IBERET FOLIC® 500
Multivitamin and Mineral

1. NAME OF THE MEDICINAL PRODUCT

Iberet Folic® 500 Filmtab (Controlled-Release Iron with Vitamin C and Vitamin B-complex including Folic Acid)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Iberet Folic® 500 Filmtab contains 329.7 mg of Dried Ferrous sulfate (Equivalent to 105 mg of elemental iron) in a unique controlled-release vehicle, the Gradumet. In addition, this product contains ascorbic acid present as sodium ascorbate and the B-complex vitamins including folic acid.

Each Filmtab tablet provides:

Ferrous Sulfate Dried in controlled-release form (Gradumet)	329.7 mg (equivalent to 105 mg of elemental iron)
Vitamin C (Sodium ascorbate)	500 mg
Niacinamide	30 mg
Calcium pantothenate	10 mg
Vitamin B1 (Thiamine mononitrate)	6 mg
Vitamin B2 (Riboflavin)	6 mg
Vitamin B6 (Pyridoxine hydrochloride)	5 mg
Vitamin B12 (Cyanocobalamin)	25 mcg
Folic Acid	800 mcg

For the full list of excipients, see section List of Excipients.

The Gradumet is an inert, porous, plastic matrix which is impregnated with ferrous sulfate. Iron is leached from the Gradumet as it passes through the gastrointestinal tract, and the expended matrix is excreted harmlessly in the stool. Controlled-release iron is particularly helpful in patients who have demonstrated intolerance to oral iron preparations.

3. PHARMACEUTICAL FORM

Iberet Folic Film Coated Tablet is a smooth, film seal coating, raspberry rose in color, and has characteristic odor.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Iberet Folic® 500 Filmtab is indicated for anemia due to iron deficiency, megaloblastic anemia where there is an associated deficiency of Vitamin C and Vitamin B-complex particularly in pregnancy.

4.2 Posology and Method of Administration

Iberet Folic® 500 Filmtab is administered orally and may be taken on an empty stomach.
Adults and Pregnant adults: For treatment of iron deficiency and prevention of folic acid deficiency the recommended dose is one tablet daily or according to the doctor's directions.

4.3 Contraindications

Iberet Folic® 500 Filmtab is contraindicated in individuals known to be hypersensitive to any of its components. Iberet Folic® 500 Filmtab is contraindicated in patients with thalassemia, sideroblastic anemia, hemochromatosis and hemosiderosis.
This product should not be used in pediatric patients.
Iberet Folic® 500 Filmtab is also contraindicated in the rare instance of hypersensitivity to folic acid.

4.4 Special Warnings and Precautions for Use

General

Patients should be advised to keep these products out of the reach of children.

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under six years of age. Keep this product out of the reach of children. In cases of accidental overdose, call a doctor or seek medical advice immediately.

Iron therapy could induce relapse of erythropoietic, protoporphyria. Iron overloads has been suggested as being involved in pathogenesis of porphyria cutanea tarda.

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B12 is deficient.

Where anemia exists, its nature should be established and underlying cause determined.

Iberet Folic® 500 Filmtab contains increased amounts (see above) of folic acid per tablet. Folic acid especially in dose above 0.1 mg daily may obscure pernicious anemia, in that hematologic remission may occur while neurological manifestation remains progressive. Concomitant parenteral therapy with vitamin B12 may be necessary in patients with deficiency of vitamin B12. Pernicious anemia is rare in women of childbearing age, and the likelihood of its occurrence along with pregnancy is reduced by the impairment of fertility associated with vitamin B12 deficiency.

Caution should be exercised when dosing ascorbic acid in patients with chronic renal failure and in patients receiving acetylsalicylic acid.
Like other oral iron preparations, Iberet Folic® 500 Filmtab should be stored out of the reach of children to guard against accidental poisoning (see OVERDOSE).

Laboratory Tests
In older patients and those with conditions tending to lead to vitamin B12 depletion, serum B12 levels should be regularly assessed during treatment with Iberet Folic® 500 Filmtab.
False occult blood tests are possible.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction
Absorption of iron is inhibited by magnesium trisilicate, antacids or cholestyramine.

With concomitant use of alcohol, toxic delirium and lactic acidosis have been noted.

Ferrous sulfate may interfere with the absoption of tetracyclines. Therefore, these drugs should be given two to three hours apart.

Concomitant use of niacin and nicotine has been reported to cause increased flushing and dizziness.

Since pyridoxine is noted to have effects on dopamine, drug interactions are possible. A drug interaction with levodopa is noted but can be avoided if levodopa is given in combination with decarboxylase inhibitor.

Prothrombin times are decreased when ascorbic acid is used concomitantly with anticoagulants.

Concurrent administration of oral iron preparations may interfere with the oral absorption of some quinolone anti-infective agents (e.g. ciprofloxacin, norfloxacin, ofloxacin) resulting in decreased serum and urine concentration of the quinolones. Therefore, oral iron preparations should not be ingested with or within two hours of a dose of an oral quinolone.

Drug Food Interactions
Eggs inhibit iron for absorption. Coffee and tea consumed with a meal or one hour after a meal may significantly inhibit the absorption of dietary iron. Its clinical significance has not been determined. Oral iron preparations should not be taken within one hour or two hours after ingestion of the above-mentioned food products.

4.6 Fertility, Pregnancy and Lactation

Pregnancy Category A

Studies in pregnant women have not shown that Iberet Folic® 500 Filmtab increases the risk of fetal abnormalities if administered during pregnancy. If this drug is used during pregnancy, the possibility of fetal harm appears remote. Because studies cannot rule out the possibility of harm, however, Iberet Folic® 500 Filmtab should be used during pregnancy only if clearly needed.

Nursing Women

Folic acid, ascorbic acid, and B-complex vitamins are excreted in breast milk.

4.7 Effects on Ability to Drive and Use Machines

No effects on ability to drive and use machines have been observed.

4.8 Undesirable Effects

The likelihood of gastric intolerance to iron in the controlled-release Gradumet vehicle is remote. If such should occur, the tablet may be taken after a meal. Allergic sensitizations has been reported following both or oral and parenteral administration of folic acid.

Allergic reactions, including rash, pruritus, and anaphylaxis have been reported with vitamin use.

Components of products have been associated with gastrointestinal effects such as heartburn, eructation, abdominal pain and cramps, diarrhea, vomiting, nausea, and anorexia.

Hepatic dysfunction with abnormal liver function tests, including hyperbilirubinemia has been noted.

Deterioration of acneiform vulgaris, or eruption of acneiform exanthema, has been noted with several components.

Bright yellow urine discoloration has been reported with riboflavin usage.

Niacinamide has strong vasodilator effects, most often characterized by flushing, dizziness and faintness.

Peripheral sensory neuropathies have been noted with usage of pyridoxin.

Stone formation, crystalluria, and oxalosis, with ascorbic acid usage, have been reported in the literature.

Black discoloration of the stool has been reported with iron usage.

Isolated cases of injury to mouth and pharynx, oesophageal ulcer, haemataemesis, and ileus have been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:
Pusat Farmakovigilans/MESO Nasional Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif
Badan Pengawas Obat dan Makanan
Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560
Email: pv-center@pom.go.id
Website: https://e-meso.pom.go.id/ADR
or via pv.indonesia@abbott.com

4.9 Overdose

Acute overdosage of iron may cause nausea and vomiting and, in severe cases, hepatic necrosis, cardiovascular collapse and death. The lethal dose of orally ingested elemental iron is estimated to be 180 to 300 mg/kg of body weight. However, a dose of elemental iron as low as 30 mg/kg may be toxic in some individuals and ingestion of doses as low as 60 mg/kg have resulted in death.

Toxicity that occurs with an acute iron overdosage results from a combination of the corrosive effects on the gastrointestinal mucosa and the metabolic and hemodynamic effects caused by the presence of excessive elemental iron.

The signs and symptoms of acute iron poisoning may occur within 10 to 60 minutes or be delayed for several hours, Initial clinical manifestations may encompass acute gastrointestinal irritation, including epigastric pain, nausea, vomiting, diarrhea of green and subsequently tarry stools, melena and hematemesis which may be associated with drowsiness, pallor, cyanosis, lassitude, seizures, shock and coma. Hepatic necrosis and hepatic failure may develop. Because of potential toxic effects of overdosage, immediate medical attention is warranted.

Iron poisoning should be treated by emptying the stomach via ipecac-induced vomiting or preferably, by gastric lavage with a large bore tube. If the patient has experienced multiple episodes of vomiting, especially if the vomitus contains blood, ipecac syrup should not be administered.

Vomitus should be examined for returned Gradumet tablets. If sufficient tablets are not returned, the possibility of whole gut lavage with 0.9% sodium chloride solution plus a saline cathartic should be considered. Surgical removal of iron tablets which are visible in abdominal radiographs may be required if other means of removing the drug are unsuccessful.

The best method for assessing the severity of an iron ingestion is to measure the serum iron and the total iron binding capacity (TIBC). If the serum iron level is greater than TIBC, the potential for systemic toxicity exists. Serum iron and total iron-binding capacity levels may be used as guidelines for use of deferoxamine, an agent used to chelate elemental iron.

Chelation therapy with deferoxamine should be considered when the following conditions exist:
1. a potential lethal dose (180 to 300 mg/kg or more) of elemental iron has been ingested;
2. serum iron concentration are greater than 400 to 500 µg/dL.
3. serum iron concentration exceed total iron binding capacity, and/or;
4. patients have severe symptoms of iron intoxication such as coma, shock, or seizure.

Hemodialysis is of little value in the treatment of iron intoxication.

Supportive treatment, including suction and maintenance of airway; correction of acidosis and control of shock and dehydration with intravenous fluids or blood, oxygen and vasopressors, should be administered as required.

High doses of individual components of the product have been associated with eczematous and exanthematous skin lesions, fatigue, and insomnia.

In higher niacinamide doses, liver damage, gout and ulcer formation have been noted.

Vasodilatory effects such as giddiness, faintness, vasovagal attacks, and anaphylactic shock have also been reported.

In high doses of pyridoxine, peripheral sensory neuropathy and vesicular skin lesions have been reported.

Hemolysis has been reported at high doses of ascorbic acid, especially in patients with glucose 6 phosphate dehydrogenase deficiency.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Iron, as an essential mineral, is a component of hemoglobin, myoglobin and a number of enzymes. The total body content of iron is approximately 50 mg/kg in man and 35 mg/kg in women.

Iron is primarily stored in the body as hemosiderin or ferritin, found in the reticuloendothelial cells of the liver, spleen, and bone marrow. Approximately two-thirds of total body iron is in the circulatory red blood cell mass in hemoglobin, the major factor in oxygen transport. Concentration

of plasma iron and the total iron-binding capacity of plasma vary greatly in different physiological conditions and disease states.

Approximately two-thirds of folic acid is bound to plasma proteins. Half of the folic acid stored in the body is found in the liver. Folic acid also concentrated in spinal fluid.

5.2 Pharmacokinetic Properties

Absorption

The absorption is increased when iron stores are depleted or red blood cell production is increased. Conversely, high iron blood concentrations decrease absorption. The average dietary intake of iron of iron is 18 to 20 mg/day. Approximately 10% of this iron is absorbed in healthy individuals and about 20% to 30% in iron-deficient individuals.

Folic acid and iron are absorbed in the proximal small intestine, particularly the duodenum. Folic acid is absorbed maximally and rapidly at this site, and iron is absorbed in a descending gradient from the duodenum distally. After absorption, folic acid is rapidly converted into its metabolically active forms. Except for the folates ingested in liver, yeast, and egg yolk, the precentage of absorption of food folates averages about 10%.

The ferrous salt form is absorbed three times more readily than the ferric form. The common ferrous salts (sulfate, gluconate, fumarate) are absorbed almost on a milligram-for-milligram basis, but differ in the content of elemental iron. Ferrous sulfate comprises 20% of elemental iron content.

Oral iron is absorbed most efficiently when it is administered between meals. However, conventional iron preparations frequently cause gastric irritation when taken on an empty stomach. Although food can decrease the absorption of iron by 40% to 66%; gastric intolerance may necessitate administering the drug with food.

Studies with iron in the Gradumet have indicated that relatively little iron is released in the stomach, gastric intolerance is seldom encountered and hematologic response ranks with that obtained from plain ferrous sulfate. Therefore, potential gastric irritation is minimized when iron is administered in the Gradumet form in comparison with conventional oral iron preparations.

Large amounts of ascorbic acid administered orally with ferrous sulfate have been shown to enhance iron absorption. This is apparently due to the ability of ascorbic acid to prevent the oxidation of ferrous iron to the less effectively absorbed ferric form.

The B-complex vitamins are absorbed by an active transport process; they are rapidly eliminated and therefore are not stored in the body.

Calcium pantothenate is absorbed readily from the gastrointestinal tract and distributed to all body tissues.

Distribution

Ferrous iron passes through gastrointestinal mucosal cells directly into the blood and is immediately bound to transferrin. Transferrin, a glycoprotein B I-globulin, transports iron to the bone marrow where it is incorporated into the hemoglobin.

Small excesses of iron within the villous epithelial cells are oxidized to the ferric state. Ferric iron combines with the protein apoferritin to yield ferritin and is stored in mucosal cells which are exfoliated at the end of their life span and excreted in the feces.

Elimination

Iron metabolism occurs in a virtually closed system. The majority of iron liberated by destruction of hemoglobin is conversed and reused by the body. The daily excretion of iron from urine, sweat and sloughing of intestinal mucosal cells amount to approximately 0.5 to 1 mg in healthy men and 1 to 2 mg in menstruating women. The half-life of ferrous sulfate is approximately six hours.

PRE-CLINICAL SAFETY DATA

Carcinogenesis, Mutagenesis, and Impairment of Fertility

Adequate data are not available on long-term potential for carcinogenesis in animals or humans.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Methacrylic Acid and Methyl Methacrylate Copolymer, magnesium stearate, povidone, polyethylene glycol 8000, magnesium oxide, FD&C Blue No. 1, talc, stearic acid, talc, ethanol, acetone, Coating Solution Aqueous Maroon (Opadry 80W56400), Coating Solution Aqueous Clear (Opadry OY-S-29019)

Incompatibilities

Not applicable

Shelf life

Expiry date is indicated on the packaging

Special Precautions for Storage

Store at below 30ºC

Nature and Contents of Container

IBERET FOLIC® 500 Filmtab. List No. 7125

Box, 10 strips @10 film-coated tablets
Reg. No.: DBL9600202317A1

Manufactured by:
PT. Abbott Indonesia
Jl. Raya Jakarta Bogor km. 37
Depok, Indonesia

Under Controlled by:
Abbott Laboratories, ILL, USA

Date of Revision: 21 January 2026
L003/01/26

INFORMASI UNTUK PASIEN
IBERET FOLIC® 500
(Multivitamin dan Mineral)

Baca seluruh isi brosur ini secara seksama sebelum Anda mulai minum obat ini karena brosur ini berisi informasi penting bagi Anda.
- Simpan brosur ini. Anda mungkin perlu membacanya lagi.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter atau apoteker Anda.
- Obat ini hanya diresepkan untuk Anda. Jangan memberikannya kepada orang lain. Hal ini dapat membahayakan mereka, bahkan jika gejalanya sama dengan Anda.
- Jika Anda mengalami efek samping, sampaikan kepada dokter atau apoteker Anda. Termasuk kemungkinan efek samping yang tidak tercantum di dalam brosur ini. Lihat bagian 4.

Apa yang ada di dalam brosur ini:

1. Apa itu Iberet Folic® 500 dan apa kegunaannya?

Iberet Folic® 500 adalah tablet salut selaput yang mengandung zat besi dengan pelepasan terkendali melalui teknologi Gradumet (*Gradual-metered release*), vitamin C, dan vitamin B kompleks, dan Asam Folat.

Obat ini digunakan untuk:
- Mengatasi anemia akibat kekurangan zat besi.
- Mengatasi anemia megaloblastik yang disertai kekurangan vitamin C dan vitamin B-kompleks, terutama pada masa kehamilan.

Tablet ini bekerja melepaskan zat besi secara perlahan di saluran cerna sehingga lebih mudah ditoleransi oleh pasien yang biasanya sensitif terhadap suplemen zat besi biasa.

2. Hal yang perlu Anda ketahui sebelum mengonsumsi Iberet Folic® 500

Jangan mengonsumsi obat ini bila Anda:
- Alergi terhadap salah satu kandungan produk.
- Memiliki thalassemia, sideroblastic anemia, hemochromatosis, atau hemosiderosis.
- Memiliki riwayat alergi terhadap asam folat.
- Anak-anak (produk ini tidak untuk penggunaan pada anak).

Peringatan dan tindakan keselamatan
- Jauhkan dari jangkauan anak-anak. Suplemen zat besi dapat menyebabkan keracunan serius bila tertelan anak-anak secara tidak sengaja.
- Jika terjadi overdosis, segera cari pertolongan medis.
- Asam folat dosis tinggi dapat menutupi gejala kurang vitamin B12, sehingga penyebab anemia perlu dipastikan oleh dokter.
- Berhati-hati bila Anda memiliki gangguan ginjal atau menggunakan obat lain yang mengandung aspirin.
- Pada orang yang mudah kekurangan vitamin B12 (misalnya usia lanjut), dokter mungkin memeriksa kadar B12 secara berkala.

Interaksi obat dan makanan

Beritahu dokter bila Anda sedang mengonsumsi obat lain. Beberapa hal yang perlu diperhatikan:

- Penyerapannya berkurang bila diminum bersamaan dengan antasida, magnesium trisilicate, atau cholestyramine.
- Jarakkan 2–3 jam jika sedang mengonsumsi tetrasiklin atau antibiotik golongan kuinolon.
- Alkohol dapat meningkatkan risiko efek samping tertentu.
- Obat ini dapat mengurangi efek levodopa. Beri tahu dokter jika Anda sedang menggunakannya.
- Penggunaan bersama niasin atau nikotin dapat menyebabkan wajah memerah atau rasa panas, dan pusing.
- Antikoagulan (pengencer darah) dapat memengaruhi kerja obat pengencer darah dan meningkatkan risiko perdarahan.
- Kopi, teh, dan telur menghambat penyerapan zat besi bila diminum dekat waktu konsumsi suplemen.

Kehamilan dan menyusui

- Aman dikonsumsi sesuai anjuran dokter selama kehamilan (Kategori A).
- Vitamin C, asam folat, dan vitamin B-kompleks dapat keluar melalui ASI dan umumnya aman bila digunakan sesuai kebutuhan medis.

Mengemudi dan Mengoperasikan Mesin:

Tidak ada efek terhadap kemampuan mengemudi atau menjalankan mesin.

3. Bagaimana cara mengonsumsi Iberet Folic® 500?

- Telan 1 tablet per hari, atau sesuai anjuran dokter.
- Dapat diminum saat perut kosong, namun bila terasa mual dapat diminum sesudah makan.
- Untuk ibu hamil, penggunaan berdasarkan anjuran dokter untuk mencegah kekurangan zat besi dan asam folat.

Jika Anda lupa minum obat

Minumlah segera saat ingat. Jangan menggandakan dosis untuk mengganti dosis yang terlewat.

Jika mengonsumsi terlalu banyak (overdosis)

Tanda overdosis zat besi dapat muncul dalam 10–60 menit berupa: mual, muntah, nyeri perut, diare berwarna gelap, pucat, mengantuk, kejang, hingga syok. Pada kasus berat dapat terjadi kerusakan hati dan kegagalan jantung. Segera cari pertolongan medis bila ini terjadi.

4. Kemungkinan efek samping

Seperti obat lainnya, Iberet Folic® 500 dapat menimbulkan efek samping pada beberapa orang.

Efek yang dapat muncul antara lain:

- Reaksi alergi: Ruam, gatal, kemerahan, atau reaksi anafilaksis (sangat jarang).
- Gangguan pencernaan: Mual, muntah, diare, sembelit, nyeri perut, kembung, *heartburn*. Feses dapat menjadi hitam akibat kandungan zat besi (hal ini tidak berbahaya).
- Gangguan fungsi hati (sangat jarang). Pada beberapa orang, obat ini dapat menyebabkan perubahan pada hasil pemeriksaan fungsi hati. Biasanya tidak menimbulkan gejala, tetapi pada kasus tertentu dapat disertai rasa lelah, mual, atau tidak enak badan. Jika Anda memiliki riwayat masalah hati atau merasakan keluhan yang tidak biasa, segera hubungi dokter.
- Lain-lain:
  - Urine berwarna kuning terang (akibat vitamin B2).
  - Wajah memerah, pusing, atau sensasi panas (akibat niacinamide).

- Pembentukan batu ginjal/urin keruh akibat vitamin C dosis tinggi.
- Kesemutan bila mengonsumsi vitamin B6 dosis besar.
- Perburukan jerawat

Jika Anda mengalami keluhan yang berat atau tidak biasa, segera hentikan obat dan hubungi tenaga medis.

Pelaporan efek samping
Jika Anda mengalami efek samping apapun, bicarakan dengan dokter atau apoteker Anda. Ini mencakup kemungkinan efek samping yang tidak tercantum dalam brosur ini. Anda juga dapat melaporkan efek samping secara langsung ke: pv.indonesia@abbott.com
Dengan melaporkan efek samping Anda dapat membantu memberikan informasi lebih lanjut tentang keamanan obat ini.

5. Bagaimana cara menyimpan Iberet Folic® 500?

Simpan pada suhu di bawah 30°C. Simpan tablet ini di tempat yang aman, kering, yang terlindung dari cahaya.
Jauhkan obat ini dari penglihatan dan jangkauan anak-anak.
Jangan menggunakan tablet ini setelah tanggal kedaluwarsanya (exp.) yang tercetak di dusnya dan yang tercantum di strip blister.
Jangan membuang obat melalui air limbah atau limbah rumah tangga. Tanyakan kepada apoteker Anda bagaimana cara membuang obat yang tidak Anda gunakan lagi. Langkah-langkah ini akan membantu melindungi lingkungan.

6. Isi kemasan dan informasi lainnya

Komposisi per tablet:
- Ferrous sulfate kering (Gradumet) 329,7 mg (setara 105 mg zat besi elemental)
- Vitamin C 500 mg
- Niacinamide 30 mg
- Calcium pantothenate 10 mg
- Vitamin B1 6 mg
- Vitamin B2 6 mg
- Vitamin B6 5 mg
- Vitamin B12 25 mcg
- Asam folat 800 mcg

Zat tambahan (eksipien):
Termasuk methacrylic acid & methyl methacrylate copolymer, magnesium stearate, povidone, PEG 8000, magnesium oksida, pewarna, talc, ethanol, aseton, dan bahan pelapis tablet.

Seperti apa penampakan tablet Iberet Folic® 500 dan isi kemasan
Tablet salut selaput warna merah raspberry dengan aroma khas.
Dus, 10 strip @ 10 tablet salut selaput

Reg. No.: DBL9600202317A1

Diproduksi oleh:
PT Abbott Indonesia
Jl. Raya Jakarta Bogor Km. 37
Depok, Indonesia
Atas lisensi dari:
Abbott Laboratories, ILL, USA