

**Fefol Spansule 150 mg/ 0.5 mg Modified Release Capsules**  
**Package leaflet text 29/10/2020**

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FEFOL SPANSULE CAPSULES 150 mg/0.5 mg MODIFIED RELEASE CAPSULES  
Dried Ferrous Sulphate and Folic Acid

**PATIENT INFORMATION LEAFLET**

This leaflet contains a summary of the information about Fefol Spansule Capsules. Please read it before using the capsules and do not throw it away until you have finished your course of treatment; you may wish to read it again. If you have any questions about this medicine, please ask your doctor or pharmacist.

**What is in your medicine?**

The name of your medicine is Fefol Spansule 150 mg/0.5 mg Modified Release Capsules. The capsules are clear and green with red, yellow and white pellets inside. The box contains 30 capsules.

Each hard capsule contains 150 mg dried ferrous sulphate (equivalent to 47mg iron) and 0.5 mg folic acid as the active ingredients.

Fefol Spansule Capsules also contain, 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).

Fefol Spansule Capsules are one of 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 which is carried in the red blood cells.

**Marketing Authorisation Holder**

Intapharm Labs Ltd  
Achamon 25  
Lakatamia  
2305 Nicosia  
Cyprus

**Manufacturer**

Movianto Ltd, Progress Park  
Elstow, Bedford, MK42 9XE, UK

**What is your medicine used for?**

Fefol Spansule Capsules are used to prevent iron and folic acid deficiency during pregnancy, after the first thirteen weeks.

**Before using this medicine**

Fefol Spansule capsules contain 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.

Before you use this medicine, please answer the following questions:

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- Are you less than thirteen weeks pregnant?
- Have you used this medicine before and suffered a reaction to it, or been told you are allergic to Fefol Spansule Capsules?
- Are you allergic to any of the ingredients?
- Have you been told you suffer from Vitamin B12 deficiency, or any other blood disorder?
- Do you or other members of your family have too much iron in the body e.g from haemochromatosis?
- Do you or other members of your family have any other blood disorders e.g. haemolytic anaemia, red cell aplasia?
- Are you taking any other medicines, especially antibiotics, (tetracyclines), antacids, thyroxine, dopamine precursors, drugs used for epilepsy or penicillamine (used for rheumatoid arthritis)?

If the answer to any questions is YES, you must tell your doctor immediately, BEFORE taking this medicine. Your doctor can advise you what to do.

**How to use this medicine**

- 1) One capsule should be taken daily after thirteen weeks of pregnancy, or as directed by your doctor.
- 2) The capsules should be swallowed whole with a glass of water and not chewed or sucked. The effect of Fefol Spansule Capsules may be reduced if taken with tea, coffee, eggs or milk. If you are unable to swallow the capsules the contents may be sprinkled onto soft, cool food and swallowed, but not chewed.
- 3) Some pregnant patients may need a higher dose of iron and should seek the advice of their doctor

**DO NOT EXCEED THE STATED DOSE.**

Keep taking this medicine for as long as your doctor tells you to, even if you feel better.

**What to do if you take too many**

This product contains iron. Keep out of the reach and sight of children as overdose may be fatal. If you or someone else takes too many capsules contact your doctor or local hospital emergency department immediately.

Signs and symptoms of an iron overdose include stomach pain, diarrhoea, feeling and being sick, blood present in the vomit and collapse. In severe cases, iron overdose can cause brain disease, liver damage or kidney failure.

**What to do if you miss a dose**

If you miss a dose, take one when you remember, but never take two doses on the same day. If you miss several doses, take a single dose and let your doctor know when you next see him or her.

**Possible side effects**

This medicine can cause upset stomach, stomach discomfort, loss of appetite, sickness, constipation or diarrhoea. Darkening of the stools may occur. Rarely this medicine can cause an allergic reaction which may be a rash, shortness of breath or collapse.

This medicine may cause severe allergic reaction (anaphylactic reaction). The frequency is not known.

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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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**Storage of your medicine**

Do not store above 25°C and store in the original package to protect from light and moisture.

**KEEP THIS AND ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN**

Do not use after the Use-by date on the carton and blister strips.

**What to do with unused capsules**

If your doctor decides to stop your medicine, or you have some left at the end of treatment, return any unused capsules to your pharmacist for safe disposal.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist who will have the information you need.

This information applies only to Fefol Spansule Capsules.

**This leaflet was last revised in October 2020.**