

## 1. Composition

Each veg capsule contains:

Ferric Pyrophosphate equivalent to Elemental Iron of 30mg

# 2. Dosage form and strength

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

# 3. Clinical particulars

### 3.1 Therapeutic indication

Patient with anaemia of CKD

# 3.2 Posology and method of administration

As directed by physician.

#### 3.3 Contraindication

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

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

# 3.4 Special warnings and precautions for use

None.

### 3.5 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)

### 3.6 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).

#### 3.7 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.

#### 3.8 Undesirable effects

- Nausea/Vomiting
- GI Upset

#### 3.9 Overdose

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

# 4. Pharmacological properties

#### 4.1 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.

#### 4.2 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

### 4.3 Pharmacokinetic properties

# 5. Nonclinical properties

# 5.1 Animal Toxicology or Pharmacology

Not required.

#### 6. Description

Already mentioned and covered in the above points.



# 7. Pharmaceutical particulars 7.1 Incompatibilities

There are no known incompatibilities.

# 7.2 Shelf-life

18 months.

# 7.3 Storage and handling instructions

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