

Anschlarin

syrup

Active ingredient : ferrous fumarate 140 mg / 5 ml equivalent to 45 mg elemental iron / 5 ml

In-active ingredients :

Glycerin , sorbitol solution 70 % , sodium benzoate , tutti frutti flavor liquid , sucrose , citric acid anhydrous , xanthan gum , purified water .

CLINICAL PARTICULARS

Therapeutic indications

Prophylaxis and treatment of iron deficiency states.

For prophylaxis during pregnancy, a combination of iron and folic acid is usually recommended.

Posology and method of administration

Each 5 ml of Anschlarin syrup contains 140 mg Ferrous Fumarate which approximates to 45 mg of elemental iron .

Shake the bottle well before use

For oral administration

Prevention of iron deficiency:

Adults and elderly:

Anschlarin syrup one 5 ml spoonful twice a day.

Children:

6-24 months of age: 12.5mg/day

2-5 years of age: 20-30mg/day

6-11 years of age: 30-60mg/day

Older children: 60mg/day

Premature infants: 5mg elemental iron per day. Iron supplementation in premature infants is only recommended in those of low birth weight who are solely breast fed. Higher doses up to 2mg/kg of elemental iron per day might be needed to cover the needs of growing exclusively breastfed infants. Supplementation should be commenced 4-6 weeks after birth and continued until mixed feeding is established.

Treatment of iron deficiency:

Adults and elderly:

Anschlarin syrup two 5 ml spoonfuls twice a day

Children:

Full term infants and children: 3 to 6 mg elemental iron/Kg/day given in 2 to 3 divided doses. Total daily dose should not exceed 180 mg elemental iron.

Administration to infants and children should take place under medical advice.

Medical advice should be sought if symptoms do not improve after four weeks of use of this product as these symptoms may reflect an underlying disease process.

Contraindications

Known hypersensitivity to any of the ingredients of the product. Paroxysmal nocturnal haemoglobinuria. Haemosiderosis, haemochromatosis. Active peptic ulcer. Repeated blood transfusions. Regional enteritis and ulcerative colitis. Must not be used in anaemias other than those due to iron deficiency.

Special warnings and precautions for use

Some post-gastrectomy patients show poor absorption of iron. Care is required when treating patients with iron deficiency anaemia who have treated or controlled peptic ulceration.

Duration of treatment of uncomplicated iron deficiency anaemia should not usually exceed 6 months (3 months after reversal of the anaemia has been achieved).

Because anaemia due to combined iron and Vitamin B12 or folate deficiencies may be microcytic in type, patients with microcytic anaemia resistant to treatment with iron alone should be screened for Vitamin B12 or folate deficiency.

Anschlarin syrup should be kept out of the reach of children.

Long-term treatment with Anschlarin syrup may increase the risk of dental caries. Adequate dental hygiene must be maintained. Since Anschlarin syrup contains sugar, care must be exercised when using in patients with diabetes mellitus.

This product contains 1.5 gm sucrose per 5 ml, this should be taken into account in patients with diabetes mellitus.

This may be harmful to the teeth when the product may be intended for chronic use e.g. for 2 weeks or more.

Interaction with other medicinal products and other forms of interaction

Iron reduces the absorption of penicillamine, bisphosphonates, ciprofloxacin, entacapone, levodopa, levofloxacin, levothyroxine (thyroxine) (give at least 2 hours apart), moxifloxacin, mycophenolate, norfloxacin, ofloxacin, zinc. Absorption of both iron and antibiotic may be reduced if Anschlarin 140mg/5ml is given with tetracycline. Absorption of oral iron is reduced by calcium salts, Magnesium salts (as magnesium trisilicate), Trientine.

Chloramphenicol delays plasma iron clearance, incorporation of iron into red blood cells and interferes with erythropoiesis. Some inhibition of iron absorption may occur if it is taken with cholestyramine, tea, eggs or milk.

Avoid concomitant use of iron with dimercaprol.

Oral iron antagonises hypotensive effect of methyldopa.

Pregnancy and lactation

Pregnancy

Ferrous fumarate can be used during pregnancy if clinically indicated.

Lactation

No adverse effects of ferrous fumarate have been shown in breastfed infants of treated mothers. Ferrous fumarate can be used during breast-feeding if clinically indicated.

Effects on ability to drive and use machines

None known.

Undesirable effects

The commonest side effects relate to gastrointestinal irritation (nausea, epigastric pain, constipation or diarrhoea). In the event of these ADRs, it may be helpful to reduce the dose or switch to an alternative iron salt.

Overdose

Symptoms:

Ingestion of 20 mg/kg elemental iron is potentially toxic and 200-250 mg/kg is potentially fatal. No single method of assessment is entirely satisfactory - clinical features as well as laboratory analysis must be taken into account. The serum iron taken at about 4 hours after ingestion is the best laboratory measure of severity.

Serum Iron	Severity
< 3 mg/L (55 micromol/L)	Mild toxicity
3-5 mg/L (55-90 micromol/L)	Moderate toxicity
> 5 mg/L (90 micromol/L)	Severe toxicity

Early signs and symptoms include nausea, vomiting, abdominal pain and diarrhoea. The vomit and stools may be grey or black. In mild cases early features improve but in more serious cases there may be evidence of hypoperfusion (cool peripheries and hypotension), metabolic acidosis and systemic toxicity. In serious cases there can be recurrence of vomiting and gastrointestinal bleeding, 12 hours after ingestion. Shock can result from hypovolaemia or direct cardiotoxicity. Evidence of hepatocellular necrosis appears at this stage with jaundice, bleeding, hypoglycaemia, encephalopathy and positive anion gap metabolic acidosis. Poor tissue perfusion may lead to renal failure. Rarely, gastric scarring causing stricture or pyloric stenosis (alone or in combination) may lead to partial or complete bowel obstruction 2-5 weeks after ingestion.

Management:

Supportive and symptomatic measures include ensuring a clear airway, monitor cardiac rhythm, BP and urine output, establishing IV access and administering sufficient fluids to ensure adequate hydration. Consider whole bowel irrigation. If metabolic acidosis persists despite correction of hypoxia and adequate fluid resuscitation, an initial dose of 50 mmol sodium bicarbonate may be given and repeated as necessary, for adults guided by arterial blood gas monitoring (aim for a pH of 7.4). Consider the use of desferrioxamine, if /the patient is symptomatic (other than nausea), serum iron concentration is between 3-5 mg/L (55-90 micromol/L) and still rising. Haemodialysis does not remove iron effectively but should be considered on a supportive basis for acute renal failure as this will facilitate removal of the iron-desferrioxamine complex.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Iron is an essential constituent of the body, and is necessary for haemoglobin formation and for the oxidative processes of living tissues. Iron and iron salts should be given for the treatment or prophylaxis of iron deficiency anaemias. Preparations of iron are administered by mouth, by intramuscular or intravenous injection.

Soluble ferrous salts are most effective by mouth. Ferrous fumarate is an easily absorbed source of iron for replacement therapy. It is a salt of ferrous iron with an organic acid and is less irritant to the gastrointestinal tract than salts with inorganic acids.

Pharmacokinetic properties

In the acid conditions of the gastric contents, ferrous fumarate is dissociated and ferrous ions are liberated. These ions are absorbed in the proximal portion of the duodenum.

The ferrous iron absorbed by the mucosal cells of the duodenum is oxidised to the ferric form, and this is bound to protein to form Ferritin.

Ferritin in the mucosal cells releases iron into the blood, where it is bound to transferrin and passed into the iron stores - liver, spleen, and bone marrow.

These stores are a reserve of iron for synthesis of haemoglobin, myoglobin, and iron containing enzymes. Iron is lost from the body through loss of cells in urine, faeces, hair, skin, sputum, nails, and mucosal cells, and through blood loss.

Ferrous fumarate has the same pattern of absorption and excretion as dietary iron.

Storage conditions :

Store at temperature not exceeding 30 ° C , in dry place .

Shake the bottle well before use .

Package :

Carton box contains amber glass bottle 120 ml covered with plastic cap. + inner leaflet .

*Produced by Averroes pharma for pharmaceutical industries
Block NO.6048,6th industrial zone , sadat city , Egypt .*

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