1. NAME OF THE MEDICINAL PRODUCT

Thiamine multichem, 50mg, tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 50mg tablet contains 50mg of thiamine hydrochloride.

Excipients with known effect

Thiamine multichem contains Lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Thiamine multichem 50mg tablets are white, round, 8mm in diameter, biconvex, engraved with "APO' on one side and "THI" over "50"on the other side. Each tablet contains 50mg thiamine hydrochloride.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prophylaxis and treatment of vitamin B1 deficiency states including beriberi and Wernicke's encephalopathy.

4.2 Dose and Method of administration

Dose

In preventing vitamin deficiencies adequate dietary intake is preferred over supplementation whenever possible. An adequate human diet in most circumstances is one containing between 0.8 and 1.5mg vitamin B_1 daily.

The usual adult dose to treat deficiency is 5-30mg either as a single or in divided doses. In severe thiamine deficiency including treatment of beriberi doses of up to 300mg daily in three divided doses may be given.

Method of administration

In severe thiamine deficiency including treatment of beriberi doses of up to 300mg daily in three divided doses may be given. Even higher daily doses may be given in Wernicke's encephalopathy although the intravenous route is usually chosen under these circumstances.

4.3 Contraindications

Hypersensitivity to vitamin B_1.

4.4 Special warnings and precautions for use

Serious sensitivity reactions can occur with deaths having resulted from I.V. use.

Simple vitamin B1 deficiency is rare. Multiple vitamin deficiencies should be suspected in any case of dietary inadequacy.

4.5 Interaction with other medicines and other forms of interaction

None have been reported.

4.6 Fertility, pregnancy and lactation

Pregnancy

No adverse effects have been reported with the intake of normal daily requirements during pregnancy.

Lactation

Although thiamine appears in breast milk, no adverse effects have been reported with intake of normal daily requirements during lactation.

4.7 Effects on ability to drive and use machines

Presumed to be safe or unlikely to produce and effect on the ability to drive or use machinery.

4.8 Undesirable effects

Feeling of warmth, pruritus, urticaria, weakness, sweating, nausea, restlessness, tightness of the throat, angioneurotic oedema, cyanosis, pulmonary oedema, haemorrhage into the gastrointestinal tract, collapse and death have been rarely reported mainly following repeated I.V. administration.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professional are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose

Overdosage has not been reported and intake in excess of the body's requirements is excreted in the urine.

Should overdosage occur and adverse reactions result, treatment should be supportive and symptomatic. Fluid intake should be maintained.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: alimentary tract and metabolism. ATC code: A11DA01.

Mechanism of Action

Thiamine hydrochloride (vitamin B_1) is a water-soluble vitamin. It is an essential co- enzyme for carbohydrate metabolism in the form of the diphosphate (thiamine pyrophosphate, cocarboxylase). Its role in carbohydrate metabolism is the decarboxylation of pyruvic acid and alpha-ketoacids to acetaldehyde and carbon dioxide. Increased levels of pyruvic acid in the blood indicate vitamin B_1 deficiency.

Thiamine deficiency can occur when dietary intake is inadequate (after approximately 3 weeks of total absence of the vitamin from the diet). Deficiency may occur in alcoholics and food faddist or in special clinical situations such as haemodialysis, chronic peritoneal dialysis, or after administration of glucose to a vitamin B_1 depleted patient. Requirements may be increased due to burns, chronic fever, gastrectomy, intestinal disease, liver disease and hyperthyroidism. Deficiency of vitamin B_1 eventually leads to beriberi or Wernicke's encephalopathy. The cardiovascular and/or nervous system may be affected.

Cardiovascular involvement is manifested by high output, biventricular heart failure and oedema. CNS symptoms include peripheral neuropathy and an encephalopathy syndrome characterised by nystagmus, ophthalmoplegia, fever, ataxia and progressive mental deterioration which may ultimately result in coma and death.

5.2 Pharmacokinetic properties

Small amounts of thiamine are absorbed from the gastrointestinal tract mainly from the duodenum by both active and passive processes. However absorption of doses greater than 5mg is limited.

It is widely distributed to most body tissue and appears in breast milk. Body stores (as the phosphorylated form) are approximately 30mg with a 1mg daily turnover. Storage is mainly in skeletal muscles, heart, liver, kidneys and brain.

Amounts of thiamine in excess of the body's requirements are excreted in the urine as either unchanged thiamine or as metabolites. Thiamine is metabolised in the liver.

It is transformed by phosphorylation into active co-enzyme thiamine pyrophosphate. Dephosphorylation can occur in the kidneys and probably other organs and excess quantities of the free vitamin and the pyrimidine are excreted in the urine. The urinary excretion is depends in part on the urine volume and during diuresis large amounts of thiamine may be lost. Small quantities are excreted in the sweat.

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiamine multichem 50mg tablet contains the following excipients:

- Lactose monohydrate
- Microcrystalline cellulose
- Magnesium stearate

6.2 Incompatibilities
Not applicable

6.3 Shelf life
3 years.

6.4 Special Precautions
Store below 30°C
Protect from heat, light and moisture. Keep the container tightly closed.

6.5 Nature and contents of container
HDPE bottles of 100 or 500 tablets.
Not all pack sizes maybe marketed.

6.6 Special precautions for disposal
No special requirements for disposal.
Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

General Sale Medicine.

8. SPONSOR

Multichem NZ Ltd
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Takapuna
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Telephone: (09) 488 0330

9. DATE OF FIRST APPROVAL

31 December 1969

10. DATE OF REVISION OF THE TEXT

20 December 2021

SUMMARY TABLE OF CHANGES

Section	Change
Whole datasheet	Minor formatting and trade name changes.
8	Updated to new sponsor details.