

**Package leaflet: Information for the user**  
**Galfer 140 mg/5 ml Oral Suspension**  
ferrous fumarate

**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 have told you.

This medicine is available without prescription. However, you still need to take Galfer Oral Suspension carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need any more information or advice.
- 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 after 28 days.

**What is in this leaflet:**

1. What Galfer Oral Suspension is and what it is used for
2. What you need to know before you take Galfer Oral Suspension
3. How to take Galfer Oral Suspension
4. Possible side effects
5. How to store Galfer Oral Suspension
6. Contents of the pack and other information

**1. What Galfer Oral Suspension is and what it is used for**

Galfer Oral Suspension contains ferrous fumarate which is used to replace low levels of iron in the blood. It is used to treat and prevent anaemia caused by iron deficiency.

This product should only be used for the treatment of iron deficiency anaemia diagnosed by laboratory testing under the supervision of a doctor.

**2. What you need to know before you take Galfer Oral Suspension**



**Do not take the medicine if you or your child have....**

- An **allergy** to any of the ingredients listed in section 6.
- Other **problems with iron in the blood** (including conditions that lead to iron building up in soft tissues, or problems with red blood cells).
- A **stomach ulcer** or other **stomach or bowel problem**.
- Had **repeated blood transfusions** in the past.
- **Anaemia not related to low levels of iron**.
- Are currently **having iron injections**.
- Or are taking dimercaprol for metal poisoning.



**Take special care with Galfer Oral Suspension if you or your child have....**

- A family history of conditions that lead to iron building up or iron overload in the blood.
- A history of stomach ulcers.
- Had part or all of the stomach removed.
- Vitamin deficiency particularly vitamin B12 or folic acid.



**Children under 12 years....**

The doctor will decide how much your child needs to take and how often. Talk to your doctor or pharmacist if you have not been told how much to give your child.

- People having tests on stool samples should tell the doctor as this medicine may turn stools black and effect test results.

Talk to your doctor or pharmacist before taking Galfer Oral Suspension in these cases.



#### **Other medicines and Galfer Oral Suspension....**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. If you or your child are taking any of the following talk to your doctor before taking Galfer Oral Suspension.

- Antibiotics for infections such as tetracyclines (e.g. oxytetracycline), chloramphenicol or fluoroquinolones (e.g. ciprofloxacin).
- Penicillamine for arthritis.
- Indigestion remedies, calcium, magnesium, zinc and other mineral supplements.
- Levodopa, carbidopa or entacapone for Parkinson's Disease.
- Bisphosphonates for osteoporosis.
- Trientine for Wilson's Disease.
- Methyldopa for high blood pressure.
- Colestyramine mainly used for high cholesterol.
- Levothyroxine for thyroid problems.



#### **Pregnancy and breastfeeding....**

You can take Galfer Oral Suspension after the first 13 weeks of pregnancy. Talk to your doctor first before using the medicine if you are pregnant or breastfeeding. You may also need to take folic acid.



#### **Important information about some of the ingredients**

##### **Galfer Oral Suspension contains...**

- Parahydroxybenzoates: May cause allergic reactions (possibly delayed).
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- Maltitol 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. May have a mild laxative effect. Calorific value 2.3 kcal/g.
- Sodium benzoate: This medicine contains 5.2 micrograms sodium benzoate in each 10 ml dose. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- Benzyl alcohol: This medicine contains 1.3 micrograms benzyl alcohol in each 10 ml dose. Benzyl alcohol may cause allergic reactions. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gaspings syndrome") in young children. Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor. Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build up in your body and may cause side effects (called "metabolic acidosis"). Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").
- Ethanol: This medicine contains 0.234 micrograms of alcohol (ethanol) in each 10 ml. The small amount of alcohol in this medicine will not have any noticeable effects.
- This medicine contains less than 1 mmol sodium (23 mg) per 10 ml dose, that is to say essentially 'sodium-free'.
- Lactose: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **3. How to take Galfer Oral Suspension**

Always take this medicine exactly 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.

### **Important things you need to know first....**

- Take this medicine before meals on an empty stomach if possible. If Galfer Oral Suspension upsets your stomach, take it with or after food.
- Some foods such as tea, eggs and milk may reduce the amount of iron absorbed by the body. Check with the doctor or pharmacist about which foods to avoid.
- Galfer Oral Suspension may make your stools darker than usual. This is a normal effect of medicines containing iron.
- Galfer Oral Suspension may blacken the teeth. To help prevent this, rinse your mouth with water after taking.
- Vitamin C and drinks containing citric acid may increase the amount of iron absorbed.
- If your symptoms have not started to improve after 28 days, you should ask your doctor for advice.
- Treatment should not normally carry on for more than 3 months after the iron deficiency has been corrected. Your doctor will advise you when to stop.

### **Dosage**

Take this medicine by mouth.

**SHAKE THE BOTTLE WELL BEFORE USE.**

**Adults, the elderly and children over 12 years:**

- **To prevent iron deficiency** take two 5 ml spoonfuls once a day.
- **To treat iron deficiency** take two 5 ml spoonfuls twice a day.

### **Children under 12 and infants**

- The doctor will decide how much to give your child. Follow the instructions on the pharmacist's label.
- Prolonged use in children should be supervised by the doctor, as excessive use may lead to dangerous levels of iron in the blood.



#### **If you take more Galfer Oral Suspension than you should**

If you accidentally take too much, see a doctor **immediately as an overdose may be fatal.**

Take the pack with you to show which medicine you have swallowed.



#### **If you forget to take Galfer Oral Suspension**

Take the next dose as soon as you remember.

You can then carry on with the next dose at the correct time.

**Do not** take a double dose to make up for a 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, this medicine can cause side effects, although not everybody gets them.

### **Important side effects:**

If you think you have any of the following side effects or symptoms, stop using this medicine immediately and see a doctor as soon as possible.

- Allergic reactions which cause difficulty in breathing, fever, swelling of the mouth, lips or skin, severe rashes, itching or stomach pain.

### **Other possible side effects:**

- Loss of appetite.
- Feeling sick.

- Sickness.
- Stomach discomfort.
- Constipation, particularly in the elderly.
- Diarrhoea, particularly in those with bowel complaints.
- Darkening of the stools.
- Blackening of the teeth.

If any of the side effects gets serious or you notice any side effect not included above, stop use and tell your doctor or pharmacist. They will tell you what to do.

### **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 national reporting system:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Galfer Oral Suspension**

- **This product contains Iron, keep it out of the sight and reach of children as overdose may be fatal.**
- Do not store above 25°C
- 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. Use within 28 days of first opening.
- 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 Galfer Oral Suspension contains**

##### **The active substance per 5 ml is:**

ferrous fumarate 140 mg (equivalent to 45 mg of elemental iron).

##### **The other ingredients are:**

Aluminium magnesium silicate, parahydroxybenzoates (E215, E219), citric acid (E330), liquid maltitol, chocolate flavour (contains milk (lactose), ethanol, propylene glycol (E1520), benzyl alcohol (E1519), sodium benzoate (E211)), peppermint flavour (contains propylene glycol (E1520), benzyl alcohol (E1519)) and purified water.

#### **What Galfer Oral Suspension looks like and contents of the pack**

Galfer Oral Suspension is a thick brown liquid with a minty chocolate flavour. It is supplied in 100 ml bottles.

#### **Marketing authorisation holder and manufacturer**

Clonmel Healthcare Ltd., Waterford Road, Clonmel, Co. Tipperary, E91 D768, Ireland.

#### **This leaflet was last revised in June 2021**

Galfer is a trade mark of Thornton and Ross Ltd.