SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Metatone

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Metatone contains Vitamin B1 (Thiamine hydrochloride Ph Eur) 750 micrograms, Calcium glycerophosphate Ph Eur 45.6 mg, Potassium glycerophosphate 45.6 mg, Sodium glycerophosphate 22.8 mg, and Manganese glycerophosphate NFX 697 micrograms in each 5 ml.

Excipients with known effect:

0.513mg Amaranth (E123) per 5 ml

438 mg ethanol per 5 ml

1.436g sucrose per 5ml

0.455g glucose syrup per 5ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A clear red liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Metatone is indicated in the management of convalescence and debility.

4.2 Posology and method of administration

Adults and children 12 years and over:

Oral. One or two 5 ml spoonfuls, preferably diluted, two or three times daily before meals.

Maximum daily dose: 30 ml

Children aged 6 years and over:

Oral. One 5 ml spoonful, preferably diluted, two or three times daily before meals.
Maximum daily dose: 15 ml

Children under 6 years:

Metatone 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.

4.3 Contraindications

Metatone is contra-indicated in individuals with known hypersensitivity to the product or any of it's components.

4.4 Special warnings and precautions for use

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

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

Metatone contains 11% ethanol (alcohol), i.e. up to 438 mg per 5ml dose, equivalent to11 ml beer or 5 ml wine per dose.

A dose of (30 ml) of this medicine administered to (an adult weighing 70 kg) would result in exposure to 37.57 mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of about 8767.02 mg/100 ml.

The alcohol in this preparation is likely to affect children, with effects including feeling sleepy, changes in behaviour, affected ability to concentrate or take part in physical activities. The amount of alcohol in this medicine can affect the ability to drive or use machines. Ethanol content should be taken into account in patients with epilepsy, liver problems, addiction to alcohol, who are breast-feeding or pregnant. The amount of alcohol in this medicine may alter the effects of other medicines. Co-administration with medicines containing e.g. propylene glycol or ethanol may lead to accumulation of ethanol and induce adverse effects, in particular in young children with low or immature metabolic capacity.

This medicine contains less than 1 mmol sodium (23 mg) per 10ml, that is to say essentially 'sodium-free'.

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

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, Pregnancy and lactation

There are no or limited amount of data from the use of Metatone in pregnant or breast-feeding women or from animal studies.

As a precautionary measure it is preferable to avoid the use of Metatone in pregnant or breast-feeding women.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on ability to drive and use machines.

4.8 Undesirable effects

Immune system disorders: Hypersensitivity (including allergic skin reactions)

Gastrointestinal disorders: Abdominal discomfort, nausea, vomiting, diarrhoea, constipation

General disorders and administration site conditions: Malaise

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

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

Vitamin B1

Vitamin B1 is essential for proper carbohydrate metabolism and plays an essential role in the decarboxylation of alpha keto acids. Vitamin B1 deficiency may lead to the clinical condition known as Beri-Beri.

Glycerophosphates

Glycerophosphates were introduced on the grounds that lecithin contains phoshorus in the form of the glycerophosphate radical and that glycerophosphates would therefore be a source of phosphorus that would be more easily assimilated by the tissues, particularly by the brain. Phosphorus is essential for most metabolic processes. As calcium phosphate, phosphorus is a major constituent of bones and teeth. In addition phosphates are a major constituent of all oils and as adenosine phosphates, play an essential role in energy liberation and utilisation.

Calcium

Calcium is a major component of bones and teeth and is necessary for the clotting of blood, the integrity of many cells, especially those of the neuromuscular system and for cardiac function. The consequence of decreased calcium levels in its extreme includes convulsions, tetany, behaviour and personality disorders, mental growth retardation and bone deformities, the most common being rickets in children and osteomalacia in adults.

Manganese

Manganese is required for the synthesis of the mucopolysaccharides of cartilage, glucose utilisation, steroid biosynthesis and for the activity of pyruvate carboxylase.

Sodium and Potassium

Sodium is present as the sodium ion in all body fluids and in particular in extracellular fluids, whilst potassium as the potassium ion is largely present intracellulary. Together, sodium and potassium control many cellular events, with a critical role in maintaining fluid balance and in muscle and nerve activity.

5.2 Pharmacokinetic properties

Vitamin B1

Vitamin B1 is well absorbed in the gastro-intestinal tract. An active transport process is involved. After absorption, Vitamin B1 is widely distributed to all tissues and appears in the foetal circulation during pregnancy; active transfer is involved. Vitamin B1 appears in breast milk at concentrations which are dependent on the maternal serum levels.

Vitamin B1 is not stored to an appreciable extent, and excess is excreted, unchanged, together with the products of hepatic metabolism, in the urine.

Calcium

In the digestive tract, the total quantity of calcium available for absorption is augmented by the calcium in intestinal secretions. Calcium is incompletely absorbed from the gut and normally, depending on the intake, 70- 80% of calcium from the diet is excreted in the faeces.

Manganese

Little information is available on the pharmacokinetics of manganese, however, presumably, sufficient of this trace element is absorbed from the G.I. tract to maintain health in normal individuals.

Sodium and Potassium

Dietary sodium and potassium are readily absorbed and excessive amounts are excreted mainly via the kidneys.

5.3 Preclinical safety data

There is insufficient information available to determine whether some of the active ingredients have mutagenic, carcinogenic, teratogenic potential, or the potential to impair fertility.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose

Phosphoric acid (66.3%)

Glucose syrup (41° Baume)

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

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precautions for storage

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

Store below 25°C.

6.5 Nature and contents of container

300 ml or 500 ml amber glass bottle with ROPP cap or with ROPP cap contained in a cardboard carton.

300 ml or 500 ml amber glass bottle with 3 piece plastic child resistant, tamper evident closure fitted with a polyester faced wad or with a 3 piece plastic child resistant, tamper evident closure fitted with a polyester faced wad contained in cardboard carton.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

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Suite 12

Bunkilla Plaza

Bracetown Business Park

Clonee

County Meath

Ireland

8 MARKETING AUTHORISATION NUMBER(S)

PL 35104/0056

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30th November 2004

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21/10/2024