PROFESSIONAL INFORMATION

SCHEDULING STATUS
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1 NAME OF THE MEDICINE
FERROUS FORTE (Syrup)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 6ml contains:

Ingredient	Per 6 mℓ
Iron (Ferrous bisglycinate chelate 10 %)	24 mg
Glycine (Ferrous bisglycinate chelate 10 %)	7,36 mg
Folic acid (Folic acid)	420 µg
Vitamin B12 (Cyanocobalamin 0,1 %)	18 µg

Preservatives: Potassium sorbate 0,1% m/v and Sodium benzoate 0,1 % m/v
Contains sugar: maltitol 5,82 g/6ml

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Yellow, citrus flavoured syrup.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

FERROUS FORTE syrup 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: Take 6ml daily, or as directed by a healthcare provider.

Children (2 years and older): Take 3ml twice daily, or as directed by a healthcare provider.

Children (1 – 24 months): Take 2ml three times daily, or as directed by a healthcare provider.

Shake the bottle before use.
Do not exceed the recommended dosage.

4.3 Contraindications

Not for use in patients who 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**.**

4.5 Interaction with other medicines and other forms of interaction

No interaction studies were performed on FERROUS FORTE. The below 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
- Methyldopa
- Penicillamine
- Tetracycline antibiotics
- Quinolone antibiotics.

4.6 Fertility, pregnancy and lactation

FERROUS FORTE is suitable for use during pregnancy and lactation at the recommended dose and at the discretion of a healthcare professional.

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 and vitamin B12 also contribute to normal cognitive function, reduction of fatigue and to the normal function of the immune system.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid monohydrate, orange flavour and propylene glycol.
Preservatives: Potassium sorbate 0,1% m/v and Sodium benzoate 0,1 % m/v
Contains sugar: maltitol 5,82 g/6ml
Alcohol and tartrazine 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 and protect from sunlight and moisture.
KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container
Amber glass or amber plastic bottle filled with 150 mℓ syrup.

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
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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