1. What Ferrous Gluconate 300 mg Coated Tablets are and what they are used for

- Ferrous Gluconate 300 mg Coated Tablets contain the active substance Ferrous gluconate.
- Ferrous gluconate belongs to a group of drugs called anti-anaemic preparations (used to treat iron deficiency anaemia).
- Ferrous gluconate is a form of iron. Iron has an important role in the oxygen-carrying pigment, haemoglobin. It is involved in the formation of myoglobin, a pigment which stores oxygen in muscles for use during exercise.
- Ferrous gluconate is used for the prevention and treatment of iron deficiency in adults (including the elderly) and children aged 6 years and above.

2. What you need to know before you take Ferrous Gluconate 300 mg Coated Tablets

Do not take Ferrous Gluconate 300 mg Coated Tablets if you:
- are allergic to Ferrous gluconate, other iron preparations or any of the other ingredients of this medicine (listed in section 6)
- have a disease which causes the body to absorb and/or store too much iron (haemochromotosis, haemosiderosis)
- have a condition which causes loss of the protein haemoglobin through urination
- have anaemia which is not due to a lack of iron
- receive repeated blood transfusions or iron by injection
- suffer from Crohn’s disease, active peptic ulcer or inflammation of the colon
- have hepatitis (inflammation of the liver)
- suffer from alcoholism.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Ferrous Gluconate 300 mg Coated Tablets if you:
- suffer from breakdown of red blood cells (haemolytic anaemia)
- have an iron absorption disorder
- have a disease affecting your stomach or intestines
- have strictures or diverticulae (intestinal narrowing/bulges which may be accompanied by inflammation or infection)
- are elderly.

Other medicines and Ferrous Gluconate 300 mg Coated Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is particularly important if you are taking medicines in the table below. Follow the instructions to help maintain the effectiveness of each medicine:

<table>
<thead>
<tr>
<th>Other Medicines</th>
<th>Take Ferrous Gluconate 300 mg Coated Tablets:</th>
</tr>
</thead>
<tbody>
<tr>
<td>antacids (medicines)</td>
<td>at least 1 hour before or 2 hours after taking these medicines</td>
</tr>
<tr>
<td>other medicines</td>
<td>at least 2 hours before or 2 hours after taking these medicines</td>
</tr>
<tr>
<td>bisphosphonates</td>
<td>at least 4 hours before or 4 hours after taking these medicines</td>
</tr>
<tr>
<td>eltrombopag</td>
<td>at least 4 hours before or 4 hours after taking these medicines</td>
</tr>
<tr>
<td>levodopa, carbidopa or entacapone</td>
<td>at least 3 hours before or 2 hours after taking these medicines</td>
</tr>
<tr>
<td>mycophenolate</td>
<td>at least 2 hours before or 2 hours after taking these medicines</td>
</tr>
<tr>
<td>tetracyclines</td>
<td>at least 2 hours before or 2 hours after taking these medicines</td>
</tr>
<tr>
<td>acetohydroxamic acid</td>
<td>at least 1 hour before or 2 hours after taking these medicines</td>
</tr>
<tr>
<td>ciprofloxacin, levofloxacin, norfloxacin, ofloxacin, nalidixic acid</td>
<td>at least 2 hours before or 2 hours after taking these medicines</td>
</tr>
<tr>
<td>dimercaprol</td>
<td>at least 2 hours before or 2 hours after taking these medicines</td>
</tr>
<tr>
<td>levodopa, carbidopa or entacapone</td>
<td>at least 2 hours before or 2 hours after taking these medicines</td>
</tr>
<tr>
<td>methylthio</td>
<td>at least 2 hours before or 2 hours after taking these medicines</td>
</tr>
<tr>
<td>mycophenolate</td>
<td>at least 2 hours before or 2 hours after taking these medicines</td>
</tr>
<tr>
<td>proton pump inhibitors</td>
<td>at least 2 hours before or 2 hours after taking these medicines</td>
</tr>
<tr>
<td>trentine</td>
<td>at least 2 hours before or 2 hours after taking these medicines</td>
</tr>
<tr>
<td>vitamin E or calcium, aluminium and zinc salts</td>
<td>at least 2 hours before or 2 hours after taking these medicines</td>
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</table>

Please also tell your doctor or pharmacist if you are taking or have recently taken these other medicines:

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Ferrous Gluconate 300 mg Coated Tablets with food and drink

Coffee, tea, eggs, milk, milk products and whole grain breads and cereals may slow down the absorption of iron. Follow your doctor’s advice when taking Ferrous Gluconate 300 mg Coated Tablets with the food and drink listed.

Pregnancy and breast-feeding

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. Although Ferrous Gluconate 300 mg Coated Tablets may be taken, you should check with your doctor before taking if you are pregnant or breast-feeding.

Driving and using machines

No effects on the ability to drive and use machines have been reported to date with Ferrous Gluconate 300 mg Coated Tablets.

Ferrous Gluconate 300 mg Coated Tablets contain sucrose

If you have been told by your doctor that you have an intolerance to some sugars, check with your doctor before taking this medicine.

3. How to take Ferrous Gluconate 300 mg Coated 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.

Swallow the tablets whole with a drink of water, preferably 1 hour before meals. Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is normally as follows:

For adults (including the elderly)

Prevention of iron deficiency: Take 2 tablets daily

Treatment of iron deficiency: Take 4 to 6 tablets daily in divided doses

For children 6 to 12 years

Prevention and treatment of iron deficiency: Take 1 to 3 tablets daily (in divided doses)

If you take more Ferrous Gluconate 300 mg Coated Tablets than you should

Contact your doctor straight away or go to the nearest hospital casualty department. Take with you any remaining tablets and the pack so that the medicine can be identified.

If you have taken too much Ferrous Gluconate you may feel or be sick (possibly with blood), have stomach pain, diarrhoea, bleeding from the bottom, lack of energy, chest pain, breathlessness, dizziness or coma.

If you forget to take Ferrous Gluconate 300 mg Coated Tablets

Do not take a double dose to make up for a forgotten dose.

If you forget to take a dose of this medicine, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and take the next dose at the usual time.

Taking Ferrous Gluconate 300 mg Coated Tablets with food and drink

See Section 2.

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.

If any of the following occur STOP TAKING the tablets IMMEDIATELY and contact your doctor:

- an allergic reaction (symptoms may include shortness of breath, blocked nose, rash, itching, swollen face or lips).
- haemorrhage/blood loss (symptoms may include being in a ‘state of shock’)
- circulatory failure/collapse (symptoms may include chest pain, breathlessness or dizziness)
- severe diarrhoea
- prolonged constipation
- vomiting
- vomiting blood (haematemesis)

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 side effects:

- loss of appetite
- feeling sick
- stomach discomfort
- heartburn
- darker coloured stools than usual.

Continuous use may cause constipation and faecal impaction which is when stools become hard and dry and collect in your rectum, sometimes causing an obstruction (blockage).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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/yelllowcard By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ferrous Gluconate 300 mg Coated Tablets

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

>>> These tablets could harm them. An overdose could be fatal. <<<

Store the medicine in a dry place below 25°C. Keep the tablets in the original packaging (i.e. store the blister strips inside the carton when not in use) in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the blister strips (i.e. labelling) and carton after ‘EXP’. 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 300 mg Coated Tablets contain

The active substance is Ferrous gluconate. The other ingredients are: Purified talc, Starch (potato), Sucrose, Maize starch, Shellac, Dispersed red 15011 (which is a colourant containing Carmoisine Lake [E122] and Ponceau 4R Lake [E124] which may cause allergic reactions), IMS, Titanium dioxide and Opaglos 6000 (which comprises of Carnauba wax, Beeswax and Shellac).

What Ferrous Gluconate 300 mg Coated Tablets look like and contents of the pack

Ferrous Gluconate 300 mg Coated Tablets are red, shiny and round. The tablets are sugar-coated. The tablets are presented in a child resistant blister pack with each pack containing 28 tablets (arranged as two strips of fourteen tablets).

Marketing Authorisation Holder and Manufacturer

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Cookham Dean, Maidenhead
Berks SL6 6PT, United Kingdom
Tel: +44 (0)1628 771800
E-mail: medinfo@intrapharmlabs.com; sales@intrapharmlabs.com

This leaflet was last revised in March 2016.

Other sources of information

Detailed information on this medicine is available on the website of the (UK) Medicines and Healthcare products Regulatory Agency.