

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 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 140MG/5ML SYRUP

Important warning: contains iron.

Keep this medicine out of the sight and reach of children, as overdose may be fatal.

Do not store above 25°C. Keep the bottle in the outer carton in order to protect from light. Shake the bottle before use.

Replace the cap after taking your dose.

If you have any of your medicine left after finishing your treatment, return it to your pharmacist.

Do not use this medicine if the bottle is damaged or after the Expiry Date which is stated on the bottle 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.

REMEMBER

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

The active substance is ferrous fumarate. Each 5 ml spoonful contains 140mg ferrous fumarate (approximately 45mg elemental iron). Ferrous fumarate is an iron compound.

The other ingredients are nipastat, methyl cellulose, glucose liquid, sucrose, lecithin vegetable, elderberry flavour, sodium metabisulphite (E223) and purified water.

Nipastat contains methyl hydroxybenzoate, ethyl hydroxybenzoate, propyl hydroxybenzoate, butyl hydroxybenzoate and isobutyl hydroxybenzoate.

What Ferrous Fumarate 140mg/5ml Syrup looks like and contents of pack

Ferrous Fumarate 140mg/5ml Syrup is a smooth brown suspension which separates on standing with an elderberry smell. It is packed in amber glass bottles containing 200ml suspension.

Marketing authorisation holder

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

Manufacturer:

Kleva Pharmaceuticals S.A.,
Parnithos Ave. 189,
Acharnai Attiki,
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Package leaflet: Information for the patient Ferrous Fumarate® 140mg/5ml Syrup

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

This medicine is available without prescription. However, you still need to take Ferrous Fumarate 140mg/5ml Syrup carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, 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 symptoms 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.

What is in this leaflet:

1. What Ferrous Fumarate 140mg/5ml Syrup is and what it is used for
2. What you need to know before you take Ferrous Fumarate 140mg/5ml Syrup
3. How to take Ferrous Fumarate 140mg/5ml Syrup
4. Possible side effects
5. How to store Ferrous Fumarate 140mg/5ml Syrup
6. Contents of the pack and other information

1. WHAT FERROUS FUMARATE 140MG/5ML SYRUP IS AND WHAT IT IS USED FOR

Ferrous Fumarate 140mg/5ml Syrup contains 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 140mg/5ml Syrup is 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 140MG/5ML SYRUP

Do not take Ferrous Fumarate 140mg/5ml Syrup 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.

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AMS Component No.: **LF-126802-01**
Product Description: **Ferrous fumarate
140mg/5ml Syr
UK 200 ml**
Component: Leaflet
Product Code: 101817
Country: UK
Vendor Name: Kleva Pharmaceu-
ticals Ltd
Proof Number: 1
Revision Date: 28-Jun-2023
Revised by: DAJ

Dimension: 128 x 252 mm
Commodity No.: 041964-002-DD.MM.2023
Pharma Code: 199
Print Colours: Black
Non-Print Colours: **Cutter**
Min. Font Size: 9.5 pt

AMS Component No.: **LF-126802-01**
 Product Description: **Ferrous fumarate 140mg/5ml Syr UK 200 ml**
 Component: Leaflet
 Product Code: 101817
 Country: UK
 Vendor Name: Kleva Pharmaceuticals Ltd
Proof Number: 1
 Revision Date: 28-Jun-2023
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 Print Colours: Black
 Non-Print Colours: **Cutter**
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Warnings and precautions

Talk to your doctor or pharmacist before taking Ferrous Fumarate 140mg/5ml Syrup if:

- You suffer or have suffered from a peptic ulcer
- You have problems associated with narrowing of your intestine (stricture) or outpocketing of the inner layer of your intestine (diverticular disease)
- You have difficulty in absorbing certain sugars (glucose or galactose)
- You have had some or all of your stomach removed as this may make it difficult for you to absorb iron
- You have diabetes.

If any of these conditions apply to you, speak to your doctor before you take this medicine. 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 140mg/5ml Syrup

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 or of Ferrous Fumarate 140mg/5ml Syrup 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.
- 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, used during change of organs (transplant).

Ferrous Fumarate 140mg/5ml Syrup with food and drink

Ferrous Fumarate 140mg/5ml Syrup 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 its effect.

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 140mg/5ml contains sodium metabisulphite, sodium parahydroxybenzoates, sucrose and liquid glucose

Ferrous Fumarate 140mg/5ml Syrup contains sodium metabisulphite and parahydroxybenzoates as preservatives.

Sodium metabisulphite may rarely cause severe hypersensitivity reactions and bronchospasm.

Parahydroxybenzoates (methyl hydroxybenzoate, ethyl hydroxybenzoate, propyl hydroxybenzoate) may cause allergic reactions (possibly delayed).

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

This medicine also contains Sucrose and Glucose Liquid. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Also, it may be harmful to the teeth.

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3. HOW TO TAKE FERROUS FUMARATE 140MG/5ML SYRUP

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

It is important to take your medicine at the right time.

The label will tell you how much to take and how often.

The recommended dose is:

Adults and the elderly:

The usual dose to prevent Iron deficiency anaemia is one spoonful (5ml) twice a day.

Use in children

For children and premature infants, your doctor will decide the dose, according to the age and weight of the child and infant.

Your doctor will advise you on how long you should take the medicine, which is normally not more than six months. It is usually stopped three months after the anaemia has been corrected.

If you have to go to another doctor or to the hospital tell them you are taking Ferrous Fumarate 140mg/5ml Syrup.

If you take more Ferrous Fumarate 140mg/5ml Syrup than you should:

Contact your nearest hospital casualty department or doctor immediately. Take any remaining medicine and this leaflet with you so that the medical staff know exactly what you have taken.

Your medicine is very dangerous if too much is taken by young children and care should be taken to keep the medicine safely out of the reach of children.

If you forget to take your Ferrous Fumarate 140mg/5ml Syrup:

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

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.

If you stop taking Ferrous Fumarate 140mg/5ml Syrup:

If you are having no problems with Ferrous Fumarate 140mg/5ml Syrup, do not stop taking it 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

Other side effects may include:

- stomach discomfort
- pain in upper part of the stomach
- vomiting sensation
- difficulty in passing stools
- loose stools.

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 you use Ferrous Fumarate 140mg/5ml Syrup for a long time the sugar content may increase the risk of tooth decay. It may also result in blackish discolouration of the teeth. This can be reduced by daily brushing of the teeth.

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