

Product Name		Galfer FA 305mg/0.35mg Hard Capsules			Packaging Type	Leaflet		
Category/PL No.		PA 610/13/1			Text revision no.	0	Page #	1 of 4
Component	Pack size	IG Code:	Current V#:	New V#:	Revised by:	Date:		
Leaflet	28's	9279682	1803	1903				
					Authorised by:	Date:		
CRN	Description							
15907	Transfer license to Clonmel for Brexit							

PACKAGE LEAFLET: INFORMATION FOR THE USER

Galfer FA 305mg/0.35mg Hard Capsules

ferrous fumarate

folic acid

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

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

Galfer FA Capsules contain ferrous fumarate which is used to replace low levels of iron in the blood. They also contain folic acid.

They are used to treat and prevent anaemia during pregnancy caused by iron deficiency.

They can also be used to prevent megaloblastic anaemia caused by deficiencies in vitamin B₁₂ or folic acid after the first 13 weeks of pregnancy.

2. Before you take Galfer FA 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**.
- Had **repeated blood transfusions** in the past.
- **Anaemia not related to low levels of iron.**
- **Vitamin B₁₂ deficiency.**
- Are currently **having iron injections.**
- Are **not pregnant.**
- Or are **under 12 years old.**

Product Name	Galfer FA 305mg/0.35mg Hard Capsules	Category/PL No.	PA 610/13/1	
		Text revision no.	0	Page # 2 of 4

Take special care with Galfer FA Capsules....

- People having tests on stool samples should tell the doctor as this medicine may turn stools black and affect test results.
- People with erythropoietic protoporphyria, a rare condition affecting red blood cells, should talk to the doctor.

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 FA Capsules.

- Antibiotics for infections such as neomycin, cefdinir, chloramphenicol, tetracyclines (e.g. oxytetracycline) or fluoroquinolones (e.g. ciprofloxacin).
- Penicillamine for arthritis.
- Indigestion remedies (e.g. antacids, magnesium salts), calcium supplements, zinc, phosphates, oxalates and proton pump inhibitors to reduce stomach acid.
- Levodopa, carbidopa or entacapone for Parkinson's Disease.
- Bisphosphonates for osteoporosis.
- Trientine for Wilson's Disease.
- Methyldopa for high blood pressure.
- Medicine to control fits e.g. phenobarbital, phenytoin, primidone.
- Colestyramine mainly used for high cholesterol.
- Ascorbic or citric acids as these increase absorption of iron.
- Acetohydroxamic acid to treat some urinary tract problems.
- Dimercaprol used to treat effects of heavy metal poisoning.
- Levothyroxine for an underactive thyroid gland.
- Mycophenolate, an immunosuppressant drug.
- Eltrombopag for blood platelet problems.
- Raltitrexed, an anticancer drug.
- Sulfasalazine to treat some bowel diseases and rheumatoid arthritis.

Allow 2-3 hours between taking this and other medicines (or 4 hours for Eltrombopag).

Pregnancy and breast-feeding....

You can take Galfer FA 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.

3. How to take Galfer FA Capsules

Important things you need to know first....

- Take this medicine before meals on an empty stomach if possible. If Galfer FA Capsules upsets your stomach, take it with or after food.
- Some foods such as tea, coffee, wholegrain cereals, eggs and milk may reduce the amount of iron absorbed by the body. Check with the doctor or pharmacist about which foods to avoid.
- Allow 2-3 hours between taking this and other medicines (see section 2).

Product Name	Galfer FA 305mg/0.35mg Hard Capsules	Category/PL No.	PA 610/13/1	
		Text revision no.	0	Page # 3 of 4

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

Dosage

Take this medicine by mouth.

Adults:

- Take one capsule a day after the first 13 weeks of pregnancy and during the first month after the baby is born.

Children:

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

If you take more Galfer FA 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 FA 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 FA 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 (including severe anaphylactic reactions) which cause difficulty in breathing, fever, swelling of the mouth, lips or skin, severe rashes, itching or stomach pain.

Other possible side effects:

- Feeling sick or being sick.
- Gastrointestinal disturbances (stomach discomfort).
- Constipation.
- Diarrhoea.

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

Earlsfort Terrace

IRL – Dublin 2

Tel : +35316764971

Product Name	Galfer FA 305mg/0.35mg Hard Capsules	Category/PL No.	PA 610/13/1	
		Text revision no.	0	Page # 4 of 4

Fax : +35316762517

Website : www.hpra.ie

Email : medsafety@hpra.ie

5. How to store Galfer FA 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) and folic acid 350 micrograms.

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 FA Capsules are scarlet and yellow hard gelatin capsules.

They are supplied in blister packs of 28.

Marketing authorisation holder:

Clonmel Healthcare Ltd,

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

Manufacturer:

Custom Pharmaceuticals Ltd.,

Conway Street, Hove, East Sussex, BN3 3LW.

This leaflet was last approved in May 2019.

Galfer is a trade mark of Thornton and Ross Ltd.