

FELUNA

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: **S0**

1. NAME OF THE MEDICINE

FELUNA, 83,72 mg, Liquid

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml liquid contains

Ferric ammonium citrate	83,72 mg
providing Iron	18 mg

Contains Sugar: Sucrose	2 375 mg
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For a full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Liquid

Thin, dark brown liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Feluna is an iron supplement that contributes to the normal formation of red blood cells, reduction of tiredness and fatigue, normal cognitive function and the normal functioning of the immune system.

4.2 Posology and method of administration

Posology

Adults and Children 0 - 18 years:

Take one 5 ml medicine measure daily after a meal, or as directed by a healthcare professional.

Method of administration

Oral administration only.

4.3 Contraindications

Feluna is contraindicated in patients who are hypersensitive to ferric ammonium citrate, iron or to any of the excipients listed in section 6.1.

Do not give to patients receiving repeated blood transfusions or patients with anaemias not produced by iron deficiency.

4.4 Special warnings and precautions for use

Caution is advised in patients with iron-storage or iron-absorption diseases such as haemochromatosis, haemoglobinopathies, or existing gastrointestinal diseases such as inflammatory bowel disease, intestinal strictures and diverticulae.

To avoid staining of the teeth, place **Feluna** liquid on the back of the tongue with a dropper or dilute with water and drink through a straw.

Feluna contains 74,688 mg of alcohol (ethanol) in each 5 ml which is equivalent to 1,5 % v/v. The amount in 5 ml of this medicine is equivalent to less than 1 ml beer or 1 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

Feluna contains sucrose: Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

- Calcium and magnesium compounds including antacids and mineral supplements, and bicarbonates, carbonates, oxalates, or phosphates, may impair the absorption of iron.
- Zinc salts may decrease the absorption of iron.
- The absorption of iron and tetracyclines is diminished when taken together orally. Allow a 2 - 3 hour time interval between dosing.
- The response to iron may be delayed in patients receiving systemic chloramphenicol.
- Ascorbic acid and citric acid increase absorption of iron.
- Iron can decrease the efficacy of cefdinir, entacapone, bisphosphonates, fluoroquinolones, levodopa, methylidopa, mycophenolate mofetil, penicillamine and levothyroxine.

4.6 Fertility, pregnancy and lactation

Do not use when planning pregnancy, pregnant or lactating except under practitioner supervision.

No fertility data available.

4.7 Effects on ability to drive and use machines

No data is available but no effect is expected on your ability to drive and use machines.

4.8 Undesirable effects

The following side effects may occur:

Gastrointestinal disorders

Frequent: Gastrointestinal irritation, heartburn, abdominal pain, nausea, vomiting, diarrhoea, constipation, dark stools and blackening of teeth.

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>

4.9 Overdose

Iron overdose is an acute emergency and intensifies the listed side effects.

Discontinue use immediately and seek medical attention. It is essential to reduce iron absorption from the Gastrointestinal tract as quickly as possible after acute iron overdosage and gastric lavage should be considered.

For medium to severe poisoning, chelation therapy should be considered.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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Ferric ammonium citrate, the active ingredient in **Feluna**, provides iron, an essential constituent of the body necessary for haemoglobin formation and for the oxidative processes of living tissues.

5.2 Pharmacokinetic properties

Iron is irregularly and incompletely absorbed from the gastrointestinal tract. Most absorbed iron is bound to transferrin and transported to the bone marrow where it is incorporated into haemoglobin. Only very small amounts of iron are excreted as the majority released is re-used.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsicum powder,
ethyl alcohol,
ginger oil,
liquorice block liquid,
nutmeg oil,
sucrose,
purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C in a cool, dry place.

Protect from light.

Keep the bottle in the outer carton.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Clear PVC 100 ml bottle with a white aluminium 24 mm screw cap, contained in an outer carton.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Avid Brands S.A. (Pty) Ltd
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2 Old Main Road,
Hillcrest, 3610
Tel: 0860 104 061
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Email: info@avidbrands.com

8. REGISTRATION NUMBER

To be allocated.

9. DATE OF FIRST AUTHORISATION

To be allocated.

10. DATE OF REVISION OF THE TEXT

Not applicable.