

PACKAGE LEAFLET: INFORMATION FOR THE USER

FEFOL[®] SPANSULE CAPSULES

Ferrous Sulfate 150 mg and folic acid 500 micrograms

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 it carefully to get the best results from it. Always take/use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- 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.

In this leaflet:

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

1. WHAT FEFOL IS AND WHAT IT IS USED FOR

FEFOL belongs to a group of medicines called iron supplements. This medicine works by replacing body iron. Iron is a mineral that the body needs to produce red blood cells. When the body does not get enough iron, it cannot produce the number of normal red blood cells needed to keep you in good health. This condition is called iron-deficiency anaemia.

FEFOL is used to prevent or treat iron deficiency anaemia and to prevent folic acid deficiency during pregnancy.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FEFOL

Do not take FEFOL and tell your doctor if you:

- are **allergic** (hypersensitive) to the active substances, iron salts, or any of the other ingredients of this medicine (listed in section 6).
- are receiving repeated **blood transfusions**.
- are receiving iron **intravenously**.
- have a disorder in which there is **excessive absorption and storage of iron** such as haemochromatosis

Warnings and precautions

Due to the risk of mouth ulceration and tooth discolouration, capsules should not be sucked, chewed or kept in the mouth but swallowed whole with water. If you cannot follow this instruction or have difficulty swallowing, please contact your doctor.

This medicine is not recommended for children or elderly patients.

Talk to your doctor or pharmacist before taking Fefol if you have:

- **haemochromatosis** - a hereditary disorder in which excessive amounts of iron accumulate in the body tissues
- **haemolytic anaemia** - a blood disorder characterised by low number of red blood cells
- a **blood disease** (haemoglobinopathy)
- **red cell aplasia** - a blood disorder where there is no production of red blood cells
- **Vitamin B12 deficiency** or any other blood disorder
- **gastrointestinal disease**

Other medicines and FEFOL:

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription. Especially:

- tetracyclines (to treat infections)
- ciprofloxacin, norfloxacin, ofloxacin (to treat infections)
- colestyramine
- antacids (containing magnesium or aluminium, medicines used to neutralise acidity, especially in the stomach)
- medicines containing zinc, calcium, phosphorus or trientine
- methyl dopa (to treat high blood pressure)

- penicillamine (medicine used to treat rheumatoid arthritis)
- levodopa (for Parkinson's disease)
- ascorbic acid (vitamin C)
- iron-binding agents such as phosphates, oxalates and components of tea, coffee and milk which can impair the absorption of iron
- bisphosphonates (such as alendronic acid or disodium etidronate) used generally for osteoporosis
- dimercaprol used for the treatment of acute poisoning by certain heavy metals
- thyroid hormones such as levothyroxine used for the treatment of an under active thyroid. Oral iron reduces the absorption of levothyroxine (thyroxine) thus should be taken at least 2 hours apart.

Pregnancy and breast-feeding

This medicine is recommended for use during pregnancy and whilst 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.

FEFOL Spansule Capsules contains sucrose

Your medicine contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Driving and using machines

FEFOL does not affect your ability to drive or operate machinery.

3. HOW TO TAKE FEFOL

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

FEFOL should not be taken within one hour before or two hours after eating or drinking the following products: tea, coffee, milk, eggs and whole grains. These products can reduce the absorption of iron. Meat and products containing vitamin C can increase the absorption of iron. Follow the advice of your dietician or doctor when taking FEFOL with any of the food or drink listed.

- **The usual dose** is one capsule per day. Some pregnant patients may need a higher dose of iron. Your doctor may prescribe you higher a dose of FEFOL if necessary.
- **Swallow the whole** capsule with a glass of water. Although iron preparations are best absorbed on an empty stomach, they may be taken after food to reduce gastrointestinal side effects.

Do not chew or suck the capsule or keep in your mouth as side effects may be increased.

Alternatively, the capsule may be opened and the pellets mixed with soft, cool food, but they must not be chewed or sucked.

This medicine is not recommended for children or elderly patients.

Your doctor or pharmacist can advise you on how long you should continue treatment.

If you take more FEFOL than you should:

If you (or someone else) swallow a lot of capsules at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately.

Overdose in case of children may be fatal.

Symptoms of an overdose include:

- Up to 24 hours: stomach and intestinal poisoning including being sick and diarrhoea, heart disorders such as low blood pressure (hypotension) and a racing heart (tachycardia), metabolic changes such as too much acid in the body (acidosis) and high blood sugar (hyperglycaemia), nervous system depression ranging from tiredness to coma, temporary relief of symptoms may occur.
- After 24 hours: stomach and intestinal poisoning and obstruction, shock, too much acid in the body (acidosis), fits, coma, liver failure, jaundice (yellowing of the skin or whites of the eyes), low blood sugar, problems with blood clotting, low production of urine, kidney failure, fluid in the lungs.

If you forget to take FEFOL

If you forget to take a dose, take the missed dose as soon as you remember. If your next dose is due within the next two hours, take a single dose straight away and skip the next. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, FEFOL can cause side effects although not everybody gets them.

If you get any of the following serious side effects, contact your doctor straight away or seek emergency help immediately:

Allergic reactions, e.g. skin rashes, swelling of the face, lips, tongue or throat, breathlessness and/or collapse.

FEFOL may also cause the following:

- Gastro-intestinal irritation (upset stomach)
- stomach -pain
- feeling sick (nausea) or being sick (vomiting)
- constipation (occasionally faecal impaction)
- diarrhoea
- blackening of the stools

Not known (Frequency cannot be estimated from the available data)

Mouth ulceration (In case of incorrect use, when capsules are chewed, sucked or left in the mouth)

Elderly patients and patients with difficulty swallowing may also be at risk of ulceration of the throat, oesophagus (the tube that connects your mouth with your stomach) or bronchus (the major air passages of the lungs) if the capsule enters the airways.

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 Yellow Card Scheme (www.mhra.gov.uk/yellowcard).

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

5. HOW TO STORE FEFOL

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

Do not store above 25°C.

Keep the capsules in the carton in order to protect from light.

Do not take this medicine after the expiry date shown on the pack. The expiry date refers to the last day of that month.

If you notice any visible signs of deterioration such as broken capsules, take them to your pharmacist for advice before taking them.

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 FEFOL contains:

The active ingredients are: ferrous sulfate 150mg (equivalent to 47mg iron) and folic acid 500 micrograms.

The inactive ingredients are sucrose, maize starch, talc, heavy kaolin, gelatin, titanium dioxide (E171), red iron oxide (E172), povidone 30, glycerol monostearate, white beeswax, calcium sulphate dihydrate, quinoline yellow (E104) and patent blue V (E131).

What FEFOL looks like and contents of the pack:

The capsules are clear and green with red, yellow and white pellets inside.

Blister packs of 30 capsules.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

Henley Laboratories Limited

The Station House

Station Road

Whalley

Clitheroe

BB7 9RT

United Kingdom

Manufacturer

Intrapharm Laboratories Ltd

The Courtyard Barns

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