SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE
B1-100 mg, TABLETS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains:
Thiamine hydrochloride (Vitamin B_1) 100 mg
Sugar free.
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Tablets.
White, biconvex tablet with a single breakline.

4. CLINICAL PARTICULARS
4.1 Therapeutic Indications
B1-100 mg is indicated as a dietary food supplement.

4.2 Posology and method of administration

Posology
One tablet daily or more as prescribed.
Paediatric population
The safety and efficacy of B1-100 mg has not yet been established in paediatric populations.

Method of administration
Oral.

4.3 Contraindications
Hypersensitivity to Vitamin B_1 or to any of the excipients (see section 6.1).

4.4 Special warnings and precautions for use
None known.

4.5 Interaction with other medicines and other forms of interaction
Thiosemicarbazone and 5-fluorouracil are thiamine antagonists and can neutralise the effect of thiamine, patients using any of these treatments may need their thiamine dose to be 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
No fertility data available.
Safety during pregnancy and lactation has not yet been established.

4.7 Effects on ability to drive and use of machines
No studies have been conducted on the effects of B1-100 mg on the ability to drive and use machines.

4.8 Undesirable effects

Tabulated list of adverse reactions
The undesirable effects listed are based on the MedDRA system organ classes (SOC) classification system. The frequency groupings listed conform to the following convention: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1 000 to <1/100); rare (≥1/10 000 to <1/1 000); very rare (<1/10 000) and not known (cannot be estimated from the available data).

System Organ class	Frequency	Adverse reaction
Gastrointestinal disorders	Not known	Nausea, Vomiting, Diarrhoea and Abdominal pain
Skin and subcutaneous tissue disorders	Not known	Pruritus, Urticaria, Itching, Hives, Angioedema,
Cardiovascular disorder	Not known	Tachycardia, Palpitations and Shock
Respiratory, Thoracic & Mediastinal Disorders	Not known	Respiratory distress

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. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

You may also report to Adcock Ingram Pharmacovigilance department by email Adcock.AEReports@adcock.com, fax +27 86 553 0128 or call 011 635 0134.

4.9 Overdose

In overdosage, side effects can be precipitated and/or be of increased severity.
No sensitivity known to the overdosage of vitamin B_1 by the oral route.
Treatment may be symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 22.2 Vitamins – Others.

Mechanism of action
Thiamine is a coenzyme essential for carbohydrate metabolism.

5.2 Pharmacokinetics properties

Absorption
Thiamine is absorbed well from the gastrointestinal tract after oral administration, even though the absorption of large doses is limited.

Distribution
B1-100 mg is distributed to most body tissues and appears in breast milk.

Biotransformation
Thiamine is mostly presented as a diphosphate within the cell.

Elimination
Thiamine is not stored to any significant extent in the body and excess amounts of thiamine in the body are excreted in urine as unchanged thiamine or metabolites.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Dibasic calcium phosphate
- Magnesium stearate
- Maize starch
- Microcrystalline cellulose pH 101

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of the container

- White polyvinylchloride squat medical vials with white snap on pilfer proof closures containing 30, 60 and 100 tablets.
- White polypropylene securitainer with white LDPE closure containing 100 tablets.
- Blister packs in printed aluminium foil/PVC film containing 10 x 10 tablets, 2 x 14 tablets, and 6 x 14 tablets.
- White high density polyethylene container and screw cap containing 100 tablets.

Not all pack sizes may be listed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited
1 New Road
Erand Gardens
Midrand, 1685
Customer Care: 0860 ADCOCK (232625)

8. REGISTRATION NUMBER

T 1284 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13 September 1985

10. DATE OF REVISION OF THE TEXT

14 December 2023