Package leaflet: Information for the user

025081 2603

Ferrous Fumarate 210 mg Tablets

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, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Fumarate Tablets are and what they are used for
2. What you need to know before you take Ferrous Fumarate Tablets
3. How to take Ferrous Fumarate Tablets
4. Possible side effects
5. How to store Ferrous Fumarate Tablets
6. Contents of the pack and other information

1. WHAT FERROUS FUMARATE TABLETS ARE AND WHAT THEY ARE USED FOR

Ferrous Fumarate Tablets contain the active substance ferrous fumarate. Ferrous fumarate is a form of iron. Iron is usually found in foods and is necessary for the normal development of red blood cells.

A lack of iron affects the development of the red blood cells and causes a reduction in the number of red blood cells found in the body (iron deficiency anaemia). Ferrous Fumarate Tablets are used to prevent or treat iron deficiency anaemia.
The prevention of iron deficiency during pregnancy usually requires a combination of iron and folic acid.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FERROUS FUMARATE TABLETS

Do not take Ferrous Fumarate Tablets:

- If you are allergic to ferrous fumarate, any other medicine containing iron or any of the other ingredients of this medicine (listed in section 6)
- If you have noticed blood in your urine
- If you have bronze markings on your skin or you have been told that you have increased stores of iron in your tissues
- If you are suffering from a recently diagnosed stomach or duodenal ulcer
- If you are undergoing repeated blood transfusions
- If you suffer from ulcerative colitis or any other inflammatory condition of the bowels
- If you suffer from any form of anaemia, other than iron deficiency anaemia, or from any other condition where your body's iron is affected (your doctor will be able to advise you).

Speak to your doctor if any of these apply to you before you take your medicine.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Ferrous Fumarate Tablets:

- If you have had a stomach or duodenal ulcer in the past, or have one which is now under control with treatment
- If you have had major surgery to your stomach
- If you have had problems associated with narrowing of your intestine (stricture) or out pocketing of the inner layer of your intestine (diverticular disease).

If any of these conditions apply to you, speak to your doctor before you take these tablets. Your doctor will want to watch you closely, and will advise you if any additional medicine is required to treat your condition

Other medicines and Ferrous Fumarate Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The effects of any of these medicines may change or the effect of Ferrous Fumarate Tablets may change,
particularly if you are taking:

- Certain medicines for treating infections (e.g. chloramphenicol, tetracyclines, ciprofloxacin, levofloxacin, moxifloxacin, ofloxacin, norfloxacin, cefdinir, quinolone antibacterials)
- Medicines containing zinc, calcium or magnesium salts
- Levothyroxine, used for thyroid gland problems
- Medicines used for a disease known as 'Parkinson's disease' (e.g. levodopa, entacapone, carbidopa)
- Methyldopa used for increase in blood pressure
- Penicillamine used in the treatment of rheumatoid arthritis
- Colestyramine used to reduce cholesterol and fats in the blood
- Medicines for bone diseases (bisphosphonates)
- Trientine used for high copper levels in blood
- Dimercaprol used for various metal poisonings
- Mycophenolate mofetil used during organ transplants

Ferrous Fumarate Tablets with food and drink
Ferrous Fumarate Tablets may be taken with meals. This may help to relieve any stomach-related side effects. However, it is advisable not to take your medicine with tea, eggs or milk as this may reduce the effect of the tablets.

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.

Sodium content
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE FERROUS FUMARATE TABLETS

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Swallow the tablets with a glass of water. You can also chew or crush the tablets. Taking Ferrous Fumarate Tablets with meals may help to relieve any stomach related side effects.

Your doctor will advise you on how long you should take the tablets. You can stop taking the tablets three months after the anaemia has been corrected. You should not take the tablets for more than six months.

Use in adults including the elderly
The recommended dose to treat iron deficiency anaemia is one tablet two to three times a day.

The recommended dose for prevention of anaemia is one tablet once or twice a day.

Use in children
Ferrous Fumarate Tablets are not suitable for use in children.
Ferrous Fumarate Tablets is very dangerous if taken by young children and care should be taken to keep the medicine safely out of the reach of children. If you have to go to another doctor or to the hospital tell them you are taking Ferrous Fumarate Tablets.

If you take more Ferrous Fumarate Tablets than you should
If you take too many tablets, contact your nearest hospital casualty department or doctor immediately.
Take any remaining tablets and this leaflet with you so that the medical staff know exactly what you have taken. Your medicine is very dangerous if taken by young children and care should be taken to keep the medicine safely out of the reach of children.

Signs and symptoms of an iron overdose include nausea, vomiting, abdominal pain, diarrhoea, vomiting of blood (haematemesis), and rectal bleeding.

If you forget to take Ferrous Fumarate Tablets
Take your dose as soon as you remember, then go on as before. If it is almost time for the next dose, then do not take the missed dose at all. Do not take a double dose to make up for a forgotten dose.

If you stop taking Ferrous Fumarate Tablets
If you are having no problems with your tablets, do not stop taking them until your doctor tells you to.

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.
All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

They might be:
Common: may affect up to 1 in 10 people

- Heartburn
- Feeling sick or being sick
- Diarrhoea or constipation.

Also, you might find your stools are darker in colour after you have taken this medicine. This is quite commonly seen with all iron preparations and is normal.
If any of these side effects get serious, or if you notice any other side effect 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, 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 website: 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 FUMARATE TABLETS

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

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

This medicinal product does not require any special storage conditions.

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 Fumarate Tablets contain
The active substance is ferrous fumarate.
Each tablet contains 210mg of ferrous fumarate equivalent to 69mg of elemental iron.
The other ingredients are maize starch, liquid paraffin, gelatin and sodium lauryl sulfate.

What Ferrous Fumarate Tablets look like and contents of the pack
Ferrous Fumarate Tablets are light brown, round, biconvex, uncoated tablets.
They are provided in pack sizes containing 28, 56, 84 or 112 tablets.

Marketing Authorisation Holder
Kent Pharma UK Limited, 2nd Floor, Connect 38, 1 Dover Place, Ashford, Kent, England, TN23 1FB.

Manufacturer
Ofimedicine B.V.,
Archimedesweg 2,
2333 CN Leiden,
Netherlands.

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CP.FUM.210T.SP.V4P1
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27 mm
10 mm

Customer: Kent **Originated by:** DOB (AWG)
Product: Ferrous Fumarate 210mg Tablets
Dimensions: 148mm x 280mm
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