

ferro sanol® duodenal

FERROUS-(II)-GLYCINE-SULPHATE

COMPLEX

Patient information leaflet

Please read the entire package insert carefully, because it contains important information for you.

This drug is also available without prescription. However, to achieve the best possible result, you must use ferro sanol® duodenal according to the instructions.

- Keep the package insert. You may want to read it again later.
- If you need further information or advice, please ask your doctor or your pharmacist.
- If your symptoms worsen or do not improve, the consultation of a doctor is imperative.

This package insert contains information on:

1. What ferro sanol® duodenal is, and what it is used for?
2. What precautions must you observe, before taking ferro sanol® duodenal?
3. How to use ferro sanol® duodenal?
4. What side-effects are possible?
5. What storage conditions are needed for ferro sanol® duodenal?

ferro sanol® duodenal

Active substance: ferrous-(II)-glycine-sulphate complex

The pharmacologically active ingredient is: ferrous-(II)-glycine-sulphate complex
One capsule contains 567.7 mg of ferrous-(II)-glycine-sulphate complex (equivalent to 100 mg of Fe²⁺).

The excipients are:

Methacrylic acid-ethyl acrylate copolymer (1:1) (Ph. Eur.), microcrystalline cellulose, ascorbic acid, talcum, triethyl(2-acetoxy-propane-1,2,3-tricarboxylate), hydroxypropylcellulose, hypromellose, polysorbate 80, sodium dodecyl sulphate; capsule shell: gelatine, titanium dioxide (E 171), iron(III) oxide (E 172), iron oxide hydrate (E 172), iron(II,III) oxide (E 172)

ferro sanol® duodenal is available in packs with 20 (N1), 30, 50 (N2) and 100 (N3) capsules.

1. What ferro sanol® duodenal is, and what it is used for?

ferro sanol® duodenal is an oral iron substitution preparation for use against iron deficiency.

ferro sanol® duodenal is supplied by:
SANOL GmbH
Alfred-Nobel-Str. 10
D-40789 Monheim
Phone: 00 49 21 73/48-58 57
Fax: 00 49 21 73/48-58 51

Codistributor:
SCHWARZ PHARMA
Deutschland GmbH
Alfred-Nobel-Str. 10
D-40789 Monheim
Phone: 00 49 21 73/48-58 57
Fax: 00 49 21 73/48-58 51

ferro sanol® duodenal is manufactured by:

SCHWARZ PHARMA AG
Alfred-Nobel-Str. 10
D-40789 Monheim
Phone: 00 49 21 73/48-0
Fax: 00 49 21 73/48-16 08

Uses

Iron deficiency, in particular iron deficiency anaemia, during pregnancy and lactation; in childhood; in persons taking low-iron diets; after chronic or acute blood loss.

2. What precautions must you observe, before taking ferro sanol® duodenal?

2.1 ferro sanol® duodenal must not be used:

- If you are hypersensitive to the active ingredient or any of the excipients of the drug
- In iron overload (haemochromatosis, chronic haemolysis)
- In iron utilization disorders (e.g. sideroblastic anaemia, lead anaemia, thalassaemia)



Children

- Children younger than 6 years should not take ferro sanol® duodenal.

2.2 The use of ferro sanol® duodenal requires particular caution:

- In patients with intestinal ulcers.
- Especially elderly people presenting with iron deficiency/anaemia of apparently unexplainable origin have carefully to be examined for the cause of iron deficiency / the source of haemorrhage.
- Patients with anaemia secondary to serious kidney disease should receive ferro sanol® duodenal together with erythropoietin.

Pregnancy and lactation

Since the body's iron requirement is elevated during pregnancy and lactation, particular care is to be taken during these periods that ferro sanol® duodenal be taken regularly at the dosage prescribed by your doctor.

Ability to drive and to operate machines

No special precautions are required.

2.3 Interactions with other drugs:

Please inform your doctor or pharmacist when you take, or have recently taken, other drugs, even if those drugs are no prescription drugs.

Enhancement of effect through to an elevated risk of side-effects

Irritation of the gastrointestinal mucosa can be exacerbated by the concurrent administration of analgesics or antirheumatics (e.g. salicylates and phenylbutazone).

Decrease in effect

When coadministered with tetracyclines (certain antibiotics) or biophosphonates, both the absorption of iron and the absorption of the tetracyclines or biophosphonates are inhibited.

When iron is coadministered with cholestyramine or drugs containing Ca²⁺, Mg²⁺, Al³⁺ (e.g. antacids, calcium and magnesium salts for substitution), the absorption of iron is inhibited.

Penicillamine, oral gold compounds, L-methyldopa, levodopa and L-thyroxin are absorbed worse when coadministered with iron.

The absorption of certain antibiotics (fluoroquinolones such as ciprofloxacin, levofloxacin, norfloxacin and ofloxacin) is greatly reduced by iron.

The time interval between the administration of ferro sanol® duodenal and the above-mentioned drugs should be at least 2 hours.

Other possible interactions

The benzidine test can be positive during an iron therapy.

A dark coloration of the feces may occur so that the presently common tests, for occult blood in the feces may be positive.

2.4 Administration of ferro sanol® duodenal together with food or drinks:

Substances contained in vegetable food (e.g. cereals and vegetable) which form complexes with iron (e.g. phytates, oxalates and phosphates) as well as ingredients of coffee, tea, milk and cola drinks inhibit the uptake of iron into the blood.

3. How to use ferro sanol® duodenal?

Always follow the instructions of this leaflet precisely when taking ferro sanol® duodenal. Please ask your doctor or pharmacist, if you are not quite sure.

3.1 Unless otherwise

Adults and children from age 6 should usually take 1 capsule o.d. In cases of pronounced iron deficiency, adults and adolescents from age 15 or from 50 kg BW may require a dosage 2 to 3 times higher at the beginning of therapy.

3.2 Mode and duration of administration

ferro sanol® duodenal capsules should be taken without chewing with sufficient water. The drug should be taken either on an empty stomach in the morning (about 1 hour before breakfast) or at a sufficiently long interval of about 2 hours before or after a meal.

Note

If swallowing of the capsule proves difficult or is not desirable, the capsule contents can also be taken without the capsule shell. To do so, the patient, using both his/her hands, cautiously draws asunder the capsule shell over a soup spoon, in which the 300 to 400 pellets are gathered. After the capsule contents have been taken from the spoon, the patient should drink sufficient water.

Your doctor decides on the duration of therapy.

After the haemoglobin values have returned to normal, the oral iron therapy, with monitoring of the serum ferritin value, should be continued as long as is necessary to replenish the body iron stores.

Depending on the severity of anaemia and the individual situation, this will usually take between 3 and 6 months and may take even longer in individual cases.

Please consult your doctor or pharmacist, when you think that the effect of ferro sanol® duodenal is too strong or too weak.

3.3 When you have taken a greater quantity of ferro sanol® duodenal than you should have done:

After an intentional or accidental overdose, the symptoms described in section 4. "Side-effects" become more prominent. If overdose with the clinical signs of poisoning occurs, the usual rules of intoxication therapy will apply.

If too great amounts of ferro sanol® duodenal have been taken, a doctor should be informed immediately. To delay or inhibit the absorption of iron in the body, milk or egg white should be ingested.

3.4 When you missed a dose of ferro sanol® duodenal:

If you have forgotten one or several doses of ferro sanol® duodenal, the total duration of therapy, i.e., the time necessary for the serum ferritin value to return to normal will be prolonged.

Do not take the double dose the next time, but continue the treatment with the prescribed dose.

4. What side-effects are possible?

Like all drugs, ferro sanol® duodenal can cause side-effects.

The following frequency terms are commonly used in side-effect listings:

Rare: less than 1 in 1000, but more than 1 in 10,000 persons treated

Very rare: less than 1 in 10,000 persons treated, including isolated cases

Gastrointestinal complaints such as diarrhoea, constipation, heartburn or vomiting may occur. The frequency rises with the dose.

Hypersensitivity reactions (e.g. skin phenomena) may appear in rare cases.

A dark coloration of the feces as may occur during the treatment may result from the iron and is harmless.

A reversible discoloration of and near the teeth was very rarely observed.

Please inform your doctor or pharmacist of any side-effects not mentioned in this package insert.

5. What storage conditions are needed for ferro sanol® duodenal?

Store drugs out of the reach of children.

You must not use ferro sanol® duodenal after the expiry date given on the blister strips and on the folding box.

Date of the information:

January 2004

Note concerning the withdrawal from the package

To take the capsules from the film pack more easily, please take care only to press on the capsule ends. This also prevents damage to the capsules.

Each cell of the body needs iron to be fully functional. Iron-dependent enzymes are involved in all important metabolic steps. A proportion of 70 % of the iron in the body is bound in haemoglobin, the colouring matter of the red blood cells, whose

most important function is to transport oxygen from the lungs to our organs and tissues. The direct consequence of a haemoglobin deficit is an insufficient supply of the organism with oxygen. The iron deficiency manifests itself by exhaustion, weak concentration, pallor, fissures in the corners of the mouth, friability of the nails and hairs. Iron-deficiency anaemia can increase the susceptibility to infections and lead to complications in the mother and the child during pregnancy.

ferro sanol® duodenal contains ferrous sulphate in a complex compound with glycine, an amino acid. The contents of a capsule consist of about 300 to 400 pellets, which are uniformly distributed in the stomach after dissolution of the capsule; owing to their gastro-resistant coating, they pass the stomach unaltered, though. After the pellets have reached the duodenum, the iron is rapidly released from the pellets and is then present in an easily absorbable form.

This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children
Council of Arab Health Ministers
Union of Arab Pharmacists

SCHWARZ
P H A R M A

