

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Finished Pharmaceutical Product

1.1 Proprietary Name

NAT-B SOFT GELATIN CAPSULES

1.2 Strength

High Potency B Vitamins Formula

1.3 Pharmaceutical Form

Capsules, Soft Shell

2. Qualitative and Quantitative Composition

2.1 Qualitative Declaration

Name of active ingredients
Thiamine Mononitrate (Vitamin B1)
Riboflavin (Vitamin B2)
Pyridoxine Hydrochloride (Vitamin B6)
Cyanocobalamin (Vitamin B12)
Nicotinamide
Calcium Pantothenate
Folic Acid
Choline Bitartrate
Biotin
Inositol

*For full list of excipients, see section 6.1

2.2 Quantitative Declaration

Name of active ingredients	Grade	Quantity/ Capsule (mg)
Thiamine Mononitrate (Vitamin B1)	EP Current Edition	70.00
Riboflavin (Vitamin B2)	EP Current Edition	55.00
Pyridoxine Hydrochloride (Vitamin B6)	EP Current Edition	60.00
Cyanocobalamin (Vitamin B12)	USP Current Edition	0.075
Nicotinamide	EP Current Edition	55.00
Calcium Pantothenate	USP Current Edition	75.00
Folic Acid	EP Current Edition	0.15
Choline Bitartrate	FCC Current Edition	50.00
Biotin	EP Current Edition	0.06
Inositol	FCC Current Edition	50.00

3. Product description

Orange colour, oily suspension filled in 24 minim, oblong, red, opaque soft gelatin shell capsules.

4. Clinical Particulars

4.1 Therapeutic Indications

NAT-B SOFT GELATIN CAPSULES is a high content vitamin B formula for the treatment of vitamin B deficiency and support healthy function of body when your requirement is high as in emotional stress, alcoholics, surgery and sickness.

4.2 Posology and method of administration

For adults 1 capsule daily, with meal or as directed by a physician. Method of Administration: Oral

4.3 Contraindications

Hypersensitivity or intolerance to any component of the product.

4.4 Special Warnings and Precautions for Use

None.

4.5 Interaction with other medicinal products and other forms of interaction

None reported.

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4.6 Fertility, pregnancy and lactation

Pregnancy and lactation women should consult the physician before taking NAT-B.

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable Effects

NAT-B may cause yellow discoloration of the urine.

4.9 Overdose

Overdoses of NAT-B in human has not been reported to date.

5. Pharmacological properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group and ATC code: Vitamin B-Complex, INCL.

Combinations; A11E

Vitamins are involved in fundamental functions of the body such as growth, maintenance of health, and metabolism. Minerals provide the medium essential for normal cellular activity, determine the osmotic properties of body fluids, impart hardness to bones and teeth and function as obligatory cofactors in metalloenzymes activity.

5.2 Pharmacokinetic Properties

Water soluble vitamins are absorbed into portal blood and storage by binding to enzymes and transport proteins. They are excreted in the urine whenever plasma levels exceed renal thresholds.

5.3 Preclinical Safety Data

Not applicable.

6. Pharmaceutical Particulars

6.1 List of Excipients

Capsule Fill: Soyabean Oil, Vegetable oil partial hydrogenated, Beewax white,
Lecithin LV

Capsule Shell: Gelatin, Glycerin, Purified water, FD & C Red No. 40, Titanium
dioxide

6.2 Incompatibilities

None.

6.3 Shelf Life

24 months

6.4 Special Precautions for Storage

Store below 30°C in a dry place, away from direct sunlight.

6.5 Nature and Contents of Container

NAT-B is available as 10 soft gelatin capsules packed in an Alu-PVC/PVDC blister,
3 such blisters further packed in a cardboard carton along with a pack insert.

7. Special precaution for disposal and other handling

No special requirements.

8. Marketing Authorization Holder and Manufacturing Site

Addresses MEGA LIFESCIENCES Public Company Limited

384 Moo 4, Soi 6, Bangpoo Industrial Estate,

Pattana 3 Road, Phraeksa, Mueang,
Samutprakarn 10280, Thailand.

9. Marketing Authorization Number :

Rwanda: 20/1297/DGC 7 PHS/2016

10. Date of first Registration/ Renewal of the Registration:

First registration in Rwanda: 23/03/2016 **11. Date of**

revision of the text: March 2024