Product Summary

1. Name of the medicinal product
Raricap Forte®

2. Qualitative and quantitative composition
Each film coated tablet contains:
Ferrous Calcium Citrate Complex (Equivalent to Iron) 50 mg
Folic acid I.P. 0.3 mg

3. Pharmaceutical form
Film coated tablet

4. Clinical particulars
4.1 Therapeutic indications
For the prevention and treatment of Iron deficiency anaemias

4.2 Posology and method of administration
1 tablet a day or as advised by the physician.

4.3 Contraindications
Contra-indications of Iron (Ferrous calcium citrate)
1. Haemolytic anaemia unless iron deficiency anaemia is also present
2. Haemochromatosis
3. Haemosiderosis
4. Peptic ulcer
5. Regional enteritis
6. Ulcerative colitis
7. Those receiving repeated blood transfusions
4.4 Special warnings and precautions for use

Special Precautions while taking Iron (Ferrous calcium citrate)

1. Prolonged use
2. Minimise gastrointestinal discomfort by taking along with meals and gradually increasing the recommended dosage
3. Discontinue if intolerance occurs
4. Higher doses are required for geriatric patients

Special Precautions while taking Folic Acid

1. In patients with undiagnosed anaemia; because it may mask pernicious anaemia
2. In pernicious anaemia and other megaloblastic anaemia where vitamin B12 is deficient

4.5 Interaction with other medicinal products and other forms of interaction

Interactions with Raricap Forte® are unknown. However, the known interactions for individual components are as follows

Iron component of Ferrous calcium citrate.

Iron is known to interact with other drugs like Ciprofloxacin, Clodronate, Deferiprone, Demeclocycline, Etidronic acid, Gemifloxacin, Ibandronate, Levofloxacin, Methyldopa, Moxifloxacin, Norfloxacin. Always consult your physician for the change of dose regimen or an alternative drug of choice that may strictly be required.

Folic Acid

Folic acid is known to interact with other drugs like Fluorouracil, Sulphonamide, Phenytoin, Methotrexate, Sulfasalazine, Cholestyramine, And Zinc may affect the efficacy of Folic acid or vice versa. Always consult your physician for the change of dose regimen or an alternative drug of choice that may strictly be required.

4.6 Pregnancy and lactation

Iron and folic acid may be used in pregnancy. However, there is no data on any adverse events related to the use of Raricap Forte®

4.7 Effects on ability to drive and use machines
No information is available regarding the effect on ability to drive and use machines after using Raricap Forte®.

4.8 Undesirable effects
Raricap Forte® is well tolerated and the adverse effects are uncommon. Rarely gastrointestinal symptoms may be reported. However, the following should be considered.

**Side Effects of Iron (Ferrous calcium citrate)**
1. Nausea
2. Epigastric distress
3. Vomiting
4. Constipation
5. Diarrhoea
6. Black stools
7. Temporary staining of teeth with liquid formulations.

**Side Effects of Folic acid**
The common side effects are
1. Urge to vomit
2. Bloating of stomach
3. Excessive passage of wind
4. Loss of appetite
5. Worsening of vitamin B12 deficiency (when folic acid is used alone to treat anemia without investigating the cause).

Consult your doctor immediately if rash, itching, or breathlessness develops.

4.9 Overdose
No information on overdose with Raricap Forte® is available.

**Effects of Overdose of Iron (Ferrous calcium citrate)**
Treatment includes immediate support of airway, respiration, and circulation. In conscious patients induce emesis with ipecac; if not empty stomach by gastric lavage. Follow emesis with lavage, using a 1% sodium bicarbonate solution to convert iron to
less irritating poorly absorbed form. Take abdominal X-ray to determine presence of excess iron. Deferoxamine may be used for systemic chelation if serum levels of iron exceed 350mg/dl.

**Effects of Overdose of Folic Acid**
Relatively non toxic. Provide symptomatic treatment and supportive measures.

5. Pharmacological properties

5.1 Pharmacodynamic properties

- Raricap Forte® provides right dose (elemental iron 50 mg) of iron for re-establishing iron store

**Mechanism of Action of Iron (Ferrous calcium citrate)**

- Ferrous calcium citrate exerts haematinic action by being an essential constituent of haemoglobin. It is necessary for the oxidative process of living tissues.

**Mechanism of Action of Folic Acid**

Folic acid reduced by enzymes folate reductase and dihydrofolate reductase and forms dihydrofolic acid tetrahydrofolic acid respectively. Tetrahydrofolic acid acts as a coenzyme which mediates a number of one carbon transfer reactions by carrying a methyl group as an adduct. It involves a number of reactions such as

1. Conversion of homocysteine to methionine.
2. Synthesis of thymidylate which is an essential constituent of DNA from methylene-tetrahydrofolic acid.
3. Conversion of serine to glycine by tetrahydrofolic acid and forms methylene-tetrahydrofolic acid.
4. To introduce carbon units at position 2 and 8 during de novo purine synthesis requires formyl-tetrahydrofolic acid and methenyl-tetrahydrofolic acid.
5. Generation and utilization of "formate pool".
6. For mediating formino group transfer in histidine metabolism. Folic acid is required to maintain normal erythropoiesis and nucleoprotein synthesis.

5.2 Pharmacokinetic properties

- Raricap Forte® delivers iron differently
• Calcium Citrate in FCC binds to phytates & phosphates leaving iron to be absorbed.
• Raricap Forte® has three layers with an inner layer of Ferrous Calcium Citrate, the unique molecule, followed by acid-resistant coating and then film coating.
• This Multilayered Drug delivery ensures iron release in duodenum, so that there is no side effect experienced by the patients unlike other forms such as Ferrous Sulphate or Ferrous Gluconate

**Pharmacokinetics of Iron (Ferrous calcium citrate)**
*Absorption:* Absorbed orally in ferrous form and poorly absorbed in healthy individuals (about 10%) but in patients suffering from iron deficiency anaemia up to 60% dose is absorbed.
*Distribution:* Transported in a transferrin bound form in to bone marrow for incorporation in to haemoglobin.
*Metabolism:* Iron liberated by destruction of haemoglobin is reused by the body.
*Excretion:* Excretion of iron is minimal. Loss usually occurs in nails, faeces, urine, hair, sweat, and bile.

**Pharmacokinetics of Folic Acid**
*Absorption:* Well absorbed orally
*Distribution:* Widely distributed in the body and highest concentration is seen in liver. It appears in the CSF and breast milk
*Metabolism:* Metabolized in to N-methyl tetrahydrofolic acid in liver
*Excretion:* Extra drug is excreted unchanged in urine. A small portion of folate is lost by a combination of urinary and fecal excretion and oxidative cleavage of molecule.

5.3 Preclinical safety data
No data is available on preclinical safety with Raricap Forte®.

6. Pharmaceutical particulars

6.1 List of excipients
Excipients q.s
Overages are added to compensate active degradation during shelf life.

6.2 Incompatibilities
None known.

6.3 Shelf life
24 Months.

6.4 Special precautions for storage
Store in the original package below 30°C protected from light, keep all medicine out of reach of children.

Administrative data
7. Marketing authorisation holder
Strides Shasun Limited
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8. Toll free number for reporting
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9. Date of text
5th July 2016