ROUGE®

(Iron (III) Hydroxide Polymaltose Complex)
Chewable Tablets 100mg

روج ۱۰۰ ملی گرام
چبانے والی گولیاں
(آئرن (III) ہائیڈروآکسائیڈ پولی مالٹوز کمپلیکس)

QUALITATIVE AND QUANTITATIVE COMPOSITION
Rouge Chewable Tablets:
Each Chewable tablet contains:
Iron (III) Hydroxide Polymaltose Complex
eq. to Elemental Iron 100mg
(Product Specs.: Bosch)

PHARMACEUTICAL FORM
Chewable Tablets

CLINICAL PARTICULARS
THERAPEUTIC INDICATIONS
Rouge Chewable Tablets are indicated for:
- Treatment of iron deficiency in adults and adolescents where the use of ferrous iron supplements is not tolerated, or otherwise inappropriate.
- Prevention of iron deficiency in adults and adolescents at high risk where the use of ferrous iron supplements is not tolerated, or otherwise inappropriate.

POSOLOGY AND METHOD OF ADMINISTRATION
Posology
The dosage and duration of treatment depend upon the extent of iron deficiency. The daily dose can be divided into separate doses or can be taken at once. Doses below 100 mg iron cannot be achieved with Rouge Chewable Tablets.
Rouge chewable tablets can be chewed or swallowed whole and should be taken during or immediately after a meal.

Treatment of iron deficiency in adults and adolescents (children ≥ 12 years):
100 mg to 200 mg iron (1 to 2 tablets) daily preferably with food, or higher doses as directed by a medical practitioner.

Prevention of iron deficiency in adults and adolescents (children ≥ 12 years) at high risk:
100 mg iron (1 tablet) daily preferably with food, or higher doses as directed by a medical practitioner.
Regular monitoring of hematological parameters and iron store levels are recommended to assess the patient's response to treatment.

Contraindications
It is contraindicated in the following cases:
- Known hypersensitivity to iron polymaltose
- Iron overload (e.g. hemochromatosis, hemosiderosis)
- Disturbances in iron utilization (e.g. lead anemia, sidero-achrestic anemia, thalassemia)
- Anemia not caused by iron deficiency (e.g. hemolytic anemia or megaloblastic anemia due to vitamin B12 deficiency)

Special warnings and precautions for use
Iron deficiency anemia
All other causes of anemia should be considered and treated prior to initiating therapy with Iron (III) Hydroxide Polymaltose Complex.

Regular monitoring of the hematologic response is required during therapy as a risk of iron overload and liver damage exists if is too much ingested by hemochromatosis patients over a long period of time.
Do not administer to patients with iron overload or hemochromatosis.

The following medicines can affect the absorption of Iron Polymaltose,
- Injectable iron medicines. If the patient is treated with injectable iron medicines, Iron Polymaltose should not be taken in addition to that therapy.

- Infections or tumor may cause anemia. Since iron can be utilized only after correcting the primary disease, a benefit/ risk evaluation is advisable.

- During the treatment there may be dark discoloration of the feces (stool), however this is of no clinical relevance.

Laboratory tests:
Regular monitoring of Hb levels and serum ferritin levels should be performed to assess the response to supplementation as deemed appropriate by the medical practitioner.

Use in hepatic impairment: No data available.

Use in renal impairment: Very limited data available.

Use in the elderly:
Limited data available in the elderly. For use in elderly patients consult a medical practitioner.

Effects on laboratory tests:
It can cause discolored (black) stool. Discolored (black) stool may visually mask gastrointestinal bleeding. However, the hemoccult test (selective for Hb) for the detection of occult blood is not impaired, and therefore there is no need to interrupt the therapy.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
Concomitant administration of parenteral iron and Iron (III) Hydroxide Polymaltose Complex is not recommended since the absorption of oral iron would be reduced.

Interactions of iron polymaltose with tetracycline or aluminum hydroxide:
No significant reduction in the absorption of tetracycline was observed. Iron absorption from iron polymaltose was not reduced by aluminum hydroxide or tetracycline. It can be administered at the same time as tetracycline or other phenolic compounds, as well as aluminum hydroxide.

Similarly, no interactions with food constituents such as phytic acid, oxalic acid, tannin, sodium alginate, choline and choline salts, vitamin A, vitamin D3 and vitamin E, soya oil and soya flour were observed with iron polymaltose.

The hemoccult test (selective for Hb) for the detection of occult blood is not impaired, and therefore there is no need to interrupt the therapy with iron polymaltose.

Fertility, Pregnancy and Lactation
Pregnancy: Women of childbearing age, and women during pregnancy should only use after consulting a healthcare professional. A benefit/risk evaluation is advisable.

Lactation: It should only be used after consulting a medical practitioner. A benefit/risk evaluation is advisable
Fertility: The relevance of its finding is unknown.

Effects on ability to drive and use machines
No effects of this medicine on a person's ability to drive and use machines is observed.

Undesirable effects
Adverse reactions listed below are classified according to frequency and System Organ Class (SOC). Frequency categories are defined according to the following convention: Very common (≥ 1/10), Common (≥ 1/100 to < 1/10), Uncommon (≥ 1/1,000 to < 1/100), Rare (≥ 1/10,000 to < 1/1,000), Very rare (< 1/10,000), Not known (cannot be estimated from the available data)

System Organ Class	Very Common (≥1/10)	Common (≥1/100,<1/10)	Uncommon (≥1/1,000,<1/100)	Rare (≥1/10,000, <1/1,000)
Gastrointestinal Disorders	Feces discolored	Diarrhea, nausea, abdominal pain, constipation	Vomiting, Tooth discoloration, gastritis	
Skin and Subcutaneous Tissue Disorders			Pruritus, Rash, urticarial, erythema	
Nervous System Disorders			Headache	
Musculoskeletal and connective tissue disorders				Muscle spasms, myalgia

Overdose
Periodic monitoring of serum ferritin may be useful in recognizing a deleterious, progressive accumulation of iron. Over dosage should be treated with supportive measures and, if required, an iron chelating agent.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic Properties

Mechanism of action
Iron from iron polymaltose is taken up in the gut via an active mechanism. The intended pharmacological action of iron polymaltose is to provide utilizable iron to target tissues.

Iron polymaltose is effective in delivering iron across enterocytes to the iron transport protein transferrin and the iron storage protein ferritin. This iron is subsequently incorporated into hemoglobin during synthesis of red blood cells and thus facilitates correction of iron deficiency and anemia.

Pharmacokinetic Properties
Absorption
The iron of iron polymaltose is absorbed by a controlled mechanism in the small intestine. The iron from erythrocytes is recycled at the end of their life span. The relative absorption of iron decreases with increasing doses. No negative impact of food on the bioavailability of iron from iron polymaltose was found.

Distribution:
After absorption, iron is transferred to the blood, where it is bound to transferrin and distributed to the sites of demand, or stored as ferritin in liver and spleen. Most iron is incorporated into the oxygen-transport protein hemoglobin (Hb) during erythropoiesis in the bone marrow.

Metabolism:
The breakdown products of polymaltose (maltose and gluconate) are converted into glucose which is metabolized.

Excretion:
Unabsorbed iron is excreted via feces.

PHARMACEUTICAL PARTICULARS
Incompatibilities
Not known.

Shelf life
2 years

Special precautions for storage
Protect from heat, sunlight & moisture, store below 25°C.
Keep out of the reach of children.
The expiration date refers to the product correctly stored at the required condition.
Patients and healthcare professionals can also report suspected adverse drug reaction at ade@bosch-pharma.com
To be sold on the prescription of a registered medical practitioner only.

Presentation:
Rouge chewable tablets 100mg: Cold form and cold seal Alu Alu Pack of 10 tablets.

MARKETING AUTHORISATION HOLDER
Head Office:
Bosch Pharmaceuticals (Pvt.) Ltd.,
8, Modern Society, Tipu Sultan Road, Karachi-75350 (Pakistan)

Manufacturing Site:
Bosch Pharmaceuticals (Pvt.) Ltd.,
Plot No. 221-223, Sector 23, Korangi Industrial area Karachi Pakistan.

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050510

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20-11-2023

ہدایات:- دھوپ، گرمی اور نمی سے محفوظ ۲۵ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
بچوں کی پہنچ سے دُور رکھیں۔
صرف مستند ڈاکٹر کے نسخے پر فروخت کے لئے۔

Manufactured by:
Bosch Pharmaceuticals (Pvt.) Ltd.
221-223, Sector 23, Korangi Industrial Area,
Karachi - Pakistan

Bosch

For Healthcare Professionals only

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FIRST & ONLY CERTIFIED HALAAL

PHARMACEUTICAL COMPANY