Summary of Product Characteristics
(Product Data Sheet)

1. Name of the Medical Product

1.1 Product Name: **NURIFER CAPSULES (**Carbonyl Iron, Vitamins and Zinc Capsules**)**

1.2 Strength:
Each hard gelatin capsule contains:

Carbonyl Iron	
Equivalent to Elemental iron	100 mg
Folic Acid BP	1.5 mg
Vitamin B12 (Cyanocobalamin) BP	15 mcg
Vitamin C (Ascorbic acid) BP (as coated)	75 mg
Zinc Sulfate Monohydrate USP (equivalent to 22.5 mg of Elemental zinc)	61.8 mg
Excipients	q.s.

Empty hard gelatin capsule contains approved colors.
Appropriate overages of vitamins added.

1.3 Pharmaceutical Dosage Form: Capsules
Pink/White, unprinted hard gelatin capsules of size '0' filled with light grey to grey coloured powder.

2. Qualitative & Quantitative Composition:

Sr. No.	Ingredients	Specifications	Quantity per unit (mg)	Reason for inclusion
Active Ingredients				
1	Carbonyl Iron	IH	100.000	Active
2	Folic Acid	BP	2.250* (1.5)	Active
3	Vitamin B_{12} (Cyanocobalamin)	BP	0.027** (15 mcg)	Active
4	Vitamin C (Ascorbic Acid) BP (as coated)	IH	97.500*** (75)	Active
5	Zinc Sulphate Monohydrate	USP	61.800	Active
Excipients for Lubrication				
6	Microcrystalline Cellulose	USP NF	228.423	Diluent
7	Croscarmellose Sodium	USP NF	6.000	Disintegrant
8	Magnesium Stearate	BP	2.000	Lubricant
9	Hydrophobic Colloidal	USP NF	2.000	Glidant

		Silica			
	10	E.H.G Capsules size"0" pink opaque / white opaque	IH	1 No	For Encapsulation
		Total theoretical weight of filled capsule		595.00 mg	--

*50.0% overages included
** 80% overages included
*** 30% overages included
IH : In House Specification
BP : British Pharmacopoeia
USP : United States Pharmacopoeia
USP-NF: United States Pharmacopoeia- National Formulary

3. **Pharmaceutical Form:** Capsules

4. **Clinical Particulars**

4.1 Therapeutic Indications:
For the treatment of iron deficiency anemia and folate deficiency anemia. Carbonyl Iron, Vitamins and Zinc Capsules is indicated in pregnancy for the prevention and treatment of iron deficiency and to supply a maintenance dosage of folic acid.

4.2 Posology and Method of administration:
For oral use only.
Posology
One capsule daily or as directed by the physician

4.3 Contraindications:
This product is contraindicated in patients with a known hypersensitivity to any of the Ingredients.

4.4 Special warning and precautions for use:
Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemia where vitamin B12 is deficient. Do not exceed recommended dosage. The treatment of any anemic condition should be under the advice and supervision of a physician. Since oral iron products interfere with absorption of oral tetracycline antibiotics, these products should not be taken within two hours of each other. Occasional gastrointestinal discomfort (Such as nausea) may be minimized by taking with meals. Iron products may occasionally cause constipation or diarrhea.

	4.5 Interactions with other medicinal products and other forms of Interactions: Food may delay absorption of drug. Chelation may occur with tetracycline. Concurrent administration with penicillamine may diminish the effect of the latter substance. The absorption of iron and tetracylines is diminished when administered concomitantly. Antacids reduce absorption of iron.
	4.6 Pregnancy and Lactation: Can be given in pregnancy.
	4.7 Effects on ability to drive and use machine: This medication is unlikely to affect the ability to drive and operate machinery. However, the patients should initially observe how this medicine affects them and then judge if it is safe to drive or operate machinery..
	4.8 Undesirable Effects: Mild gastro intestinal disturbance. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.
	4.9 Overdosage: **Iron:** Symptoms of overdosage include epigastric pain, diarrhoea, vomiting and haematemesis. Circulatory collapse may follow. Metabolic acidosis, convulsions, coma, eventual hepatic coma and subsequent death may occur. Acute liver necrosis may develop. Possible corrosive effects on the gastro-intestinal mucosa, necrosis and perforation may occur, structure formation may subsequently follow. Patients mistakenly given iron therapy when not suffering from iron-deficiency anaemia are also at risk as are those with pre-existing iron storage or absorption diseases. Speed is essential in treating iron poisoning, in order to block absorption from the alimentary tract. In acute poisoning, desferrioxamine, an iron chelating agent should be given. If not available, the stomach should be emptied by emesis and lavage using a I to 5% solution of sodium bicarbonate: leave about 300 mL of the solution in the stomach. Other measures include correction of lost fluids. **Folic Acid:** Folic acid overdose is not known to have any deleterious effect on the human body. Usually, the excess folic acid ingested is excreted in the urine, without conducing to any health problems. However, consumption of high doses of folic on a daily basis, for a long period of time, can result in some problems. Some of the symptoms of folic acid over dosage include Diarrhea, Insomnia, Digestive problems (such as nausea or gas). Rash, Zinc deficiency, Psychotic

	behaviour, Bitter taste in the mouth, irritability, Excitability, or hyperactivity and Seizures. Moreover, high dose of folic acid is also feared to increase risks of heart attacks in people with heart diseases and are also observed to prevent action of certain medications like anti-epilepsy. **Vitamin B_{12}:** It can mask symptoms of subacute degeneration of the spinal cord, Allergic sensitivity reactions have been reported following the administration of vitamin B12 compounds, cyanocobalamin and hydrocobalamin. Cyanocobalamin and hydrocobalamin should if possible not be given to patients without first confirming the diagnosis and should not be used to treat megaloblastic anaemia of pregnancy. Administration of doses greater than 10 g may produce a haematological response in patients with a folate deficiency: indiscriminate use may mask the disease and prevent a precise diagnosis. Serum concentrations may be decreased by the concurrent administration of oral contraceptives. **Vitamin C:** Large doses may cause diarrhoea and the formulation of renal calcium oxalate calculi. Doses of 600 mg or more daily have a diuretic action. Vitamin C should be administered with care to patients with hyperoxaluria. Tolerance may be induced in patients taking high doses. **Zinc:** Ingestion of large quantities of zinc is rapidly followed by nausea and vomiting. Due to its corrosive action it causes a burning sensation in the oesophagus and stomach. Colic and diarrhoea with blood may follow, with convulsions, hypotension, coma and death. Treatment consists of emptying the stomach by aspiration and lavage and demulcents such as milk and egg white should be given freely. Sodium calcium edetate may be administered. Morphine or pethidine may be given to relieve pain. Fluid and electrolyte balance should be corrected.
5.	**Pharmacological properties**
	5.1 Pharmacodynamic Properties: ATC code: B03AE02 - Iron, Multivitamins and Folic Acid B03AE04 - Iron, Multivitamins and Minerals **Cyanocobalamin:** Cyanocobalamin (Vitamin B12) is a water-soluble organometallic compound with a trivalent cobalt ion bound inside a corrin ring. It is needed for nerve cells and red blood cells, and to make DNA. Vitamin B 12 deficiency is the cause of several forms of anemia. Cyanocobalamin (commonly known as Vitamin B 12) is the most chemically complex of all the vitamins. Cyanocobalamin's structure is based on a coring ring, which, although similar to the porphyrin ring found in heme, chlorophyll, and cytochrome, has two of the pyrrole rings directly bonded. The central metal ion is Co (cobalt). Cyanocobalamin cannot be made by plants or by animals, as the only type of organisms that have the enzymes required for the synthesis of cyanocobalamin are bacteria and archaea. Higher plants do not concentrate cyanocobalamin from the soil and so is a poor source of the substance as compared with animal tissues. Cyanocobalamin is naturally found in foods including meat (especially liver and shellfish), eggs, and milk products.

Vitamin B 12 is used in the body in two forms: Methylcobalamin and 5-deoxyadenosyl cobalamin. The enzyme methionine synthase needs Methylcobalamin as a cofactor. This enzyme is involved in the conversion of the amino acid homocysteine into methionine. Methionine in turn is required for DNA methylation. 5-Deoxyadenosyl cobalamin is a cofactor needed by the enzyme that converts L-methylmalonyl-CoA to succinyl-CoA. This conversion is an important step in the extraction of energy from proteins and fats. Furthermore, succinyl CoA is necessary for the production of hemoglobin, the substances that carries oxygen in red blood cells.

Folic Acid:
Folic acid, a water-soluble B-complex vitamin, is found in foods such as liver, kidneys, yeast, and leafy, green vegetables. Folic acid is used to diagnose folate deficiency and to treat topical sprue and megaloblastic and macrocytic anemias, hematologic complications resulting from a deficiency in folic acid. It is mainly indicated for treatment of folic acid deficiency, megaloblastic anemia and in anemias of nutritional supplements, pregnancy, infancy, or childhood.

Folic acid is a member of the vitamin B family that stimulates the hematopoietic system. It is present in the liver and kidney and is found in mushrooms, spinach, yeast, green leaves, and grasses (poaceae). Folic acid is used in the treatment and prevention of folate deficiencies and megaloblastic anemia.

Folic acid, as it is biochemically inactive, is converted to tetrahydrofolic acid and methyltetrahydrofolate by dihydrofolate reductase. These folic acid congeners are transported across cells by receptor-mediated endocytosis where they are needed to maintain normal erythropoiesis, synthesize purine and thymidylate nucleic acids, interconvert amino acids, methyl ate , tRNA, and generate and use formate. Using vitamin B 12 as a cofactor, folic acid can normalize high homocysteine levels by remethylation of homocysteine to methionine via methionine synthetase.

Ascorbic Acid Coated (Vitamin C):
In humans, an exogenous source of ascorbic acid is required for collagen formation and tissue repair. Vitamin C is a co-factor in many biological processes including the conversion of dopamine to noradrenaline, in the hydroxylation steps in the synthesis of adrenal steroid hormones, in tyrosine metabolism, in the conversion of folic acid to folinic acid, in carbohydrate metabolism, in the synthesis of lipids and proteins, in iron metabolism, in resistance to infection, and in cellular respiration.

Zinc Sulphate Monohydrate:
Zinc sulfate is a zinc salt used for the treatment of acute and persistent diarrhoea in children.

Zinc is an essential trace element which is present in a wide range of foods. It is found in all tissues. Normal growth and tissue repair depend upon adequate zinc levels. Zinc acts as an integral part of several enzymes important to protein and carbohydrate metabolism. . Severe zinc deficiency is associated with growth retardation, primary hypogonadism, skin disease, disturbances of taste and smell, and impaired immunity, with increased susceptibility to

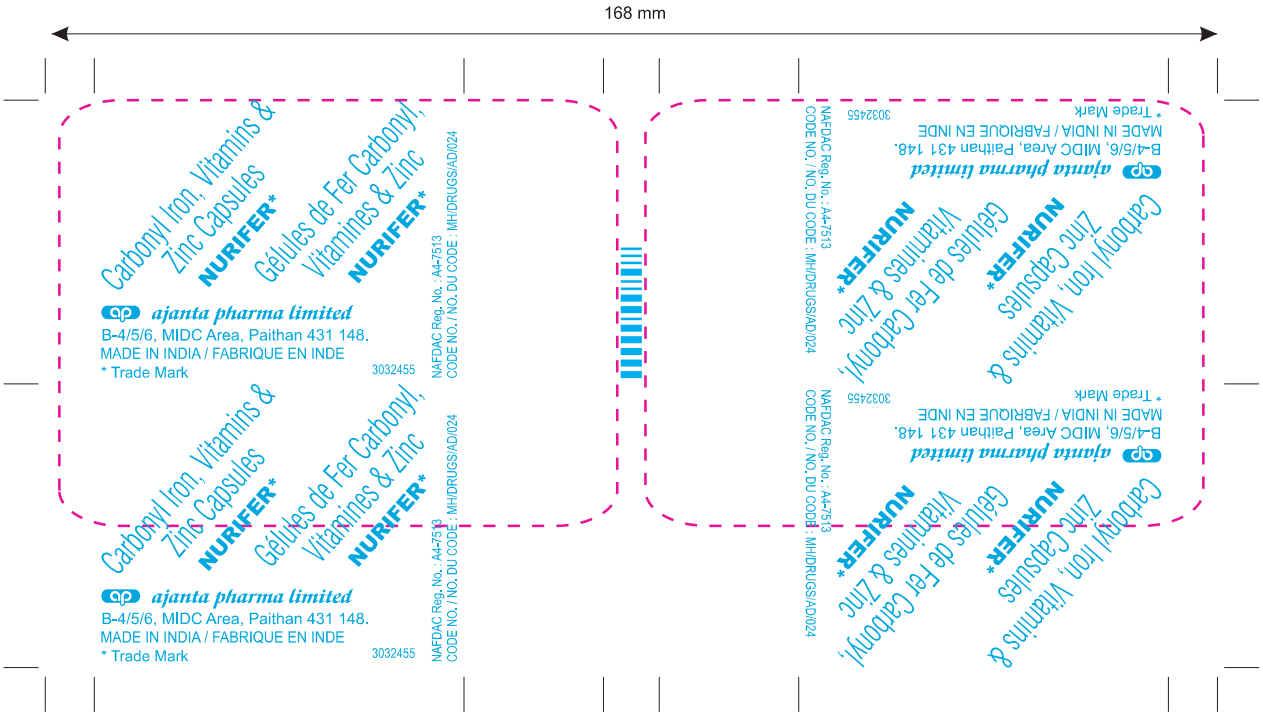
	infection. Zinc supplementation has been shown to reduce the duration and severity of diarrhea in populations of children with a high incidence of zinc deficiency, and also to reduce the frequency of recurrences in the subsequent 2-3 months. The beneficial effects of zinc are likely associated with reconstitution of the immune response, however direct inhibitory effects of zinc on enteric pathogens have also been reported. **Carbonyl Iron:** Carbonyl Iron is a micro spherical form of elemental iron as opposed to ionized iron present in iron supplements. Average particle size is 3-4 microns and 90% of particles are less than 10 microns. Carbonyl iron offers advantages like Absorption: Carbonyl Iron exhibits sustained uniform absorption. Carbonyl iron reacts slowly with gastric acid to gradually convert to Fe++. This represents as the rate-limiting step in the absorption process. Other iron salts are readily ionized due to their water solubility. The availability of excess iron causes excess iron in the body resulting in side effects/ toxicity. Iron content: 98% minimum iron, thus low dose is required.
	5.2 Pharmacokinetics Properties: **Carbonyl Iron:** Bioavailability is two time higher than other iron salts. Studies indicate that Carbonyl iron micro powder exhibits the highest Relative Biological Value (RBV) of the elemental powders available as dietary supplements. The high bioavailability of Carbonyl iron is due to its fine size and uniform spherical shape. Consequently, a large surface area is provided for assimilation of Carbonyl Iron. **Ascorbic Acid Coated (Vitamin C):** **Absorption** Absorbed almost completely from distal small intestine. **Distribution** Distributed throughout water-soluble compartments. Adrenal cortex, leukocytes, platelets, and pituitary gland contain high concentrations. **Elimination** Excreted in the urine.

6.	**Pharmaceutical particulars**
	6.1 List of Excipients: Microcrystalline Cellulose USPNF Croscarmellose Sodium USPNF Magnesium Stearate BP Colloidal Silicon Dioxide USPNF Capsule: E.H.G Capsules size "0" pink opaque/ white opaque colourless body
	6.2 Incompatibilities: Not applicable
	6.3 Shelf life: 36 months from the date of manufacturing
	6.4 Special Precautions for storage: Store below 30°C
	6.5 Nature and contents of container: A carton containing 3 blisters of 10 capsules each along with a pack insert.
	6.6 Special precautions for disposal: No special requirements. Any unused product or waste material should be disposed in accordance with local requirements.
7.	**Marketing Authorization Holder:** Ajanta Pharma Limited Ajanta House, Charkop, Kandivali (West), Mumbai- 400 067, India
	Marketing Authorization Numbers: A4-7513
8.	**Date of first authorization/ renewal of the authorization:** 28/02/2019
9.	**Date of revision of text:** Jun 30, 2023

NURIFER CASPULES
Carbonyl Iron, Vitamins and Zinc Capsules)

1.13 Artworks

Please find enclosed herewith Artworks (Foil, Carton and Pack Insert).



Pharma Code : 32455 Mini Code

Direction for Travel

Note : Pharma Code will be repeat after every 200 mm for reading feasibility on machine.

ajanta pharma limited

Name & Signature

Checked By : _____

Verified By : _____

Approved By : _____

Date : _____

Packaging Department

For : Export Market | Co-ordinator Name : Anand Gounder | Software : Corel Draw | Date : 18.05.2022

New Item Code : 3032455 | Item Type: Foil | Artist Name : Shrikant

Product Name : Nurifer Tablets | Earlier Item Code: 3020538

Material : 0.025 mm. Blister foil

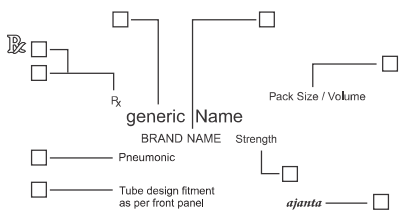
Actual Size : Width - 168 mm | Folding Size : NA | Varnish : NA

Print Repeat : 40.667mm | Drawing No. : ASD/06-0710-781

CMYK / Pantone : Pantone 2995C

Reason for Change : Foil material change from 0.020 mm to 0.025 mm

Front Panel:



Back Panel / Side Panel

Composition	☐	Barcode	☐
Colour	☐	Warnings / Schedule H	☐
Dosage	☐	Caution / Schedule G	☐
Storage	☐	Statutory Contents	☐
Made in India	☐	Directions for use	☐
Company's Name	☐	Neutral code	☐
H.O.Address	☐	Factory + H.O.Address	☐
Factory Address	☐	Red line	☐
Toll Free No. / Email ID	☐	Other	☐

Side Panels

BRAND NAME ☐

PTN☐ CKL☐ CTGN☐ LL☐ TP☐ DHJ☐ GHT☐ PMR☐

Others:

Item Code	☐	Pharma Code	☐
LIF	☐	Colour Code	☐
Printed License No.	☐	Reference Sample	☐
O.P.Zone / DGFT	☐	Back-side Printing	☐
MOH approved a/w	☐	Change Parts	☐
		Buyer/IBM approval	☐

NOTE TO PRINTERS: THE CD OUTPUT MAY / MAY NOT BE MATCHING WITH THE OUTPUT. FOR THIS COLOUR MATCH AS PER ATTACHED SAMPLE WITH A/W IF IT IS NOT MATCHING WITH THE GIVEN REFERENCE SAMPLE THE PM/PROOF REJECTION WILL BE SUPPLIERS RESPONSIBILITY. FOR CARTON GRAIN DIRECTION PERPENDICULAR TO MAIN CREASE. / REMARK: BLOCK PROOF REQUIRE BEFORE PRINTING.

Direction for Travel

Pharma Code : 20445 Standard

Nurifer*

8 901111 675212

Nurifer*

Carbonyl Iron, Vitamins & Zinc Capsules
Gélules de Fer Carbonyl ,Vitamines & Zinc

Nurifer*

Fortified Carbonyl Iron Capsules
Gélules de Fer Carbonyl Fortifié

Nurifer*

3020445

Nurifer*

UNVARNISH OPZ AREA

Each hard gelatin capsule contains:	
Carbonyl Iron equivalent to elemental Iron	100 mg
Folic Acid BP	1.5 mg
Cyanocobalamin BP	15 mcg
Ascorbic acid BP (as coated)	75 mg
Zinc Sulfate Monohydrate USP (equivalent to 22.5mg of elemental Zinc)	61.8mg
Excipients	q.s.
Chaque gélule en gélatine dure contient:	
Fer Carbonyl équivalent à Fer élémentaire	100 mg
Acide Folique BP	1.5 mg
Cyanocobalamine BP	15 mcg
Acide Ascorbique BP (enrobée)	75 mg
Sulfate de Zinc Monohydrate USP (équivalent à 22.5mg de Zinc élémentaire)	61.8 mg
Excipients	q.s.p

Appropriate overages of vitamins added.
Excédent Approprié de vitamine ajoutés.

Empty hard gelatin capsule contains approved colours.
Gélule vide en gélatine dure contient les couleurs approuvés.

Dosage : As directed by the physician.
Posologie:Selon prescription médicale.

3 x 10 Capsules / Gélules

Store below 30°C

Conserver en-dessous de 30°C.

KEEP OUT OF THE REACH OF CHILDREN.

NE PAS LAISSER A LA PORTEE DES ENFANTS.

TAN No. TZ 16 H0072
NAFDAC Reg. No. : A4-7513
Product Lic. No. : 115/056
Method of sale : P
CODE NO. / NO. DU CODE : MH/DRUGS/AD/024

Manufactured by / Fabrique par :
ajanta pharma limited
Factory : B-4/5/6 MIDC Area, Paithan 431 148.
Regd./Corp. Off. : Ajanta House, Charkop, Kandivli (W), Mumbai 400 067.
MADE IN INDIA / FABRIQUE EN INDE * Trade Mark

UNVARNISHED AREA WITH PERFORATIONS

ajanta pharma limited

Name & Signature

Checked By : _____

Verified By : _____

Approved By : _____

Date : _____

Packaging Department

For : Export Market Co-ordinator Name : Anan Software : Corel Draw Date : 26/11/2019

Item Code : 3020445 Item Type : **Cartonator Carton** Artist Name : Kiran

Product Name : Nurifer Capsules Revision of (Pcode) : NA

Material : 300 GSM ITC FBB board, (RTI) Reference Item code (P Code) : P33534

Actual Size : 86 (L) x 33 (W) x 65 (H) mm Folding Size : NA Varnish : Aqua

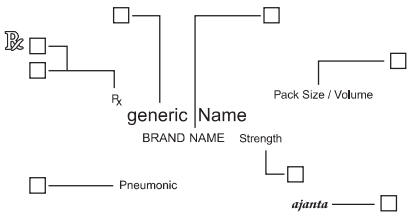
Print Repeat : NA Drawing No. : PGB092156131

CMYK / Pantone : Pantone 2365 C Pantone 2945 C Pantone 185 C Pantone 2748 C Black

Reason : Store Condition Change From 25°C to 30°C.

NOTE: THE CD OUTPUT MAY / MAY NOT BE MATCHING WITH THE OUTPUT. FOR THIS COLOUR MATCH AS PER ATTACHED SAMPLE WITH A/W IF IT IS NOT MATCHING WITH THE GIVEN REFERENCE SAMPLE THE PM/PROOF REJECTION WILL BE SUPPLIERS RESPONSIBILITY. FOR CARTON GRAIN DIRECTION PERPENDICULAR TO MAIN CREASE. / REMARK: BLOCK PROOF REQUIRE BEFORE PRINTING.

Front Panel:



Back Panel / Side Panel

Composition	☐	Barcode	☐
Colour	☐	Warnings / Schedule H	☐
Dosage	☐	Caution / Schedule G	☐
Storage	☐	Statutory Contents	☐
Made in India	☐	Directions for use	☐
Company's Name	☐	Neutral code	☐
H.O.Address	☐	Factory + H.O.Address	☐
Factory Address	☐	Red line	☐
Toll Free No. / Email ID	☐	Other	☐

Side Panels

BRAND NAME ☐

PTN ☐ CKL ☐ CTGN ☐ LL ☐ TP ☐ DHJ ☐

Others:

Item Code	☐	Pharma Code	☐
LIF	☐	Colour Code	☐
Printed License No.	☐	Reference Sample	☐
O.P.Zone / DGFT	☐	Back-side Printing	☐
MOH approved a/w	☐	Change Parts	☐
		Buyer/IBM approval	☐

Pharma Code : 20446 Standard

Direction for Travel

ajanta pharma limited

Name & Signature

Checked By :

Verified By :

Approved By :

Date :

Packaging Department

For : Export Market | Co-ordinator Name : Anand | Software : Corel Draw | Date : 08/11/2019

Item Code : 3020446 | Item Type : Carton | Artist Name : Kiran

Product Name : Nurifer Capsules | Revision of (Pcode) : NA

Material : 400 GSM ITC FBB Board, (LBTO) | Reference Item code (P Code) : P32504

Actual Size : 205 x 175 x 90 mm | Folding Size : NA | Varnish : Aqua

Print Repeat : NA | Drawing No. : NA

CMYK / Pantone : Pantone 2365 C Pantone 2945 C Pantone 185 C Pantone 2748 C Black

Reason : Store Condition Change From 25°C to 30°C.

NOTE: THE CD OUTPUT MAY / MAY NOT BE MATCHING WITH THE OUTPUT. FOR THIS COLOUR MATCH AS PER ATTACHED SAMPLE WITH A/W IF IT IS NOT MATCHING WITH THE GIVEN REFERENCE SAMPLE THE PM/PROOF REJECTION WILL BE SUPPLIERS RESPONSIBILITY. FOR CARTON GRAIN DIRECTION PERPENDICULAR TO MAIN CREASE. / REMARK: BLOCK PROOF REQUIRE BEFORE PRINTING.

Front Panel:

Rx

Rx

generic Name

BRAND NAME Strength

Pack Size / Volume

Pneumonic

ajanta

Back Panel / Side Panel

Composition	☐	Barcode	☐
Colour	☐	Warnings / Schedule H	☐
Dosage	☐	Caution / Schedule G	☐
Storage	☐	Statutory Contents	☐
Made in India	☐	Directions for use	☐
Company's Name	☐	Neutral code	☐
H.O.Address	☐	Factory + H.O.Address	☐
Factory Address	☐	Red line	☐
Toll Free No. / Email ID	☐	Other	☐

Side Panels

BRAND NAME ☐

PTN ☐ CKI ☐ CTGN ☐ LI ☐ TP ☐ DHL ☐

Others:

Item Code	☐	Pharma Code	☐
LIF	☐	Colour Code	☐
Printed License No.	☐	Reference Sample	☐
O.P.Zone / DGFT	☐	Back-side Printing	☐
MOH approved a/w	☐	Change Parts	☐
		Buyer/IBM approval	☐

3020446

UNVARNISHED AREA WITH PERFORATIONS

15 x 3 x 10 Capsules

Carbonyl Iron, Vitamins & Zinc Capsules

Nurifer*

Fortified Carbonyl Iron Capsules

Each hard gelatin capsule contains:	
Carbonyl Iron equivalent to elemental Iron	100 mg
Folic Acid BP	1.5 mg
Cyanocobalamin BP	15 mcg
Ascorbic acid BP (as coated)	75 mcg
Zinc Sulfate Monohydrate USP (equivalent to 22.5mg of elemental Zinc)	61.8 mg
Excipients	q.s.

Chaque gélule en gélatine dure contient:

Fer Carbonyl équivalent à Fer élémentaire	100 mg
Acide Folique BP	1.5 mg
Cyanocobalamine BP	15 mcg
Acide Ascorbique BP (enrobée)	75 mcg
Sulfate de Zinc Monohydrate USP (équivalent à 22.5mg de Zinc élémentaire)	61.8 mg
Excipients	q.s.p

Appropriate overages of vitamins added.
Excédent Approprié de vitamine ajoutes.

Empty hard gelatin capsule contains approved colours.
Gélule vide en gélatin e dure contient les couleurs approuvés.

Dosage : As directed by the physician.
Posologie : Selon prescription médicale.

Store below 30°C
Conserver en-dessous de 30°C.

KEEP OUT OF THE REACH OF CHILDREN.
NE PAS LAISSER A LA PORTEE DES ENFANTS.

15 x 3 x 10 Gélules

Gélules de Fer Carbonyl ,Vitamines & Zinc

Nurifer*

Gélules de Fer Carbonyl Fortifié

8 901111 013784

* Trade Mark

Manufactured by / Fabrique par :

ajanta pharma limited

Factory : B-4/5/6 MIDC Area, Paithan 431 148.
Regd./Corp. Off. : Ajanta House, Charkop, Kandivli (W), Mumbai 400 067.

MADE IN INDIA / FABRIQUE EN INDE

CODE NO./ NO. DU CODE : MH/DRUGS/AD/024

UNVARNISH
OPZ AREA 86 x 80 mm

Front

3020447

Carbonyl Iron, Vitamins & Zinc Capsules
NURIFER*

COMPOSITION

Each hard gelatin capsule contains:

Carbonyl Iron equivalent to Elemental Iron	100 mg
Folic Acid BP	1.5 mg
Cyanocobalamin BP	15 mcg
Ascorbic Acid BP (as coated)	75 mg
Zinc Sulphate Monohydrate USP (equivalent to 22.5mg of elemental Zinc)	61.8 mg
Excipients	q.s.

Appropriate overages of Vitamins added.
Empty hard gelatin capsule contains approved colours.

DESCRIPTION

NURIFER capsules provide water-soluble vitamins, Zinc and iron (as carbonyl iron).

CLINICAL PHARMACOLOGY

Carbonyl iron is a micro spherical form of elemental iron as opposed to ionized iron present in iron supplements. Average particle size is 3-4 microns and 90% of particles are less than 10 microns. Carbonyl iron offers advantages like

Absorption: Carbonyl Iron exhibits sustained uniform absorption.
Carbonyl Iron reacts slowly with gastric acid to gradually convert to Fe + +. This represents as the rate-limiting step in the absorption process. Other iron salts are readily ionized due to their water solubility. The availability of excess iron causes excess iron in the body resulting in side effects / toxicity.

Gastro Intestinal Tolerance: It shows better GI Tolerance. Fifteen times of normal Carbonyl Iron dose is required to have similar GI Side effects of Iron sulphate.

Iron content: 98% minimum iron, thus low dose is required.

Bioavailability:
Bioavailability is two times higher than other iron salts. Studies indicate that Carbonyl iron micro powder exhibits the highest Relative Biological Value (RBV) of the elemental powders available as dietary supplements. The high bioavailability of Carbonyl Iron is due to its fine size and uniform spherical shape. Consequently, a large surface area is provided for assimilation of Carbonyl Iron.

Zinc: Zinc is an important trace element and plays an important role in metabolism. Deficiency of zinc provides an array of signs and symptoms. Zinc deficiency in pregnancy limits the foetal growth and if severe then causes teratogenic anomalies. Zinc deficiencies can cause infertility, prolonged labour, intrauterine growth retardation, and embryonic and foetal death

Folic Acid and Vitamin B_{12} : Folic Acid administration alone reverses the hematological abnormalities thus makes the Vitamin B_{12} deficiency, which can then proceed to severe neurological dysfunction and disease. Therefore megaloblastic anemia should not be treated with Folic Acid alone but rather with a combination of folate with Vitamin B_{12}. Optimum dose of Folic Acid appears to be between 0.65-1.5 mg/day.

Vitamin B_{12}: It is also used for pernicious anemia and certain disorders of Gastro Intestinal absorption.

Vitamin C: It acts as an antioxidant by playing a specific role in hydroxylation of proteins, collagens. It is concerned with the formation and maintenance of intracellular cell structures. It also acts as a cofactor for transformation of folic acid into folinic acid.

INDICATIONS

For the treatment of iron deficiency anemia and folate deficiency anemia. NURIFER is indicated in pregnancy for the prevention and treatment of iron deficiency and to supply a maintenance dosage of folic acid.

CONTRAINDICATIONS

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

WARNINGS

Folic acid alone is improper therapy inthe treatment of pernicious anemia and othermegaloblastic anemia where vitamin B_{12} is deficient. Do not exceed recommended dosage. The treatment of any anemic condition should be under the advice and supervision of a physician. Since oral iron products interfere with absorption of oral tetracycline antibiotics, these products should not be taken within two hours of each other. ccasional gastrointestinal discomfort (such as nausea) may be minimized by taking with meals. Iron products may occasionally cause constipation or diarrhea.

ADVERSE REACTIONS

Mild gastro intestinal disturbance. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

POSSIBLE SIDE EFFECTS

There are no known side effects to the use of vitamins and trace elements contained in Nurifer capsules, there are a few possible side effects to contend with. These may include stomach cramps, constipation, heartburn, difficulty breathing, diarrhea, unusually weak or tired, nausea, and vomiting.

PREGNANCY AND LACTATION

Can be given in pregnancy

INTERACTIONS WITH FOOD AND DRUGS

Food may delay absorption of drugs.
Chelation may occur with tetracycline. Concurrent administration with penicillamine may diminish the effect of the latter substance. The absorption of iron and tetracyclines is diminished when administered concomitantly. Antacids reduce absorption of iron.

OVERDOSAGE AND ITS TREATMENT

Iron: Symptoms of overdosage include epigastric pain, diarrhoea, vomiting and haematemesis. Circulatory collapse may follow. Metabolic acidosis, convulsions, coma, eventual hepatic coma and subsequent death may occur. Acute liver necrosis may develop. Possible corrosive effects on the gastro-intestinal mucosa, necrosis and perforation may occur, stricture formation may subsequently follow. Patients mistakenly given iron therapy when not suffering from iron-deficiency anaemia are also at risk as are those with pre-existing iron storage or absorption diseases. Speed is essential in treating iron poisoning, in order to block absorption from the alimentary tract. In acute poisoning, desferrioxamine, an iron chelating agent should be given. If not available, the stomach should be emptied by emesis and lavage using a 1 to 5% solution of sodium bicarbonate; leave about 300 mL of the solution in the stomach. Other measures include correction of lost fluids.

Folic Acid: Folic acid overdose is not known to have any deleterious effect on the human body. Usually, the excess folic acid ingested is excreted in the urine, without conducing to any health problems.
However, consumption of high doses of folic on a daily basis, for a long period of time, can result in some problems. Some of the Symptoms of folic acid over dosage include Diarrhea, Insomnia, Digestive problems (such as nausea or gas), Rash, Zinc deficiency, Psychotic behavior, Bitter taste in the mouth, Irritability, Excitability, or Hyperactivity and Seizures. Moreover, high dose of folic acid is also feared to increase risks of heart attacks in people with heart diseases and are also observed to prevent action of certain medications like anti-epilepsy.

Vitamin B_{12}: It can mask symptoms of subacute degeneration of the spinal cord. Allergic sensitivity reactions have been reported following the administration of vitamin B_{12} compounds, cyanocobalamine and hydrocobalamine.
Cyanocobalamine and hydrocobalamine should if possible not be given to patients without first confirming the diagnosis and should not be used to treat megaloblastic anaemia of pregnancy. Administration of doses greater than 10 g may produce a haematological response in patients with a folate deficiency; indiscriminate use may mask the disease and prevent a precise diagnosis. Serum concentrations may be decreased by the concurrent administration of oral contraceptives.

Vitamin C: Large doses may cause diarrhoea and the formulation of renal calcium oxalate calculi. Doses of 600 mg or more daily have a diuretic action. Vitamin C should be administered with care to patients with hyperoxaluria. Tolerance may be induced in patients taking high doses.

Zinc: Ingestion of large quantities of zinc is rapidly followed by nausea and vomiting. Due to its corrosive action it causes a burning sensation in the oesophagus and stomach. Colic and diarrhoea with blood may follow, with convulsions, hypotension, coma and death. Treatment consists of emptying the stomach by aspiration and lavage and demulcents such as milk and egg white should be given freely. Sodium calcium edetate may be administered. Morphine or pethidine may be given to relieve pain. Fluid and electrolyte balance should be corrected.

Generally: Treatment is symptomatic and supportive.

DOSAGE

One capsule daily or as directed by a physician.

PRESENTATION

Available in blister pack of 10 capsules

Store below 30°C.

KEEP OUT OF THE REACH OF CHILDREN.

Date of publication / review : Sep. 2013

A product of

ajanta pharma limited

Ajanta House, Charkop, Kandivli (W), Mumbai 400 067.

* Trade Mark

25 mm

100 mm

300 mm

150 mm

Gélules de Fer Carbonyle, Vitamines & Zinc

NURIFER*

Formule': Chaque gélule en gélatine dure contient:

Fer Carbonyle équivalent à Fer Elémentaire	100 mg
Acide Folique BP	1.5 mg
Cyanocobalamine BP	15 mcg
Acide Ascorbique BP (enrobée)	75 mg
Sulfate de Zinc Monohydrate USP (équivalent à 22.5 mg de Zinc élémentaire)	61.8 mg
Excipients	q.s.p

Surplus Approprié de Vitamines ajoutés.
Gélule vide en gélatine dure contient les couleurs approuvés.

Description: NURIFER gélules fournit les vitamines soluble d'eau, Zinc et Fer (comme Fer carbonyle).

PHARMACOLOGIE CLINIQUE
Fer Carbonyle est une forme de Fer élémentaire micro sphérique comme oppoosé à Fer ionisé présent dans les suppléments de Fer.
La dimension moyenne de particule est 3-4 microns et 90% des particules sont moins de 10 microns.
Fer Carbonyle offre les avantages telle que

Absorption: Fer Carbonyle exhibe une absorption uniforme soutenue.
Fer Carbonyle réagit lentement avec l'acide gastrique à graduellement convertit à Fe + +. Ceci représente comme l'étape de taux-limitant dans les procédures d'absorption.
Autre sels de Fer sont volontairement ionisé due à leur solubilité d'eau. La disponibilité d'excès de Fer cause l'excès de Fer dans le corps résultant dans des effets secondaires/toxicité.

Tolérance Gastro-intestinal: Il montre une meilleure Tolérance Gl. 15 fois la dose normale de Fer Carbonyle est requit pour avoir des effets secondaires similaire de sulfate de Fer.

Contenu de Fer: 98% minimum de Fer, ainsi une faible dose est nécessaire.

Bio disponibilité: La bio disponibilité est deux fois plus élevé que d'autre sels de Fer. Les études indiquent que la poudre micro de Carbonyle de Fer exhibe la plus haute Valeur Biologique Relatif (RBV) de la poudre élémentaire disponible comme suppléments diététique. La haute bio disponibilité de Fer Carbonyle est due à ses dimensions fine et forme sphérique uniforme. En conséquence, une large surface est fournit pour l'assimilation de Fer Carbonyle.

Zinc: Zinc est une trace d'élément important et joue un rôle important dans le métabolisme. La déficience de zinc fournit une variété de signes et symptômes. La déficience de Zinc pendant la grossesse limite la croissance foetal et si sévère cause des anomalies teratogénique. La déficience de Zinc peut causer l'infertilité, le travail prolongé, retard de croissance intra-utérin, et mort embryogénique et foetale.

Acide Folique et Vitamine B_{12}: L'administration d'Acide folique seule renverses les anomalies hématologique ainsi fait la déficience de Vitamine B_{12}, qui peut ensuite continuer aux dysfonctions neurologique sévère et maladies. Donc, l'anémie mégaloblastique ne doit pas être traité avec l'Acide folique seul mais but plutôt avec une combinaison de folate avec Vitamine B_{12}.
La dose Optimum de l'Acide folique apparaisse d'être entre 0.65-1.5 mg/jour.

Vitamine B_{12}: Il est aussi utilisé pour l'anémine pernicieuse et certain trouble de l'absorption Gastro-intestinal.

Vitamine C: Il agit comme un antioxydant en jouant un rôle spécifique dans l'hydroxylation des protéines, collagènes.
Il est concerné avec la formation et le maintient des structures de paroi cellulaire. IL agit aussi comme un co-facteur pour la transformation de l'acide folique en acide folinique.

Indications: Pour le traitement de l'anémie de la déficience de Fer et anémie de déficience folate.

NURIFER est indiqué pendant la grossesse pour la prévention et traitement dé déficience de Fer et pour fournir le dosage de maintient de l'acide folique.

Contre-indications: Ce produit est contre indiqué chez les patients avec une hypersensibilité connue à tout ingrédients.

AVERTISSEMENTS: L'Acide folique seul est une thérapie inapproprié dans le traitement d'anémie pernicieuse et autre anémie mégasloblastique où la vitamine B_{12} est déficitaire. Ne pas dépasser la dose recommandé. Le traitement de tout condition anémique doit être sous l'avis et la supervision d'un médecin. Puisque les produits de Fer oral interfèrent avec l'absorption des anitbiotiques tétracycline oral, ces produits ne doivent pas être prise en deux heures de chacune. La malaise occasionnelle gastro-intestinal (telle que la nausée) peut êtreminimisé en prenant avec un repas. Les produits de Fer peut occasionnellement causer la constipation ou la diarrhée.

Effets indésirables: Trouble gastro-intestinal léger. La sensibilisation allergique a été rapporté suivant l'administration oral et parentéral de l'acide folique.

EFFETS SECONDAIRES POSSIBLES
Il n'y a pas d'effets secondaires connus à l'utilisation de vitamines et oligo-éléments contenus dans des capsules Nurifer mais il y a quelques effets secondaires possibles à combattre. Ceux-ci peuvent inclure des crampes d'estomac, une constipation, des brûlures d'estomac, des difficultés respiratoires, de la diarrhée, une faiblesse ou une fatigue inhabituelle, des nausées et des vomissements.

GROSSESSE ET ALLAITEMENT: Peut être donné pendant la grossesse

INTERACTIONS AVEC LES ALIMENTS ET LES MÉDICAMENTS: Les aliments peuvent retarder l'absorption desmédicaments La chélation peut se produire avec de la tétracycline. L'administration concomitante avec la pénicillamine peut diminuer l'effet de cette dernière substance.
L'absorption du fer et des tétracyclines est diminuée lorsque l'administration est concomitante. Les antiacides réduisent l'absorption du fer.

SURDOSAGE ET SON TRAITEMENT
Fer: Les symptômes du surdosage incluent la douleur épigastrique, la diarrhée, les vomissements et l'hématémèse. Un collapsus circulatoire peut suivre.
Une acidose métabolique, des convulsions, un coma, un éventuel coma hépatique et la mort subséquente peuvent se produire. Une Nécrose hépatique aiguë peut se développer. D'éventuels effets corrosifs sur la muqueuse gastro-intestinale, une nécrose et une perforation peuvent se produire, la formation de sténose peut alors suivre. Les patients qui reçoivent un traitement de fer à tort lorsqu'ils ne sont pas atteints d'anémie causée par une carence en fer sont également à risque car ils font partie de ceux qui ont une maladie pré-existante liée au stockage du fer ou une maladie liée à l'absorption.
La vitesse est essentielle dans le traitement de l'empoisonnement par le fer, afin de bloquer l'absorption dans le tractus digestif. En cas d'intoxication aiguë, de desferrioxamine, un agent chélateur du fer doit être donné. S'il n'est pas disponible, l'estomac doit être vidé par vomissements et par lavage avec une solution de 1 à 5% de bicarbonate de sodium. Toutefois, laisser environ 300 mL de la solution dans l'estomac. D'autres mesures comprennent la correction des liquides perdus.

Acide folique: Le surdosage d'acide folique n'est pas connu pour avoir un effet nuisible sur le corps humain. Habituellement, l'excès d'acide folique ingéré est excrété dans l'urine, sans conduire à d'éventuels problèmes de santé.
Cependant, la consommation de doses élevées d'acide folique sur une base quotidienne, pendant une longue période de temps, peut entraîner certains problèmes. Le cas échéant, les symptômes d'un surdosage d'acide folique incluent la diarrhée, l'insomnie, les problèmes digestifs (tels que les nausées ou les gaz), une éruption cutanée, une carence en zinc, un comportement psychotique, un goût amer dans la bouche, l'irritabilité, l'excitabilité, ou une hyperactivité et enfin des saisies. En outre, une dose élevée d'acide folique fait également craindre une augmentation des risques d'attaques cardiaques chez les personnes souffrant de maladies cardiaques et fait aussi l'objet d'une observation afin de prévenir l'action de certains médicaments comme les anti-épileptiques.

Vitamine B_{12}: Il peut masquer les symptômes de la dégénérescence subaiguë de la moelle épinière. Des réactions d'hypersensibilité allergiques ont été signalées après l'administration de composés de la vitamine B_{12}, telles que la cyanocobalamine et l'hydrocobalamine.
La cyanocobalamine et l'hydrocobalamine ne devraient pas, si possible, être administrées aux patients sans au préalable une confirmation du diagnostic et ne doivent pas être utilisées pour traiter l'anémie mégaloblastique durant la grossesse. L'administration de doses supérieures à 10g peut produire une réponse hématologique chez les patients présentant une carence en folate. L'utilisation sans discernement peut masquer une maladie et empêcher un diagnostic précis. Les concentrations sériques peuvent être diminuées par l'administration simultanée de contraceptifs oraux.

Vitamine C: De fortes doses peuvent causer la diarrhée et la formation de calculs rénaux d'oxalate de calcium. Des doses de 600 mg ou plus par jour ont une action diurétique. La vitamine C doit être administrée avec précaution chez les patients présentant une hyperoxalurie. La tolérance peut être induite chez les patients prenant des doses élevées.

Zinc: L'ingestion de grandes quantités de zinc est rapidement suivie par des nausées et des vomissements. En raison de son action corrosive il provoque une sensation de brûlure dans l'œsophage et l'estomac. Des coliques et de la diarrhée, contenant du sang, peuvent suivre, accompagnées de convulsions, d'hypotension et d'un coma pouvant aller jusqu'à la mort. Le traitement consiste à vider l'estomac par aspiration et en effectuant un lavage. Ensuite, des émollients tels que le lait et le blanc d'œuf doivent être donnés librement. Du calcium édétate de sodium peut être administré. La morphine ou la péthidine peuvent être administrées pour soulager la douleur. L'équilibre hydro-électrolytique doit être corrigé.

En général
C'est un traitement symptomatique et de soutien.

Posologie: Un gélule par jour ou selon prescription médicale.

Présentation: Disponible en étui de 10 gélules.

Conserver en-dessous de 30ºC.

NE PAS LAISSER A LA PORTEE DES ENFANTS.

Date de publication/révision : Sep. 2013

Un produit de
ajanta pharma limited
Ajanta House, Charkop, Kandivli (W), Mumbai 400 067.
* Nom de Marque

150 mm

300 mm

Pharma Code : 20447 Minicode

Direction for Travel

ajanta pharma limited

Name & Signature

Checked By :

Verified By :

Approved By :

Date :

Packaging Department

For : Export Market | Co-ordinator Name : Anand | Software : Corel Draw | Date : 26/12/2019

Item Code : 3020447 | Item Type : Pack Insert | Artist Name : Kiran

Product Name : Nurifer Capsules | Revision of (Pcode) : NA

Material : 40 GSM Bible Paper | Reference Item code (P Code) : P32031

Actual Size : 300 x 150 (F/B) | Folding Size : 25 x 150 mm | Varnish : NA

Print Repeat : NA | Drawing No. : CL-673

CMYK / Pantone : Pantone 2748 C

Reason : New development as per Cartonator.

NOTE: THE CD OUTPUT MAY / MAY NOT BE MATCHING WITH THE OUTPUT. FOR THIS COLOUR MATCH AS PER ATTACHED SAMPLE WITH A/W IF IT IS NOT MATCHING WITH THE GIVEN REFERENCE SAMPLE THE PM/PROOF REJECTION WILL BE SUPPLIERS RESPONSIBILITY. FOR CARTON GRAIN DIRECTION PERPENDICULAR TO MAIN CREASE. / REMARK: BLOCK PROOF REQUIRE BEFORE PRINTING.

Front Panel:

℞ ☐ Rx

generic Name

BRAND NAME Strength

Pack Size / Volume

Pneumonic

ajanta

Back Panel / Side Panel

Composition	☐	Barcode	☐
Colour	☐	Warnings / Schedule H	☐
Dosage	☐	Caution / Schedule G	☐
Storage	☐	Statutory Contents	☐
Made in India	☐	Directions for use	☐
Company's Name	☐	Neutral code	☐
H.O.Address	☐	Factory + H.O.Address	☐
Factory Address	☐	Red line	☐
Toll Free No. / Email ID	☐	Other	☐

Side Panels

BRAND NAME ☐

PTN ☐ CKL ☐ CTGN ☐ LL ☐ TP ☐ DHJ ☐ GHT ☐

Others:

Item Code	☐	Pharma Code	☐
LIF	☐	Colour Code	☐
Printed License No.	☐	Reference Sample	☐
O.P.Zone / DGFT	☐	Back-side Printing	☐
		Change Parts	☐