

## PROFESSIONAL INFORMATION

### SCHEDULING STATUS

S0

### 1 NAME OF THE MEDICINE

FERROUS FORTE KIDS (fizzy)

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

| Ingredients                                | Per tablet |
|--|------------|
| Vitamin C (Ascorbic acid)                  | 60 mg      |
| Iron (Ferrous bisglycinate chelate 20%)    | 24 mg      |
| Glycine (Ferrous bisglycinate chelate 20%) | 8,832 mg   |
| Folic Acid (Quatrefolic®)                  | 199 ug     |
| Vitamin B12 (Vitamin B12 0,2 %)            | 7,5 ug     |

For full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Round, flat, light yellow tablet.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indication

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

#### 4.2 Posology and method of administration

Children 4 years and older: One tablet daily, dissolved in water, after food, or as directed by a healthcare provider.  
Do not exceed the recommended dosage.

#### 4.3 Contraindications

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

#### 4.4 Special warnings and precautions for use

- Use in children under the age of 4 years is at the discretion of a healthcare professional.
- Caution is advised when prescribing iron preparations to individuals with history of peptic ulcer.
- FERROUS FORTE KIDS contain sugar (mannitol) which may affect blood sugar levels in patients with *diabetes mellitus*. Patients with the rare hereditary condition of sorbitol/mannitol intolerance should not take this medicine.

#### 4.5 Interaction with other medicines and other forms of interaction

No interaction studies were performed on FERROUS FORTE. The following 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 Undesirable effects

Possible side effects are:

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

### 4.7 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

Aerosil, citric acid, effersoda, mango flavour, polyethylene glycol, sunset yellow.

Contains sugar: mannitol 0,7 g/fizzy

Contains sweetener: sucralose 0,03 g/fizzy

### 6.2 Incompatibilities

Unknown

### 6.3 Shelf life

2 years

### 6.4 Special precautions for storage

Store at or below 25 °C. Keep tube tightly closed to protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

### 6.5 Nature and contents of container

White tubes containing 10 fizzies each.

### 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](http://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