

Package Leaflet: Information for the user
FERROUS GLUCONATE 300mg TABLETS BP

Read all of this leaflet carefully before you start to taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

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1. What Ferrous Gluconate Tablets and what it is used for

The name of your medicine is Ferrous Gluconate 300mg Tablets BP. The active substance present is Ferrous Gluconate. Ferrous Gluconate Tablets is used for the treatment and prevention of iron deficiency.

Ferrous Gluconate is a form of iron. Iron is necessary for the production of haemoglobin (protein in red blood cells), which carries oxygen around the body. Iron is involved in the formation of myoglobin, a pigment that stores oxygen in muscles for use during exercise.

2. What you need to know before you take Ferrous Gluconate Tablets

DO NOT take Ferrous Gluconate 300mg Tablets if you:

- are allergic (hypersensitive) to Ferrous Gluconate Tablets or medicine containing iron or any of the other ingredients of this medicine (listed in section 6)
- have a build-up of too much iron in the body (haemochromatosis)
- suffer from iron storage (haemosiderosis) or absorption (haemoglobinuria)
- have anaemia not caused by Iron deficiency
- receive regular blood transfusions or iron by IV infusion (drip)
- have an ulcer of the stomach or small intestine
- have hepatitis (inflammation of the liver)
- suffer from alcoholism

Warnings and precautions

Talk to your doctor or pharmacist before taking Ferrous Gluconate Tablets if you:

- are having tests for occult (hidden) blood in the stools, this medicine can colour faeces black
- are elderly as there is an increased risk of unwanted effects
- suffer from breakdown of red blood cells (haemolytic anaemia)
- also have deficiency of vitamin B12 or folic acid
- have diabetes as these tablets contain sugar
- have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product
- have a history of stomach ulcers
- suffer from inflammatory bowel disease
- have intestinal strictures or suffer from diverticular disease
- have had an operation to remove all part of the stomach (gastrectomy)

If any of the conditions listed above apply to you please talk to your doctor or pharmacist.

Other medicines and Ferrous Gluconate Tablets

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without prescription.

You must tell your doctor or pharmacist if you are taking any of the medicines listed below:

- antibiotics (used to treat bacterial infections, e.g. tetracyclines, flouroquinolones, chloramphenicol or neomycin). Do not take these medicines for two hours before and after taking Ferrous Gluconate 300mg Tablets
- zinc salts and aluminium
- antacids (used to treat indigestion) and mineral supplements e.g. calcium, magnesium, bicarbonates, carbonates, oxalates, or phosphates. Do not take these medicines for two hours before and after taking Ferrous Gluconate 300mg Tablets
- penicillamine (used in the treatment of rheumatoid arthritis)
- trientine (used to treat conditions of too much copper in the body e.g. Wilson's disease). Do not take these medicines for two hours before and after taking Ferrous Gluconate 300mg Tablets
- cholestyramine, used to reduce blood cholesterol and control diarrhoea
- levodopa, carbidopa, co-careldopa and entacapone (used in the treatment of Parkinson's disease)
- thyroxine, a thyroid hormone. Do not take these medicines for two hours before and after taking Ferrous Gluconate 300mg Tablets
- bisphosphonates (used in the treatment of bone diseases e.g. osteoporosis). Do not take these medicines for two hours before and after taking Ferrous Gluconate 300mg Tablets
- aminopterin (a cytotoxic drug used in the treatment of certain types of cancers)
- methyldopa (used in the treatment of high blood pressure)
- mycophenolate, a drug given after an organ transplant
- drugs to control epilepsy
- proton pump inhibitors, e.g. omeprazole, used to treat stomach ulcers
- dimercaprol (used in the treatment of heavy metal poisoning)
- Vitamin E
- Acetohydroxamic acid (used in the treatment of bladder infections)
- Eltrombopag (to treat low blood platelet counts)

Ferrous Gluconate Tablets with food, drink and alcohol

If you drink large amounts of tea, coffee or milk or milk products, or eat eggs and whole grain breads and cereals at the same time as taking Ferrous Gluconate Tablets, your body may absorb less of the iron contained in the tablets which can reduce the effects of ferrous gluconate. If you are worried that you are not getting the full effect of ferrous gluconate speak to your doctor or pharmacist.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

During the first 12 weeks of pregnancy only take Ferrous Gluconate 300mg Tablets if your doctor has specifically recommended it. This medicine may be taken during pregnancy and while breast-feeding if you are at risk of developing iron deficiency anaemia.

Driving and using machines

No effects of Ferrous Gluconate Tablets are known.

Ferrous Gluconate Tablets contains Ponceau 4R and Sucrose

- Ponceau 4R Red (E124): may cause allergic reactions
- Sucrose: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Ferrous Gluconate Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Do not take more than the recommended dose.

- Swallow the tablets with water.
- Take the tablets about 1 hour before meals.

Adults (including the elderly) and children over 12 years

- For the prevention of iron deficiency: take two tablets daily.
- For the treatment of iron deficiency: take four to six tablets daily in divided doses.

Children (aged 6-12 years)

- For the prevention of iron deficiency: take one or two tablets daily.
- For the treatment of iron deficiency: take three tablets daily in divided doses.

Children less than 6 years of age

Ferrous Gluconate Tablets are NOT recommended for children under 6 years of age.

If you take more of your medicine than you should

If you, or anyone else, has taken too many tablets, contact your doctor or nearest casualty department IMMEDIATELY. If you have taken too much Ferrous Gluconate you may experience nausea, vomiting (including vomiting blood), abdominal pain, bleeding from the bottom, diarrhoea, low blood pressure, lack of energy, changes in metabolism, coma, seizures and liver problems. An overdose in children can be fatal.

If you forget to take your medicine

If you forget to take a dose leave out that dose and take the next dose when it is due.

DO NOT take a double dose to make up for the forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Ferrous Gluconate Tablets and contact your doctor immediately if you experience any of the following signs and symptoms that may indicate:

- a serious allergic reaction (symptoms include: swelling of the hands, feet, ankles, face, lips or throat, problems with breathing, skin rash, itching or hives) and chest pain which can be a sign of a potentially serious allergic reaction called Kounis Syndrome.
- Haemorrhage/ blood loss (symptoms may include being in a 'state of shock', vomiting blood)
- Circulatory failure/ collapse (symptoms may include chest pain, breathlessness or dizziness)
- vomiting blood (haematemesis)
- Severe diarrhoea

High doses in some people may have an effect on the lining of the stomach or gut, which may become narrower or perforated. Symptoms of this are stomach pain and bloody stools

Other less serious side effects include:

- nausea
- vomiting
- heartburn
- abdominal pain
- diarrhoea
- constipation
- dark coloration of stools
- lack or loss of appetite

Contact irritation can occur with ferrous gluconate tablets resulting in erosion or ulceration, particularly if they become lodged in the upper gastrointestinal tract (oesophagus, stomach and duodenum).

If any of the side effects becomes serious or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ferrous Gluconate Tablets

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original container and tightly closed

Do not use this medicine after the expiry date (EXP.) which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ferrous Gluconate Tablets contain

Active substance: Each tablet contains 300mg of Ferrous Gluconate

Other ingredients: Core: Sodium starch glycollate Type A, stearic acid, colloidal anhydrous silica.

Sugar Coating: Sucrose, purified talc, calcium carbonate, acacia, titanium dioxide E171, Industrial Methylated Spirit, Ponceau 4R, Opaglos 6000.

What Ferrous Gluconate Tablets look like and the contents of the pack

Ferrous Gluconate 300mg Tablets are red, circular biconvex, sugar-coated, printed with APS and 1701

Ferrous Gluconate Tablets come in the bottles of 100, 250, 500, 1000 and 5000 packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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