

1. Generic Name

Ferric Pyrophosphate

2. Qualitative and Quantitative Composition

Each veg capsule contains:

Ferric Pyrophosphate equivalent to Elemental Iron of 30mg

3. Dosage form and strength

I for U is available in the strength of 30mg elemental iron capsule.

4. Clinical particulars

4.1 Therapeutic indication

Patient with anaemia of CKD

4.2 Posology and method of administration

As directed by physician.

4.3 Contraindication

The use of I for U is contraindicated in patients with:

- Known hypersensitivity to any ingredient in this product.
- Severe Anaemia

4.4 Special warnings and precautions for use

None.



4.5 Drug interactions

• Antacids or aluminium-containing phosphate binders

May decrease iron absorption

• Calcium supplements

Decrease iron absorption

• Chloramphenicol

Possible delayed response to iron therapy

• Food

Iron absorption may be inhibited by polyphenols (e.g., from certain vegetables), tannins (e.g., from tea), phytates (e.g., from bran), and calcium (e.g., from dairy products)

• H2-receptor antagonists

Increased gastric pH and possibly decreased GI absorption of oral iron preparations that depend on gastric acidity for dissolution and absorption

• Iron, parenteral

Iron toxicity

Methyldopa

Pharmacokinetic (decreased oral absorption of methyldopa) and pharmacologic (decreased hypotensive effect) interactions

Penicillamine

May decrease the cupruretic effect of penicillamine, probably by decreasing its absorption

• Quinolone anti-infectives

Pharmacokinetic interaction (iron may interfere with quinolone absorption)

Tetracyclines



Pharmacokinetic interaction (decreased oral absorption of both iron and tetracyclines)

• Thyroid agents

Possible pharmacokinetic interaction (decreased thyroxine absorption)

• Vitamin C

Increased absorption of iron from GI tract (with >200 mg Vitamin C per 30 mg elemental iron)

4.6 Use in special population

- Paediatric: Safety and effectiveness of I for U in paediatric patients have not been established.
- Geriatric: Safety and effectiveness of I for U in geriatric patients have not been established.
- Liver impairment: No data available.
- Renal failure: Consultation with doctor is recommended.
- Pregnancy and lactation: Category A: Adequate and well-controlled human studies have failed to demonstrate a risk to the foetus in the first trimester of pregnancy (and there is no evidence of risk in later trimesters).

4.7 Effects on ability to drive and use machine

Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to I for U is known.

4.8 Undesirable effects

- Nausea/Vomiting
- GI Upset

4.9 Overdose

There is limited experience of overdose with for U. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.



5. Pharmacological properties

5.1 Mechanism of action

I for u is a micronized and microencapsulated source of iron which enhances the bioavailability of iron and does not taste metallic or oxidize unsaturated fats. Liposomal like complex is absorbed through M cells (microfold cells) that are present throughout the intestine and may be carried by macrophages through the lymphatic circulation directly into the liver, where they are broken down into their smaller subparts by enzymatic actions, releasing the iron mineral.

5.2 Pharmacodynamic properties

Iron supplementation typically results in increases in serum iron, transferrin-bound iron, and iron-stored in the form of ferritin in hepatocytes and macrophages. The available iron is usually used in bone marrow for the synthesis of haemoglobin

5.3 Pharmacokinetic properties

NA.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

NA.

7. Description

Iron(3+) phosphate is an inorganic phosphate having Fe(3+) as the counterion. It is an iron molecular entity and an inorganic phosphate. It contains an iron(3+).

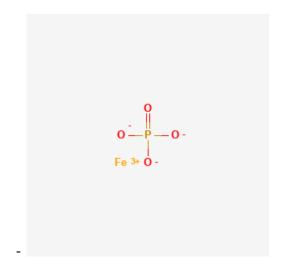
Chemical Name- iron(3+);phosphate

Molecular Weight- 150.82 g/mol

Molecular Formula- FeO₄P

Structure-





Pharmaceutical particulars 8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

18 months.

8.3 Packaging Information

I for U is available in 3 X 10 capsules per pack.

8.4 Storage and handling instructions

Store at dark place at temperature not exceeding 25°C. Protect from direct sunlight.

9. Patient Counselling Information

9.1 Adverse Reactions

Refer part 4.8

9.2 Drug Interactions

Refer part 4.5

9.3 Dosage



Refer part 4.2

9.4 Storage

Refer part 8.4

9.5 Risk Factors

Refer part 4.4

9.6 Self-monitoring information

NA

9.7 Information on when to contact a health care provider or seek emergency help

Patients are advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

9.8 Contraindications

Refer part 4.3

10. Manufactured by G C CHEMIE PHARMIE LTD

11. Details of permission or license number with date

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