

Package leaflet: Information for the patient
Ferrous Fumarate 322mg
Film-Coated Tablets

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

The name of your medicine is Ferrous Fumarate 322mg Film-Coated Tablets. It will be referred to as Ferrous Fumarate Tablets for ease hereafter.

What is in this leaflet

1. What Ferrous Fumarate Tablets are and what they are used for
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3. How to take Ferrous Fumarate Tablets
4. Possible side effects
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1. WHAT FERROUS FUMARATE TABLETS ARE AND WHAT THEY ARE USED FOR

Ferrous Fumarate Tablets contain a form of iron called ferrous fumarate. 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 iron deficiency anaemia.

Ferrous Fumarate Tablets are used to prevent or treat iron deficiency anaemia.

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 or any of the other ingredients of this medicine (listed in section 6), or to any other medicine containing iron
 - You have noticed blood in your urine
 - 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)
 - You have bronze markings on your skin or you have been told that you have increased stores of iron in your tissues
 - You are suffering from a recently diagnosed stomach or duodenal ulcer
 - You are undergoing repeated blood transfusions
 - You suffer from ulcerative colitis or any other inflammatory condition of the bowels.
- Speak to your doctor if any of these apply to you before you take your medicine.

Warnings and precautions

Talk to your doctor or pharmacist 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
- You have problems associated with narrowing of your intestine (stricture) or outpocketing of the inner layer of your intestine (diverticular disease)
- You have had major surgery to your stomach.

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 or have recently taken or might take any other medicines.

The effects of any of these medicines or 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)
- 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)
- Methyl dopa, used for increase in blood pressure
- Antacids used to treat indigestion
- Penicillamine used in the treatment of rheumatoid arthritis
- Cholestyramine 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, used during change of organs (transplant).

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. Ferrous Fumarate Tablets should be taken with a glass of water.

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.

Ferrous Fumarate Tablets contains sodium

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

3. HOW TO TAKE FERROUS FUMARATE 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.

The recommended dose:

The recommended dose is one tablet a day. Occasionally it may be increased to one tablet twice a day.

To help you to remember to take your medicine, select the tablet(s) for the appropriate day of the week marked on the strips.

Swallow the tablets with a glass of water. 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. Normally this will be for 3 – 6 months after the anaemia has been rectified.

If you have to go to another doctor or to hospital, tell them you are taking Ferrous Fumarate Tablets.

Use in children

Ferrous Fumarate Tablet is not suitable for children.

Your medicine is very dangerous if taken by young children and great care should be taken to keep the medicine safely out of sight and reach of children. If a child has taken or is suspected of taking any of the tablets, immediate medical advice should be sought (see below - *If you take more Ferrous Fumarate Tablets than you should*).

If you take more Ferrous Fumarate Tablets than you should

If you take too many tablets, or a child takes or is suspected of taking any tablets at all, 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 has been taken.

If you forget to take your Ferrous Fumarate Tablets

Take another from the pack as soon as you remember, according to the day of the week. Then go on as before. If it is almost time for the next dose, then do not take the missed dose at all.

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.

Not known: frequency cannot be estimated from the available data

- Stomach discomfort
- Pain in upper part of the stomach
- Vomiting sensation
- Difficulty in passing stools
- Loose stools.

Also, you may find that your stools are darker in colour after you have taken this medicine. This is quite commonly seen with all iron preparations and is normal.

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/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 & reach of children, as overdose may be fatal.

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

Store below 25°C.

Store in the original package in order to protect from light.

Do not use your medicine if the pack is damaged.

Disposal of the product:

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 to protect the environment.

REMEMBER

This medicine is for YOU. Never give it to anyone else. It may harm them, even if their signs of illness are the same as yours.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ferrous Fumarate tablets contain:

The active substance is ferrous fumarate. Each tablet contains 322 mg ferrous fumarate (equivalent to approximately 100 mg ferrous iron). Ferrous fumarate is an iron compound.

The other ingredients are maize starch, sodium lauryl sulfate, gelatin and liquid paraffin. The film coating of the tablets contains hypromellose, acetylated monoglyceride, hydroxypropyl cellulose, titanium dioxide (E171), talc, iron oxide yellow (E172) and iron oxide red (E172).

What Ferrous Fumarate Tablets look like and contents of the pack

Each film coated tablet is brown ochre in colour and engraved FE on one face and 322 on the other. Ferrous Fumarate Tablets are usually available in cartons containing two blister strips of 14 tablets, therefore 28 tablets altogether. However, pots of 1000 tablets may also be available. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mercury Pharma Group Ltd., Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

Manufacturer:

Lusomedicamenta S.A.Sociedade Técnica, Farmaceutica 2730 055 Barcarena, Portugal

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