PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

B1-100 MG TABLETS
Thiamine hydrochloride (Vitamin B1) 100 mg
Sugar free

Read all of this leaflet carefully because it contains important information for you.

B1-100 mg is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use B1-100 mg carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share B1-100 mg with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What B1-100 mg is and what it is used for
2. What you need to know before you take B1-100 mg
3. How to take B1-100 mg
4. Possible side effects
5. How to store B1-100 mg
6. Contents of the pack and other information

1. What B1-100 mg is and what it is used for

B1-100 mg is a vitamin used as a dietary supplement.

2. What you need to know before you take B1-100 mg

Do not take B1-100 mg if you are hypersensitive to Vitamin B_1 or any of the other ingredients of B1-100 mg (listed in section 6).

Warning and precautions

None known.

Other medicines and B1-100 mg

Always tell your health care provider if you are taking any other medicine.
(This includes all complementary or traditional medicines.)

If you are taking thiosemicarbazone and 5-fluorouracil, medicines used to treat cancer and viral infections, vitamin B_1 dose may need to be adjusted as these medicines can reduce the effect of vitamin B_1.

Having blood tests or other medical tests

High concentrations of vitamin B_1 in the blood can interfere with certain medical tests. Tell your doctor or health care provider that you are taking vitamin B_1 tablets.

Pregnancy and breastfeeding and fertility

No fertility data available.
Safety during pregnancy and breastfeeding has not yet been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines
It is not always possible to predict to what extent B1-100 mg may interfere with the daily activities of a patient.
Patients should ensure that they do not engage in the above activities until they are aware of the measure to which B1-100 mg affects them.

3. How to take B1-100 mg

Do not share medicines prescribed for you with any other person.
Always take B1-100 mg exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

The usual dose is one tablet daily or more as prescribed.
Take the tablet with enough water.

Paediatric population
The safety and efficacy of B1-100 mg has not yet been established in paediatric populations.

If you take more B1-100 mg than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take B1-100 mg
Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

B1-100 mg can have side effects.

Not all side effects reported for B1-100 mg are included in this leaflet.
Should your general health worsen or if you experience any untoward effects while taking B1-100 mg please consult your health care provider for advice.

Tell your doctor if you notice any of the following:
Frequency not known

- Nausea
- Vomiting
- Diarrhoea
- Pruritus
- Urticaria
- Itching
- Hives
- Angioedema
- Abdominal pain
- Respiratory distress
- Tachycardia
- Palpitations
- Shock

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist or nurse.
You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications:
https://www.sahpra.org.za/Publications/Index/8 .
By reporting side effects, you can help provide more information on the safety of B1-100 mg.

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.

5. How to store B1-100 mg

Store at or below 25 °C.
Store all medicines out of reach of children.
Store in the original package.
Protect from light / moisture.
Do not store in a bathroom.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What B1-100 mg contains
The active substance is thiamine hydrochloride 100 mg.
The other ingredients are dibasic calcium phosphate,
Magnesium stearate, Maize starch and Microcrystalline cellulose pH 101.

What B1-100 mg looks like and contents of the pack
B1-100 mg is a white, biconvex tablet with a single breakline, packed as follows:

- 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 10x 10 tablets,
- 2 x 14 tablets, and 6 x 14 tablets.
- White high density polyethylene container and screw cap containing 100 tablets.

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