

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

De-Deon's Syrup of Haemoglobin Vitamin B₁₂

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Haemoglobin		16.0%w/v
Liver Extract		3.1%w/v
Cyanocobalamin(Vitamin B ₁₂)		0.0001%w/v
Excipients	qs	100ml

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Liquid; Brownish-red homogenous Syrup with characteristic odour and taste.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

De-Deon's Syrup of Haemoglobin Vitamin B₁₂ is indicated in anaemia caused by lack of iron, hypochromic anaemia, anaemia following surgical operations, confinements, physical depression, exhaustion, after effects of influenza and convalescence.

4.2 Posology and method of administration

Posology

Adults; 10-20mls twice daily

Children; 2-5 years: 5mls twice daily
6-12 years: 10mls twice daily

Method of administration

De-Deon's Syrup of Haemoglobin Vitamin B₁₂ can be taken pure or with water and fruit Juices and preferably with meal.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

De-Deon's Syrup of Haemoglobin Vitamin B₁₂ is a rich source of iron. Its use should be avoided in patients with too much iron in the body, including a condition called hemochromatosis as its use might make iron metabolism disorders worse.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed. However, interactions with any of the active ingredients of De-Deon's Syrup of Haemoglobin Vitamin B₁₂ are possible.

4.6 Pregnancy and lactation

Pregnancy

No reported ill effects on pregnancy or on fetal / post-natal health. However use in pregnancy should be recommended by a Doctor.

Breastfeeding

Vitamin B₁₂, and iron from haemoglobin and Liver extract; are the main active ingredients in De-Deon's Syrup of Haemoglobin Vitamin B₁₂ is excreted into the breastmilk and it is also a normal component of human milk. No effects have been shown in breast-fed infants. However use during breastfeeding should be according to Doctor's advice and prescription.

4.7 Effects on ability to drive and use machines

De-Deon's Syrup of Haemoglobin Vitamin B₁₂ has no influence on the ability to drive and use of machines.

4.8 Undesirable effects

Undesirable effects due to the use of De-Deon's Syrup of Haemoglobin Vitamin B₁₂ are rare if used according to the recommended dosage. However possible undesirable effects includes; stomach upset and pain, constipation or diarrhea, nausea, vomiting, headache Itching, swelling, nervousness and anxiousness may occur.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antianaemic Preparation, ATC code: B03AE01

Mechanism of action:

De-Deon's Syrup of Haemoglobin Vitamin B₁₂ contains vitamin B₁₂ which acts by maturation of developing red blood cells in the bone marrow. Vitamin B₁₂ helps make haemoglobin, a

protein in the body responsible for the transport of oxygen. Each haemoglobin protein contains four haem molecules, and each haem molecule contains one iron atom, which binds to oxygen from the air breathe in and releases it back into the tissues. Vitamin B₁₂ helps create the haem portion of haemoglobin. If there isn't enough vitamin B₁₂ in the body, the body cannot produce enough haemoglobin to make functional red blood cells. As a result, people with vitamin B12 deficiency often develop anaemia, which causes weakness, a sore and red tongue and a pale complexion.

Iron in the liver extract contained in De-Deon's Syrup of Haemoglobin Vitamin B₁₂ acts by combining with porphyrin and globin chains to form haemoglobin, which is critical for oxygen delivery from the lungs to other tissues. Erythropoiesis is generally enhanced by the components of De-Deon's Syrup of Haemoglobin Vitamin B₁₂.

5.2 Pharmacokinetic properties

Absorption: After oral administration, vitamin B₁₂ contained in De-Deon's Syrup of Haemoglobin Vitamin B₁₂ is absorbed irregularly from the distal small intestine. Vitamin B₁₂ is protein-bound, and this bond must be split by proteolysis and gastric acid before absorption. Absorption depends on sufficient intrinsic factor and calcium. Vitamin B₁₂ is inadequate in malabsorptive states and in pernicious anaemia. After oral administration of doses of less than 3 mcg, peak plasma levels aren't reached for 8 to 12 hours.

Distribution: Distributed into the liver, bone marrow, and other tissues, including the placenta. At birth, the vitamin B₁₂ level in neonates is three to five times that in the mother. Vitamin B₁₂ appears in breast milk in levels about equal to the maternal vitamin B₁₂ level.

Metabolism: Vitamin B₁₂ is metabolised in the liver.

Excretion: In healthy people receiving only dietary vitamin B₁₂, about 3 to 8 mcg of the vitamin is secreted into the GI tract daily, mainly from bile, and all but about 1 mcg is reabsorbed; less than 0.25 mcg is usually excreted in the urine daily. When vitamin B₁₂ is administered in amounts that exceed the binding capacity of plasma, the liver, and other tissues, it's free in the blood for urinary excretion.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

EDTA

Glycerine

Sodium Nipasept

Sodium Benzoate

Sucrose

Orange tincture

Simethicone

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store in a dry place below 30°C

6.5 Nature and contents of container

150ml and 280ml liquid content in Amber Type III glass bottle with a ROPP Aluminium cap packed in individual monocardon.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Daily-Need Industries Limited.

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8. MARKETING AUTHORISATION NUMBER

04-4042

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

June/2019