

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

FERROUS FORTE Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredient	Per tablet
Vitamin C (Ascorbic acid 97 %)	60 mg
Iron (Iron bisglycinate 20 %)	20 mg
Glycine (Iron bisglycinate 20 %)	7,36 mg
Folic acid (Folic acid)	350 µg
Vitamin B12 (Cyanocobalamin 0,1 %)	15 µg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Round red coated tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

FERROUS FORTE is an iron supplement. Iron helps to form red blood cells and helps in their proper function.

4.2 Posology and method of administration

Adults and children 13 years and older: Take one tablet daily, or as directed by a healthcare provider.

4.3 Contraindications

Do not use FERROUS FORTE if you are hypersensitive to any of the ingredients, including excipients.

4.4 Special warnings and precautions for use

Caution is advised when prescribing iron preparations to individuals with history of peptic ulcers. Use in children under the age of 13 years is at the discretion of a healthcare professional.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies were performed on FERROUS FORTE. The following interactions are noted in the monographs of the active ingredients:

Iron can form insoluble complexes with some medicines in the gastrointestinal tract and thereby reduce the absorption of these medicines. Advise patients to separate doses with iron supplement doses by at least two hours. The following medicines are of concern:

- Bisphosphonates
- Integrase inhibitors
- Levodopa
- Levothyroxine
- Methyl dopa
- Penicillamine
- Tetracycline antibiotics
- Quinolone antibiotics.

4.6 Fertility, pregnancy and lactation

Suitable for use during pregnancy and lactation under the supervision of a healthcare provider.

4.7 Effects on ability to drive and use machines

The effects on ability to drive and use machines has not been studied.

4.8 Undesirable effects

Possible side effects are:

- gastrointestinal discomfort (nausea, vomiting, abdominal pain, diarrhoea, constipation)
- black stools

4.9 Overdose

Acute overdosage, 60 mg/kg and more, can cause vomiting, hematemesis and diarrhea, followed by cardiovascular, liver or metabolic toxicity, and death. Seek medical attention immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Health Supplement
D34.12 Multiple substance formulation

5.2 PHARMACOLOGICAL ACTION

- Iron, folic acid and vitamin B12 help with the formation of healthy red blood cells and haemoglobin which play a role in oxygen transport in the body.
- Iron, vitamin B12 and vitamin C also contribute to normal cognitive function, reduction of fatigue and to the normal functioning of the immune system.
- Vitamin C assists with iron absorption and contributes to normal collagen formation which assists with the function of blood vessels.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet mix: Magnesium stearate, maize starch, microcrystalline cellulose, povidone, pregelatinized starch.

Coating materials: Absolute ethanol, beeswax white, carnauba wax, chloroform, Instacoat universal SFC white, Instacoat universal SFC red, polyethylene glycol, povidone, propylene glycol, shellac.

Sugar free.

6.2 Incompatibilities

Unknown

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C. Keep bottle tightly closed to protect from sunlight and moisture.
KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

White plastic containers with 30 or 60 tablets.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd
15E Riley Road, Bedfordview, 2007
Tel: (011) 087 0000 www.inovapharma.co.za

8 REGISTRATION NUMBER

To be allocated

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority for its quality, safety or intended use.

9 DATE OF PUBLICATION OF PROFESSIONAL INFORMATION

September 2020