

PACKAGE LEAFLET: INFORMATION FOR THE USER

Galfer 305mg Hard Capsules

ferrous fumarate 305mg

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 Capsules 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 you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Galfer Capsules are and what they are used for
2. Before you take Galfer Capsules
3. How to take Galfer Capsules
4. Possible side effects
5. How to store Galfer Capsules
6. Further information

1. What Galfer Capsules are and what they are used for

Galfer Capsules contains ferrous fumarate which is used to replace low levels of iron in the blood. They are 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 Capsules

✗ Do not take the medicine if you 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**.
- **Inflammatory bowel disease** including **ulcerative colitis** or **regional enteritis**.
- Had **repeated blood transfusions** in the past.
- **Anaemia not related to low levels of iron before**.
- Or are currently **having iron injections**.

⚠ Take special care with Galfer Capsules if you have....

- A history of stomach ulcers.
- Had part or all of the stomach removed.
- Vitamin deficiency particularly vitamin B₁₂ or folic acid.
- Or are a **male**, as iron deficiency is less common in men than women, and the causes may need investigating further by the doctor.
- People having tests on stool samples should tell the doctor as this medicine may turn stools black and affect test results.

Talk to your doctor or pharmacist before you take Galfer Capsules.

⚠ 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 are taking any of the following talk to your doctor before taking Galfer Capsules.

- Antibiotics for infections such as tetracyclines (e.g. oxytetracycline) or fluoroquinolones (e.g. ciprofloxacin).
- Penicillamine for arthritis.
- Indigestion remedies, calcium supplements and zinc.
- Levodopa, carbidopa or entacapone for Parkinsons Disease.
- Bisphosphonates for osteoporosis.
- Trientine for Wilsons Disease.
- Methylodopa for high blood pressure.

⚠ Pregnancy and breast-feeding....

You can take Galfer Capsules when pregnant or breastfeeding. Talk to your doctor first before using the medicine particularly if you are in the first 3 months of pregnancy. You may also need to take folic acid.

3. How to take Galfer Capsules

i Important things you need to know first....

- Take this medicine before meals on an empty stomach if possible. If Galfer Capsules 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.

Turn over ↗

24176606
PM/20/374



Product Title		Galfer 305mg Hard Capsules Irish (Custom)	
Component	Leaflet		
Pack Size	28's		
IG Code	24176606		
Dimensions	210mm x 148mm		
Proof No.	3	Date	18.09.2014
Colours Used		Process Black	
Fonts Used		Helvetica	
		Keyline (Does not print)	

MHRA Header Box

How to take (continued)

- Galfer Capsules may make your stools darker than usual. This is a normal effect of medicines containing iron.
- 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.

i Dosage

Take this medicine by mouth.

Adults, the elderly and children over 12 years:

- **To prevent iron deficiency** take one capsule a day.
- **To treat iron deficiency** take one capsule twice a day.

i Children under 12 years:

Do not give to children under 12 unless your doctor tells you to.

⚠ If you take more Galfer Capsules than you should

If you accidentally take too much, see a doctor immediately. Take the pack with you to show which medicine you have swallowed.

⚠ If you forget to take Galfer Capsules

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.

4. Possible side effects

Like all medicines, Galfer capsules 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.
- Diarrhoea.
- Darkening of the stools.

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 Capsules

• 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.
- Store in the original packaging.
- 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 capsule is: ferrous fumarate 305mg (equivalent to 100mg of elemental iron).

The other ingredients are:

microcrystalline cellulose, gelatin and colours: quinoline yellow (E104), erythrosine (E127), indigotine (E132) and titanium dioxide (E171).

What the medicine looks like

Galfer Capsules are scarlet and green hard gelatin capsules.

They are supplied in blister packs of 28.

Marketing authorisation holder:

Thornton and Ross Ltd., Huddersfield, HD7 5QH, UK.

Manufacturer:

Custom Pharmaceuticals Ltd., Conway Street, Hove, East Sussex, BN3 3LW.

This leaflet was last approved in January 2015.

Galfer is a trade mark of Thornton and Ross Ltd.

24176606
PM/20/374

PCPHeader Box

Operator	gill.kennedy		Approved by Date
Artwork No	532025		
CRN	11407	Suffix	A
Reason for Change	Addition of reporting of side effects in line with QRD template.		
			Issued by Date
MHRA/IMB submission required	Yes		

FRONT FACE

REVERSE FACE

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(continued)

Turn over ↗
24179005

MHRA Header Box

Product Title	Galfer 305mg Hard Capsules Irish (Strides)	Leaflet	28's	24179005	210mm x 148mm	3	18.09.2014
Component							
Pack Size							
IG Code							
Dimensions							
Proof No.							
Colours Used	Process Black	Keyline (Does not print)					
Fonts Used	Helvetica						

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Tel : +35316764971
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email : medsafety@hpra.ie

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24179005

PCPHeader Box

Operator	gill.kennedy			Approved by
Artwork No	532024			Date
CRN	11407	Suffix	B	
Reason for Change	Addition of reporting of side effects in line with QRD template.			
				Issued by
				Date
MHRA/IMB submission required	Yes			

24179005