

Patient information leaflet

FEFOL[®] SPANSULE CAPSULES

Ferrous Sulphate 150 mg and folic acid 500 micrograms

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 it carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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 Fefol is and what it is used for
2. Before you take Fefol
3. How to take Fefol
4. Possible side effects
5. How to store Fefol
6. Further information

1. WHAT FEFOL IS AND WHAT IT IS USED FOR

Fefol belongs to a group of medicines known as haematinics, which improve the blood's ability to carry oxygen. They do this by increasing the amount of haemoglobin, the iron-containing respiratory pigment, which is carried in the red blood cells. Fefol is used to prevent iron and folic acid deficiency during pregnancy, after the first thirteen weeks.

2. BEFORE YOU TAKE FEFOL

Do not take Fefol if you:

- are **allergic** (hypersensitive) to Fefol or any of its ingredients
- are **less than 13 weeks** pregnant
- have **too much iron** in your body

Important information about some of the ingredients of Fefol

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.

This medicine should not be given to children or elderly patients.

Take special care with Fefol and inform your doctor if you:

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

Taking other medicines

You should tell your doctor if you are taking or have taken any of the following medicines as they may interact with Fefol:

- tetracyclines (antibiotics)
- antacids (medicines used to neutralise acidity, especially in the stomach)
- penicillamine (medicine used to treat severe arthritis)

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

Food and drink

The effect of Fefol may be reduced if taken with tea, coffee, eggs or milk.

Artwork Specification

Company	Intrapharm Laboratories Ltd
Product	Fefol Spansule Capsules
Volume/ Size	30 capsules / leaflet
Dimensions	148mm x 210mm
Date created	27/02/13
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Colours:

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Pregnancy and breast-feeding

Do not use this medicine during the first thirteen weeks of pregnancy. Your doctor will decide if you need to take this medicine during the remaining period of pregnancy.

Driving and using machines

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

3. HOW TO TAKE FEFOL

- **The usual dose** is one capsule per day after 13 weeks of pregnancy. 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. **Do not chew or suck the capsule** 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 should not be given to children or elderly patients.

If you take more Fefol than you should:

This product contains iron. Keep out of the reach of children. If you or someone else has taken too many Fefol capsules contact your doctor or local hospital immediately.

Overdose in case of children may be fatal.

Early signs (up to 6 hours after taking the capsules) of overdose include:

- stomach pain
- diarrhoea
- feeling and being sick
- blood present in the vomit or stool

Other signs include:

- collapse of the body's circulation (shock)
- liver damage
- kidney failure
- fits
- coma
- lack of desire to do anything
- bleeding in the stomach
- jaundice
- fluid on the lungs
- low blood sugar
- blood disorders (clotting disorders)
- excessive acidity of the blood
- pyloric stenosis - narrowing of part of the stomach which leads into the small intestine

If you forget to take Fefol

Take that dose as soon as you remember. Then take the next dose at the usual 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Fefol can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you experience any of the following symptoms:

- difficulty in breathing
- rash affecting your body
- if you collapse

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If you experience the following symptoms while you are taking this medicine contact your doctor as soon as possible:

- upset stomach
- stomach discomfort
- loss of appetite
- feeling sick or being sick
- constipation
- diarrhoea
- darkening of the stools

If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE FEFOL

Keep out of the reach and sight of children.

Do not store above 25° C.

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

Do not use after the expiry date on the pack.

6. FURTHER INFORMATION

What Fefol contains:

The active ingredients are: ferrous sulphate 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:

Intrapharm Laboratories Ltd
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Choke Lane
Cookham Dean
Maidenhead
Berkshire SL6 6PT
United Kingdom

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