Package leaflet: Information for the user

FEOSPAN® SPANSULE CAPSULES
Dried Ferrous sulfate 150 mg

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.

What is in this leaflet:
1. What Feospan is and what it is used for
2. What you need to know before you take Feospan
3. How to take Feospan
4. Possible side effects
5. How to store Feospan
6. Contents of the pack and other information

1. WHAT FEOSPAN IS AND WHAT IT IS USED FOR

Feospan 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.

Feospan is used to prevent or treat iron deficiency anaemia.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FEOSPAN

Do not take Feospan and tell your doctor if you:
• are allergic to the active substance, 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.

Talk to your doctor or pharmacist before taking Feospan if you have:
• haemolytic anaemia
• a blood disease (haemoglobinopathy)
• haemochromatosis - a hereditary disorder in which excessive amounts of iron accumulate in the body tissues
• gastrointestinal disease

This medicine should not be given to children under 1 year.

Other medicines and Feospan
Tell your doctor or pharmacist if you are taking, 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
• methyldopa (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.

Feospan Spansule Capsules contains Sucrose and Sunset Yellow (E110)
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 medicine.
Your medicine also contains a small amount of the inactive ingredient called sunset yellow (E110) and may cause allergic reactions.

3. HOW TO TAKE FEOSPAN

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

Food and drink
Feospan 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 Feospan with any of the food or drink listed.

Swallow the whole capsule with a glass of water. Do not suck, chew or keep the capsule in your mouth. Although iron preparations are best absorbed on an empty stomach, they may be taken after food to reduce gastrointestinal side effects.

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

The recommended dose is:
Adults: one capsule per day. In more severe cases 2 capsules a day may be required.

Elderly patients: dosage as above.

Use in children over 1 year and adolescents: one capsule a day
This medicine should not be given to children under 1 year.

Do not exceed the stated dose.

An overdose in children could be fatal.
Your doctor or pharmacist can advise you on how long you should continue treatment.

If you take more Feospan 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.

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 Feospan

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, Feospan 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.
- 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.

Feospan may also cause the following:

- Gastro-intestinal irritation (Stomach upset)
- Stomach pains
- Feeling sick (nausea) or being sick (vomiting)
- Diarrhoea and constipation (occasionally faecal impaction)
- Blackening of the stools

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 at: 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 FEOSPAN

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 Feospan contains

The active ingredient is: dried ferrous sulfate 150 mg (equivalent to 47 mg iron).

The inactive ingredients are maize starch, sucrose, talc, heavy kaolin, gelatin, titanium dioxide (E171), red iron oxide (E172), povidone 30, glycerol monostearate, white beeswax, quinoline yellow (E104), indigo carmine (E132), sunset yellow (E110), erythrosine (E127) and patent blue V (E131).

See end of section 2 for further information on sucrose and sunset yellow (E110).

What Feospan looks like and contents of the pack

The capsules are clear and red with red and green pellets inside.

Blisters packs of 30.

Marketing Authorisation Holder and Manufacturer

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