

FERROUS GLUCONATE 300mg TABLETS

XXXXX

Pharma Code
Position

Read all of this leaflet carefully before you start 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

1. What Ferrous Gluconate 300mg Tablets are and what they are used for
2. What you need to know before you take Ferrous Gluconate 300mg Tablets
3. How to take Ferrous Gluconate 300mg Tablets
4. Possible side effects
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6. Contents of the pack and other information

1. WHAT FERROUS GLUCONATE 300mg TABLETS ARE AND WHAT THEY ARE USED FOR

Ferrous Gluconate 300mg Tablets are 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 300mg TABLETS**DO NOT take Ferrous Gluconate 300mg Tablets:**

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

Warnings and Precautions

Talk to your doctor or pharmacist before taking Ferrous Gluconate 300mg Tablets:

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

After correction of iron deficiency, duration of treatment should generally not exceed 3 months. Long term use of this product may cause tooth decay and infections.

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

Other medicines and Ferrous Gluconate 300mg Tablets

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

prescription especially 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
- penicillamine (used in the treatment of rheumatoid arthritis)
- 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
- 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
- methyldopa (used in the treatment of high blood pressure)
- mycophenolate, a drug given after an organ transplant
- 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 300mg Tablets with food and drink

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 300mg 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 and breast-feeding

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 300mg Tablets are known.

Ferrous Gluconate 300mg Tablets contain ponceau 4R Red (E124) 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 medicine.

3. HOW TO TAKE FERROUS GLUCONATE 300mg TABLETS

Always take this medicine as described in this leaflet or 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.

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

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 300mg Tablets are NOT recommended for children under 6 years of age.

If you take more Ferrous Gluconate 300mg Tablets 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 Ferrous Gluconate 300mg Tablets

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, Ferrous Gluconate 300mg Tablets can cause side effects, although not everybody gets them.

STOP taking Ferrous Gluconate 300mg Tablets and contact your doctor immediately if you experience:

- an allergic reaction. Symptoms include: swelling of the hands, feet, ankles, face, lips or throat, problems with breathing, skin rash, itching or hives
- 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
- lack or loss of appetite
- dark coloration of stools

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 become 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 300mg TABLETS

Do not take Ferrous Gluconate 300mg Tablets after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not store above 25°C. Store in the original container. Keep the container tightly closed. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What Ferrous Gluconate 300mg Tablets contain**

Active substance: Each tablet contains 300mg ferrous gluconate equivalent to 35mg ferrous iron.

Other ingredients: sodium starch glycollate, stearic acid, colloidal anhydrous silica, sucrose, talc, calcium carbonate, acacia, polyvinyl acetate phthalate, carnauba wax, white beeswax, shellac, titanium dioxide (E171) and ponceau 4R Red (E124).

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

Ferrous Gluconate 300mg Tablets are red, circular, biconvex, sugar coated tablets. Ferrous Gluconate 300mg Tablets come in pots containing 28, 100, 250, 500, 1000 and 5000 tablets or blister packs containing 28 tablets. Not all pack types or sizes may be marketed.

Marketing Authorisation Holder

Athlone Pharmaceuticals Limited, Ballymurray, Co. Roscommon, Ireland.

Manufacturer responsible for batch release

Surepharm Services Limited, Unit 2H, Bretby Business Park, Ashby Road East, Bretby, Burton-on Trent, DE15 0YZ, U.K.

PL30464/0026.

This leaflet was last revised in January 2021.

Customer: SP **Designer:** DOB (AWG)

Product: Ferrous Gluconate 300mg Tablets

Dimensions: 146mm x 350mm

Item Code: CP.FGL.300T.SP.V5P1

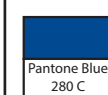
Proof No and Date: 1 21/01/2021

Revision: Addition of batch release site address

ARTWORK FOR SUBMISSION

Supersedes: CP.FGL.300T.SP.V4P1

Colours



Pantone Blue
280 C