

Ferovance Package Insert

PROFESSIONAL INFORMATION

Complementary Medicine – Health Supplement

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety, or intended use.

SCHEDULING STATUS

To be assigned

1. NAME OF THE MEDICINE

Ferovance hard gel (vegecap) capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains

400 µg	Folate (as 5-methyltetrahydrofolate)
24 mg	Iron (as ferrous bisglycinate)
25 mg	Vitamin B6 (derived from pyridoxal-5-phosphate monohydrate)
25 µg	Vitamin B12 (derived from methylcobalamin)
250 mg	Vitamin C (as ascorbic acid)

3. PHARMACEUTICAL FORM

Hard gel capsules.

Hard gel capsule with white body and white cap filled with a beige/off-white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Helps to prevent iron deficiency anaemia, form red blood cells and helps in their proper function.

4.2 Posology and method of administration

For oral use.

Take one capsule daily.

Take with food, a few hours before or after taking other medications or natural health products.

4.3 Contraindications

Do not use if you have a hypersensitivity to any of the ingredients, including excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Stop use if hypersensitivity occurs.

4.5 Interactions with other medicines

Take a few hours before or after taking other medications or natural health products.

4.6 Pregnancy and lactation

The active ingredients in this product are commonly included in prenatal products.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Some people (as a rare exception) may experience gastrointestinal discomfort (such as diarrhoea, nausea or constipation).

4.9 Overdose

Stop use if hypersensitivity occurs.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Folate: Folate is involved in the synthesis of purines and pyrimidines, which are constituents of DNA, as well as the synthesis of amino acids glycine and methionine. Deficiency leads to impaired cell division.

Iron: Iron is a component of haemoglobin, myoglobin and many enzymes that are involved in a variety of metabolic functions, including the storage of oxygen, the electron transport chain, DNA synthesis and catecholamine metabolism.

Vitamin B6: Vitamin B6 is converted to pyridoxal phosphate and pyridoxamine phosphate in erythrocytes. It is a cofactor for more than 100 reactions involved in the metabolism of carbohydrates, lipids & protein. Pyridoxal phosphate is also involved in the synthesis of neurotransmitters & metabolism of other vitamins (e.g. conversion of tryptophan to niacin (vitamin B3)).

Vitamin B12: Involved in the recycling of coenzymes responsible for folate metabolism. Also involved in the degradation of Valine, an amino acid constituent of most protein.

Vitamin C: The functions of vitamin C are based mainly on its properties as a reducing agent. It is required for: i) the formation of collagen and other organic constituents of its intercellular matrix in bone, teeth and capillaries; and ii) the optimal activity of several enzymes – it activates certain liver detoxifying enzyme systems (including drug-metabolising enzymes) and is involved in the synthesis of carnitine and noradrenaline and the metabolism of folic acid, histamine, phenylalanine, tryptophan and tyrosine. Vitamin C acts: i) as an antioxidant (reacting directly with aqueous radicals), which is important in the protection of cellular function; and ii) in enhancing the intestinal absorption of non-haem iron.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose microcrystalline
Magnesium stearate
Silica

6.2 Incompatibilities

None.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25 °C.
Keep in the original container until required for use.
Protect from moisture.

6.5 Nature and contents of container

Ten capsules contained in PVDC/Alu blister strips.
Three blister strips contained within a cardboard carton.

6.6 Special precautions for disposal

No special requirements.

7. Holder of certificate of registration

Anastellar Brands (Pty) Ltd
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8. Registration number

TBC

9. Date of first authorisation

TBC

10. Date of revision of the text

September 2019