointestinal disorders	Abdominal discomfort, nausea, vomiting, diarrhoea, constipation	Not known
Skin and subcutaneous disorders	Allergic skins reactions	Not known
General disorders and administration site conditions	Malaise	Not known

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 HPRA Pharmacovigilance Website: www.hpra.ie.

4.9 Overdose

Symptoms and signs
When taken orally, thiamine is non-toxic. If large doses are ingested they are not stored by the body but excreted unchanged by the kidneys. Excessive amounts of calcium, sodium and potassium salts may lead to hypercalcaemia, hypernatraemia and hyperkalaemia, respectively. Manganese salts are poorly absorbed.

Treatment
Treatment should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Thiamine, a water soluble vitamin, is an essential coenzyme for carbohydrate metabolism.

Calcium is essential for cellular structure, metabolic function and signal transmission. It has a structural role in bones and teeth.

Potassium is the principal cation in intracellular fluid. It is involved in numerous enzymatic reactions, physiological processes, nerve conduction, muscle contraction.

Sodium is the principal cation in extracelluar fluid. It is involved in numerous physiological processes, acid-base regulation, nerve conduction and the regulation of blood volume.

Manganese is a component of a number of enzymes and is necessary for the activation of others.

Phosphate is involved in many physiological processes, including metabolism of carbohydrates and lipids and the storage and transfer of energy.

5.2 Pharmacokinetic properties

Absorption
Thiamine is well absorbed from the gastro-intestinal tract following oral administration. No relevant information is available regarding the absorption of the other active components of Metatone Tonic.

Distribution
Thiamine, sodium, potassium, calcium, manganese and phosphate are widely distributed throughout the body.

Metabolism and elimination
Thiamine has a plasma half life of 24 hours, it is not stored to any great extent in the body. Excess ingested thiamine is excreted in the urine as either the free vitamin or as the metabolite, pyrimidine.

Sodium, potassium, calcium, manganese and phosphate are mainly excreted by the kidneys and in the faeces to a small extent.

Pharmacokinetics in Renal or Hepatic Impairment
There have been no specific studies of Metatone Tonic in renal or hepatic impairment.

Pharmacokinetics in the Elderly
No specific studies have been conducted on the use of Metatone tonic in the elderly.

5.3 Preclinical safety data

Mutagenicity, Carcinogenicity, Teratogenicity
There are no reports of mutagenicity, carcinogenicity or teratogenicity with thiamine hydrochloride. No relevant data exist regarding the other active constituents of Metatone Tonic.

Fertility
No relevant information is available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Phosphoric acid
Glucose syrup
Sodium citrate
Ethanol (96%)
Amaranth (E123)
Caramel T12

Mixed oils composed of:
Bitter orange oil
Orange oil
Nutmeg oil
Clove oil
Cassia oil
Anethole
Caraway oil
Water, purified

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

Once opened, use within 8 weeks.

6.4 Special precautions for storage

Do not store above 25°C. Keep the bottle tightly closed.

6.5 Nature and contents of container

Metatone Tonic is presented in a 300 ml or 500ml glass bottle with ROPP aluminium cap or, a three piece child resident, tamper evident closure fitted with a polyester faced wad.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Chefaro Ireland DAC
The Sharp Building
Hogan Place
Dublin 2
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1186/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th July 1975

Date of last renewal: 14th July 2009

10 DATE OF REVISION OF THE TEXT

February 2021