#### PACKAGE LEAFLET: INFORMATION FOR THF USFR Galfer 140mg/5ml Oral Suspension ferrous fumarate

Read all of this leaflet carefully because it

contains important information for 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.
- You must contact your doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if vou notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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## 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. Before you take Galfer Oral Suspension

- Do not take the medicine if you or
- vour child have....
- An alleray 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.
- 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.

## A Taking other medicines....

Please tell your pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. 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
- Levothvroxine for thvroid problems.

# 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.

## 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.

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

- This medicine contains 10g of liquid maltitol per 10ml dose (calorific value 2.3kcal/g). This may have a mild laxative effect. If you have been told by your doctor that you have an intolerance to some sugars. contact your doctor before taking this medicine.
- It also contains sodium hydroxybenzoates which may cause an allergic reaction (possibly delayed).
- 3. How to take Galfer Oral Suspension
- Important things you need to know first 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. You doctor will advise you when to stop.

# **O** 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 5ml

spoonfuls once a day. To treat iron deficiency take two 5ml 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 **A** 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

#### If you forget to take Galfer Oral **L** 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 the one missed.

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Turn over 🕉

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Product	Galfer 140mg/5r	ml Oral	Galfer 140mg/5ml Oral Suspension Irish Colours Used	0 U	lours Used	Fonts Used
Title					Process Black	Helvetica
Component	Leaflet				Keyline (Does not print)	
Pack Size	100ml					
IG Code	23195709					
Dimensions	Dimensions 338 x 148mm flat (29 x 148mm folded)	at (29 x	148mm folded)			
Proof No.	3 D	Date	Date 07.07.2015			

## 4. Possible side effects

Like all medicines, Galfer Oral Suspension 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine. Ireland HPRA Pharmacovigilance Earlsfoot Terrace IRL - Dublin 2 Tel : +35316764971 Fax : +35316762517 Website : www.hpra.ie email : medsafety@hpra.ie

- 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 after the expiry date shown on the carton. The expiry date refers to the last day of that month.
- Medicine should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Further information

#### What is in this medicine

#### The active ingredient per 5ml is:

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

#### The other ingredients are:

aluminium magnesium silicate, sodium methyl hydroxybenzoate (E219), sodium ethyl hydroxybenzoate (E215), sodium propyl hydroxybenzoate (E217), citric acid (E330), liquid maltitol (E965), chocolate and peppermint flavours and purified water.

#### What the medicine looks like

Galfer Oral Suspension is a thick brown liquid with a minty chocolate flavour. It is supplied in 100ml bottles. Marketing authorisation holder and manufacturer Thornton and Ross Ltd., Huddersfield, HD7 5QH, UK. This leaflet was last revised in July 2015 Galfer is a trade mark of Thornton and Ross Ltd.

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