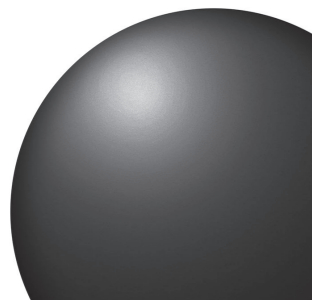


ferro sanol® gyn

FERROUS-(II)-GLYCINE-SULPHATE
COMPLEX/FOLIC ACID



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

ferro sanol® gyn

The pharmacologically active ingredients are: ferrous-(II)-glycine-sulphate complex and folic acid

One hard-gelatin capsule contains 454.13 mg of ferrous-(II)-glycine-sulphate complex (equivalent to 80 mg of Fe²⁺) and 1.0 mg of folic acid.

The excipients are:

Microcrystalline cellulose, lactose monohydrate, methacrylic acid-ethyl acrylate copolymer (1:1) (Ph. Eur.), ascorbic acid, sodium starch glycollate (2.8 – 4.2 % Na), talcum, triethyl(2-acetoxy-propane-1,2,3-tricarboxylate), hydroxypropylcellulose, hypromellose, polysorbate 80, magnesium stearate (Ph. Eur.), highly disperse silicon dioxide, sodium dodecyl sulphate; capsule shell: gelatine, purified water,

titanium dioxide (E 171), iron oxide hydrate (E 172), iron(III) oxide (E 172)

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

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

ferro sanol® gyn is an oral iron substitution preparation combined with folic acid for use against iron and folic acid deficiency.

ferro sanol® gyn is supplied by:

SANOL GmbH
Alfred-Nobel-Str. 10
D-40789 Monheim
Phone: 00492173/48-5857
Fax: 00492173/48-5851
Codistributor:

SCHWARZ PHARMA
Deutschland GmbH
Alfred-Nobel-Str. 10
D-40789 Monheim
Phone: 00492173/48-5857
Fax: 00492173/48-5851

ferro sanol® gyn is manufactured by:

SCHWARZ PHARMA AG
Alfred-Nobel-Str. 10
D-40789 Monheim
Phone: 00492173/48-0
Fax: 00492173/48-1608

Uses

For the treatment of combined iron and folic acid deficiency, particularly during pregnancy and lactation and in cases of poor or faulty nutrition.

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

2.1 ferro sanol® gyn 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)

- In megaloblastic anaemia resulting from isolated vitamin B12 deficiency (e.g. due to a lack of intrinsic factor).

Children

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

2.2 The use of ferro sanol® gyn 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® gyn together with erythropoietin.

Pregnancy and lactation

During pregnancy and lactation, ferro sanol® gyn at the recommended dosage can be used for the treatment of combined iron and folic acid deficiencies.

You should, however, take ferro sanol® gyn by your doctor's prescription only.

Ability to drive and to operate machines

No special precautions are required.

Important warnings concerning certain ingredients of ferro sanol® gyn

This drug contains lactose monohydrate. Please take ferro sanol® gyn only after having consulted your doctor, if you know to be suffering from sugar intolerance.

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).

The use of high dosages can increase the tendency towards convulsions in persons receiving an anticonvulsive therapy.

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-methyl dopa, 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.

Cytostatics, sulphonamides, antiepileptics and barbiturates impair the absorption of folic acid.

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

Other possible side-effects

As both folic acid and vitamin B12 can lead to an increase in reticulocytes (precursors of red blood cells) in the blood, the administration of one of the two vitamins alone (e.g. the administration of folic acid in ferro sanol® gyn) might conceal a deficiency of the other vitamin.

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® gyn 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® gyn?

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

3.1 Unless otherwise prescribed by your doctor, the usual dose is:

Adults and children from age 6 should usually take 1 hard-gelatin capsule once daily. In cases of pronounced iron deficiency, adults and adolescents from age 15 or from 50 kg BW may require a higher dosage (2 or 3 hard-gelatin capsules) at the beginning of therapy. The capsules should be spread over the day in such cases.

3.2 Mode and duration of administration

ferro sanol® gyn hard-gelatin 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 capsule contents 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® gyn is too strong or too weak.

3.3 When you have taken a greater quantity of ferro sanol® gyn then 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® gyn 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® gyn:

If you have forgotten one or several doses of ferro sanol® gyn, 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® gyn 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.

CNS disorders are rarely seen at high doses. 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® gyn?

Store drugs out of the reach of children.

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

Do not store above 25°C.

Date of the information:

April 2005

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.

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