

NALIS® HB₁₂ SYRUP

(HAEMOGLOBIN + B₁₂ SYRUP)

SUBMITTED BY: NALIS PHARMACEUTICALS LTD

**R67-68 NEKEDE-NAZE
INDUSTRIAL CLUSTERS,
NEKEDE, OVERRI,
IMO STATE, NIGERIA.
TEL: +2348085784400, +2349026044603**

EMAIL: info@nalispharma.com, www.nalispharma.com

SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC).

1 NAME OF THE MEDICINAL PRODUCT:

Nalis Hb₁₂ Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:
Haemoglobin B.P.....5 % w/v
Vit. B₁₂ B.P.....0.0004 % w/v

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral Syrup

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nalis Hb₁₂ Syrup is indicated for:

- Iron deficiency anaemia due to chronic blood loss, hook-worm infestation, inadequate intake of iron, etc.
- Dimorphic anaemia due to deficiency of Vitamin B12 (Cyanocobalamin).
- Anemia of pregnancy and lactation.
- Tonic in general weakness, lack of appetite, rundown conditions and convalescence.
- Post surgery and other debilitated states.

4.2 Posology and method of administration

For oral administration.

Dosage:

Adults:

2 teaspoonful 4 times daily

Children (5-12 years):

1 teaspoonful 4 times daily

Children (2-5 years):

1 teaspoonful 2 times daily

4.3 Contraindications

Nalis Hb₁₂ is contraindicated in patients with hypersensitivity to any of the active components of this drug.

4.4 Special warnings and precautions for use

This product contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products

Many drugs are known to interact with multivitamins and minerals. The interactions are classified into

- major drug interactions
- moderate drug interactions
- minor drug interaction.

Consult your physician or Pharmacist before combining multivitamins with other drugs.

4.6 Pregnancy and lactation

The IOM recommends multivitamins that contain iron, zinc, copper, folic acid, B6, B12 for some groups of pregnant women, such as those with poor-quality diets, vegetarians, cigarette smokers, and those who consume alcohol.

Water soluble vitamin supplements (e.g., B vitamins) taken by the mother usually increase breastmilk levels.

4.7 Effects on ability to drive and use machines

None expected at recommended doses and duration of therapy.

4.8 Undesirable effects

Hemoglobin

These side-effects are possible, but do not always occur. Some of the side-effects may be rare but serious. Consult your doctor if you observe any of the following side-effects, especially if they do not go away.

Diarrhea

Swelling

Rapid weight gain

Itching or mild rash

Cyanocobalamin:

No known side effects even with very large doses.

4.9 Overdose

The most sign & Symptoms of overdosage are Gastrointestinal irritation, abdominal pain with nausea, vomiting and either diarrhoea or constipation. Cardiovascular disorders such as hypotension, tachycardia, metabolic changes including acidosis and hypoglycemia. CNS depression ranging from lethargy to coma.

Vomiting is induced immediately followed by parenteral injection of desferroxamine mesylate and then gastric lavage. In the meantime, give milk and/or 5% sodium bicarbonate solution by mouth. Fluid replacement is essential. Other measures include symptomatic management and therapy of bmetabolic and cardiovascular disorders.

If overdose is suspected, your doctor should be contacted immediately.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: B03AE01

Mechanism of action:

A heme group is made up of iron (Fe) ion (charged atom) located in a heterocyclic ring, which is also called a porphyrin ring. The site of oxygen binding, the iron ion, binds with the nitrogens located in the center of the porphyrin ring. The iron ion binds with high affinity to the globular protein through the imidazole ring of the F8 residue on histidine which is found below the porphyrin ring. A sixth position can bind reversibly to oxygen, completing the formation of the octahedral group. One oxygen atom binds Fe and the other is found to protrude at an angle. When oxygen is not bound to Fe, a water molecule (weakly bound) fills the site, producing a distorted shape, often described as an octahedron.

Vitamins and minerals are considered essential nutrients—because acting in concert, they perform hundreds of roles in the body. They help shore up bones, heal wounds, and bolster your immune system. They also convert food into energy, and repair cellular damage.

5.2 Pharmacokinetic properties

Absorption of iron from the gut is carefully regulated. Because there is no active excretory process for iron once it has entered the bloodstream, the body's control of iron levels is undertaken at the level of the enterocyte.

All the B Vitamins are water soluble vitamins. Quantities in excess of the bodies requirements are excreted either unchanged or as metabolites, mainly in the urine but to a lesser extent also in the faeces.

Vitamin B₁₂ is stored in the liver, excreted in the bile and most of it in the first 8 hours; urinary excretion, however, accounts for only a small fraction in the reduction of total body stores acquired by dietary means. Vitamin B₁₂ diffuses across the placenta and also appears in breast milk.

Vitamin B₁₂ undergoes extensive enterohepatic recycling; part of a dose is excreted in the urine.

5.3 Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Nipasol, Nipagin, Xanthan Gum, Sodium Benzoate, Malt Extract, Liquid Glucose, Ethanol, Orange Flavour, Sugar, Treated Water

6.2 Incompatibilities

None stated except as in 'Interactions with other medicaments'.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C.

Keep away from light

6.5 Nature and contents of container

200ml HDPE amber pet bottle, 28mm ROPP caps

6.6 Special precautions for disposal and other handling

None

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

Nalis Pharmaceuticals Ltd

R67-68 Nekede-Naze
Industrial Clusters,
Nekede, Owerri,
Imo State, Nigeria.
Tel: +2348085784400, +2349026044603

Email: info@nalispharma.com, www.nalispharma.com

8. DRUG PRODUCT MANUFACTURER

Nalis Pharmaceuticals Ltd

R67-68 Nekede-Naze
Industrial Clusters,
Nekede, Owerri,
Imo State, Nigeria.
Tel: +2348085784400, +2349026044603

Email: info@nalispharma.com, www.nalispharma.com

9. NAFDAC REGISTRATION NUMBER(S)

A11-100042