

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

FERROUS FORTE SOMAL capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredient	Per capsule
Vitamin C (as ascorbic acid)	60 mg
Iron (from SunActive™ ferric pyrophosphate)	24 mg
Folic acid (from Magnafolate™ C calcium 5-methyl tetrahydrofolate)	350 µg
Vitamin B12 (as cyanocobalamin)	15 µg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Reddish maroon capsules with the words "FERROUS FORTE NANO" printed in white.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

FERROUS FORTE SOMAL is a combination iron supplement to help the body maintain normal iron levels. Iron helps to form red blood cells and helps in their proper function.

FERROUS FORTE SOMAL contains micronized particles (very small particle size) of ferric pyrophosphate. The ferric pyrophosphate particles are encapsulated in a lipid layer to enable absorption via endocytosis in the intestine. As a result, iron from ferric pyrophosphate is well absorbed and well tolerated.

4.2 Posology and method of administration

Adults and children 13 years and older:

Take one capsule daily, or as directed by a healthcare provider. Capsules should be swallowed with water, with or without food.

4.3 Contraindications

Do not use FERROUS FORTE SOMAL 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 SOMAL. 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 and 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 with iron supplementation include:

- diarrhoea, constipation
- black stools

4.9 Overdose

Acute overdosage of iron, 60 mg/kg and more, can cause vomiting, haematemesis 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

- FERROUS FORTE SOMAL contains micronized and encapsulated particles of ferric pyrophosphate.
- This form of iron is derived from micronization and emulsification of colloidal liquid ferric pyrophosphate using super dispersion technology.
- The microencapsulated ferric pyrophosphate particles are approximately 300 nanometres in size and are absorbed by Microfold cells (M cells) in the intestinal lumen via endocytosis and is therefore referred to as endosomal iron.
- Iron is released in the intestines, not the stomach, therefore side effects associated with the digestive system are not expected.
- Magnafolate™ C calcium 5-methyltetrahydrofolate is an activated form of folic acid.
- 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

Lecithin, magnesium stearate, maltodextrin, microcrystalline cellulose, Capsule shell: gelatin.

Sugar free.

6.2 Incompatibilities

Unknown

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C.
Store blisters in the outer carton and protect from sunlight and moisture.
KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

Blister packs of 10 capsules packed in a cardboard carton containing 6 blister packs (60 capsules.)

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

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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

August 2022