

English Back Side



RICHFER® Capsules
For oral use

RICHFER PLUS SUSPENSION
For oral use

RICHFER CAPSULES
COMPOSITION:
Each hard gelatin capsule contains:
Carbonyl Iron (equivalent to Elemental iron) 100 mg
Folic Acid BP 500 mcg
Cyanocobalamin (coated) (Vitamin B12) 15 mcg
Ascorbic Acid (coated) 75 mg
Zinc Sulphate monohydrate BP 61.8 mg
(equivalent to elemental zinc 22.5 mg)
Alpha Tocopheryl Acetate BP 15 IU
Sodium Selenate equivalent to Selenium 45 mcg
Appropriate overages of vitamins are added to compensate loss on storage.
Approved colour used in empty hard gelatin capsule.

Pharmaceutical dosage form: Capsules

RICHFER PLUS SUSPENSION
COMPOSITION:
Each 5ml Contains:
Ferric Hydroxide Polymaltose complex
Eq. to Elemental Iron 125 mg
Folic acid BP 500 mcg
Zinc Sulphate BP 15mg
Zinc Sulfate (Monohydrate) BP 33 mg
(equivalent to 12 mg of Zinc)
Sorbitol solution (70%) 10%w/v
Colour: Approved color used with
Excipient with known effect: Sodium Methyl Paraben, Sodium Propyl Paraben, Sorbitol 70% Solution, Sodium saccharine, Sucrose, Polyethylene glycol
Appropriate overages of vitamins added to compensate loss on storage.

Category: Iron supplementation.

Pharmaceutical Dosage Form: Oral Suspension

Route of Administration: Oral

DOSAGE:
RICHFER CAPSULES
Adult: One Capsule daily before food or as directed by the physician.

RICHFER PLUS SUSPENSION
This medicine has been dispensed to you personally in a particular situation: It may not be appropriate in other circumstances. Do not advise anybody else to take it.

Method and route of Administration:
Oral route.
Should preferably be taken between both feeds or before meals. This timing of administration is to be determined according to digestive tolerance. Frequency and times of administration of the medicine the total daily dose should be divided into several fractions in order to avoid adverse effects.
Shake well before use.

Treatment Duration:
This must be sufficient to correct anaemia and replenish iron stores (approximately 3 to 6 months).
Management of Overdose:
If massive ingestion occurs, consult a doctor immediately.

CONTRAINDICATIONS:
It is contraindicated in patients with known hypersensitivity to any of its component.

⚠ SIDE-EFFECTS:
Gastrointestinal irritations such as nausea, anorexia, vomiting, discomfort, constipation and diarrhoea may occur. Patients may complain of dark stool. Carbonyl Iron pellets incorporated into the capsules to reduce the possibility of gastrointestinal irritations. Rarely there may be allergic reactions.

⚠ PRECAUTION:
Special care should be taken in patients with iron overload states, such as haemochromatosis, haemolytic anaemia or red blood cell aplasia. Failure to response to the treatment requires further investigations to exclude other causes of anaemia. In patients with renal failure there may be the risk of Zinc accumulation.

⚠ Usage in pregnancy:
Use of any drug during first trimester of pregnancy should be avoided if possible. Thus administration of iron during the first trimester requires definite evidence of iron deficiency. Prophylaxis of iron deficiency where penicillamine calls for supplementary Zinc and Folic acid is justified during the remainder of pregnancy.

⚠ DRUG INTERACTIONS:
Carbonyl Iron decreases the absorption of tetracycline antibiotics, quinolone antibiotics, levodopa, levodopa, methylgluta and penicillamine. Folic Acid interacts with antileptics, so plasma concentrations of phenobarbital, phenytoin and primidone are possibly reduced.

⚠ OVERDOSEAGE AND TREATMENT:
Symptoms of Carbonyl Iron include decreased energy, nausea, abdominal pain, tarry stool, weak, rapid pulse, fever, coma, seizures.

PHARMACODYNAMICS
Carbonyl Iron (Ferrus Fumarate):
Iron, as a constituent of haemoglobin, plays an essential role in oxygen transport. Iron is also present in the muscle protein myoglobin and in the myofibrils. Deficiency of iron leads to anaemia.
Vitamin B₁₂ (Cyanocobalamin)
Vitamin B₁₂ is present in the body mainly as methylcobalamin and as adenosylcobalamin and hydroxycobalamin. These act as co-enzymes in the trans methylation of homocysteine to methionine, in the isomerisation of methylmalonyl co-enzyme to succinyl co-enzyme and with folate in several metabolic pathways respectively. Deficiency of Vitamin B₁₂ interferes with haemopoiesis and produces megaloblastic anaemia.
Folic Acid
Folic acid is reduced in the body to tetrahydrofolate which is a co-enzyme for various metabolic processes, including the synthesis of purine and pyrimidine nucleotides and hence in the synthesis of DNA. It is also involved in some amino acid conversion and in the formation and utilisation of formate. Deficiency of folic acid leads to megaloblastic anaemia.
Vitamin C (Ascorbic Acid)
Vitamin C cannot be synthesised by man therefore a dietary source is necessary. It acts as a cofactor in numerous biological processes including the hydroxylation of proline to hydroxyproline. In deficiency, the formation of collagen is, therefore, impaired. Ascorbic acid is important in the hydroxylation of dopamine to norepinephrine and in hydroxylation of connective tissue formed in the adrenals. It is a reducing agent in tyrosine metabolism and by acting as an electron donor in the conversion of folic acid to tetrahydrofolic acid is indirectly involved in the synthesis of purine and thymine. Vitamin C is also necessary for the incorporation of iron into ferritin. Vitamin C increases the phagocytic function of leucocytes; it possesses anti-inflammatory activity and it promotes wound healing. Deficiency can produce scurvy. Features include swollen inflamed gums, petechial haemorrhages and subcutaneous bruising. The deficiency of collagen leads to development of thin watery ground substances in which blood vessels are insecurely fixed and readily ruptured. The supportive components of bone and cartilage are also deficient causing bones to fracture easily and teeth to become loose. Anaemia commonly occurs probably due to Vitamin C's role in iron metabolism.
Zinc (Zinc Sulfate)
Zinc is a constituent of many enzymes and is, therefore, essential to the body. It is present with insulin in the pancreas and plays a role in DNA synthesis and cell division. Reported effects of deficiency include delayed puberty and hypogonadal dwarfism.
Vitamin E (Alpha tocopherol acetate)
Vitamin E deficiency has been linked to disorders such as cystic fibrosis where fat absorption is impaired. It is essential for the normal function of the muscular system and the blood.
Selenium (Sodium Selenate)
Selenium is an essential trace element, deficiency of which has been reported in man. It is thought to be involved in the functioning of membranes and the

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French Front Side

RICHFER GÉLULES

COMPOSITION:

Chaque gélule de gélatine dure contient :

Fer carbonylé équivalent au fer élémentaire	100 mg
Acide folique BP	500 µg
Cyanocobalamine (enrobée) [vitamine B12]	15 mcg
Ascorbate ascorbique (enrobé).....	75 mg
Sulfate de zinc monohydraté BP	61,8 mg
(équivalent à 22,5 mg de zinc élémentaire)	
Asclatate d'alcaloïde phénylpyruvique BP	15 UI

Silicate de sodium équivalent à 65 mg de silicium.

Des excipients approuvés par les autorités sont ajoutés pour compenser la perte
Orale couvrée utilisée dans une gélule de gélatine dure vide.

Forme pharmaceutique : gélule

RICHFER PLUS SUSPENSION

COMPOSITION:

Chaque 5 ml contient :

un complexe d'hydroxyde de polymalates de fer	
Equivalent au fer élémentaire	125 mg
Acide folique BP	500 µg
Vitamine B12 BP	15mcg
Sulfate de zinc (monohydraté) BP	33 mg
(équivalent à 12 mg de zinc)	
Solution de sorbitol (70%)	10% v/v

Orale : Couleur apparente utilisée

Excipients à effet notoire : Méthylparabène de sodium, Propylparabène de sodium,
Sorbitol en solution à 70%, Sodium saccharine, Sucrose, Propylène glycol.
Des excipients approuvés par les autorités sont ajoutés pour compenser la perte
Orale stockée

Catégorie: Supplémentaire en fer.

Forme pharmaceutique: Suspension Orale

Vie d'administration: Orale

POSOLOGIE

RICHFER GÉLULES

Adulte : une gélule par jour avant les repas ou

Selon les directives du médecin.

RICHFER PLUS SUSPENSION

Ce médicament vous a été dispensé personnellement dans

une situation particulière.

Cela peut ne pas être approprié dans d'autres circonstances,

demandez l'avis de votre médecin ou pharmacien avant toute prise.

Méthode et voie d'administration:

Voie orale.

la biodisponibilité du produit n'est pas entravée par les repas; il peut donc
être pris avant, pendant ou après les repas.

Fréquence et heure d'administration du médicament, la dose quotidienne totale
du sirop peut être administrée en une seule prise.

Bien agiter avant utilisation.

Durée de traitement:

Cela doit être suffisant pour corriger l'anémie et reconstituer les réserves de fer
gestion du surdosage.

En cas d'ingestion massive, consultez immédiatement un médecin.

CONTRAINDICATIONS:

Il est indiqué pour le traitement et la prophylaxie des carences en fer, acide
folique, complexe de vitamine B₁₂, vitamine C et zinc, en particulier pendant la
grossesse et l'allaitement. Il est également indiqué pour les patients gériatriques
présentant une faiblesse généralisée due à une carence en vitamines et
minéraux.

Il est également indiqué dans le traitement et la prophylaxie des anémies
ferriques chez les nourissons et les enfants en période de croissance.

CONTRE-INDICATIONS:

Il est contre-indiqué chez les patients présentant une hypersensibilité
connue à l'un de ses composants.

EFFETS SECONDAIRES:

Traitement des infections gastro-intestinales telles que : nausées, anorexie,
vomissements, inconfort, constipation/diarrhée peuvent survenir. Les patients
peuvent se plaindre de selles fermes. Granules de fer carbonylé incorporés
dans les capsules pour réduire la possibilité d'infections gastro-intestinales.
Ramenent il peut y avoir des réactions allergiques.

PRÉCAUTION:

Des précautions particulières doivent être prises chez les patients
présentant des états de surcharge en fer tels qu'une hémochromatose, une
anémie hémolytique ou une aplasie des globules rouges. L'absence de réponse
au traitement nécessite des investigations complémentaires pour exclure
d'autres causes d'anémie. Chez les patients atteints d'insuffisance rénale, il faut
avoir un risque d'accumulation de zinc.

Utilisation pendant la grossesse:

L'utilisation de tout médicament pendant le premier trimestre de la
grossesse doit être évitée si possible. Ainsi, l'administration de fer au cours du
premier trimestre nécessite des preuves positives d'une carence en fer.
Peut s'utiliser en prophylaxie de la carence en fer ou lorsqu'une alimentation
inadequate nécessite un supplément de zinc et d'acide folique pendant le reste
de la grossesse.

INTERACTIONS MÉDICAMENTEUSES:

Le fer carbonylé diminue l'absorption des antibiotiques tétracycliques, des
antibiotiques quinolones, de la levodopa, de la thyroïdienne, de la méthylphosphate
et de la pénicilline. L'acide folique interagit avec les antipéptidiques, de sorte
que les concentrations plasmatiques de phenobarbital, phénytoïne et primidone
sont éventuellement réduites.

SURDOSAGE ET TRAITEMENT:

Les symptômes du surdosage en fer peuvent comprendre une diminution de
l'énergie, des nausées, des douleurs abdominales, des selles goudronneuses,
un pouls faible et rapide, de la fièvre, un coma, des convulsions.

PHARMACODYNAMIQUE

Le fer carbonylé (Ferrochel®) [Fer II]

Le fer, en tant que constituant du hémoglobine, joue un rôle essentiel dans
le transport de l'oxygène. Il est également présent dans la myoglobine, la protéine
musculaire et dans le foie. Une carence en fer entraîne une anémie.
Vitamine B₁₂ (cyanocobalamine)

La vitamine B₁₂ est présente dans le corps principalement sous forme de méthyl
cobalamine et d'adénylos cobalamine et d'hydroxycobalamine. Ces co-agents
composés des co-enzymes dans la méthylation de l'homoéthylène en méthionine;
dans l'isomérisation de la coenzyme méthylmalonate en coenzyme succinate et
avec la folicité dans plusieurs voies métaboliques respectivement. Une carence
en vitamine B₁₂ interfère avec l'hématopoïèse et conduit à une anémie
mégaloérythrocytaire.

Acide folique

L'acide folique est réduit dans le corps en tétrahydrofolate qui est une co-
enzyme pour divers processus métaboliques, y compris la synthèse de
nucleotides de purine et de pyrimidine et donc dans la synthèse d'ADN. Il est
également impliqué dans une certaine conversion d'acides aminés et dans
la formation d'allofolate ou formate. Une carence en acide folique entraîne une
anémie mégaloérythrocytaire.

Vitamine C (acide ascorbique)

La vitamine C ne peut pas être synthétisée par l'homme, donc une source
alimentaire est nécessaire. Il agit comme cofacteur dans de nombreux
processus biologiques, y compris l'hydroxylation de la proline en dihydroxyproline.
En cas de carence, la formation de collagène est donc altérée. L'acide
ascorbique est important dans l'hydroxylation de la tyrosine en noradrénaline
dans les hydroxylation se produisant lors de la synthèse des stéroïdes dans
les surrénales. C'est un agent réducteur du métabolisme de la tyrosine et en
ajouté comme un donneur d'électrons dans la conversion de l'acide folique en
acide tétrahydrofolate, il est indirectement impliqué dans la synthèse de la
purine et de la thymine. La vitamine C est également nécessaire pour
l'incorporation du fer dans la ferritine. La vitamine C augmente la fonction
phagocytaire des leucocytes; il possède une activité anti-inflammatoire et
favorise la cicat

Product Name : Richfer - (All)		Item Code : 16/0807		Item : Insert		Version: 03		Co-ordinator : Vaishali		
Pack Size : Capsule & Suspension		Location : Safetab		Date : 20/01/2024		Artist : Unicorn Creation				
Colours: BLUE WOOL TEST VALUE 5-8 (LIGHT FASTENING DATA)										
		Pantone 2925 C				Pantone 2756 C				Black
Ink : Oil based Ink from DIC OR MICRO								Software : CorelDraw 15		
Actual Size: L x H : 240 x 200 mm				Size after folding: 80 x 50 mm		Grain Direction : Parallel to length/Parallel to printing length				
Material : Not less than 60 GSM Maplitho Paper										
Design : Folded Booklet (Back to Back Printing)				Artwork Print Size: ☒ actual ☐ scaled						
● Instructions / Remark : Keep Overprint Preview on ● Any deviation must be brought to the notice of packaging development co-ordinator immediately. ● For any clarification, please contact packaging development co-ordinator immediately. NO CHANGES IN ARTWORK SHOULD BE DONE BY THE PRINTER ● The printer should verify the e-proof against the approved artwork before submitting for approval and the e-proof should have printer details .				Checked By	Artist	PMD	R.A.	Production	Q.C.	Q.A.
				Bar Code	☒	☐	☐	☐	☐	☐
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Modification Remark : Dosage form & Excipients added dt. 16/09/2022										