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Package Leaflet: Information for the patient

Ferrous sulfate 200 mg film-coated tablets

ferrous sulfate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take 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.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse

What is in this leaflet:

1. What Ferrous sulfate tablets are and what they are used for
2. What you need to know before you take Ferrous sulfate tablets
3. How to take Ferrous sulfate tablets
4. Possible side effects
5. How to store Ferrous sulfate tablets
6. Contents of the pack and other information

1. What Ferrous sulfate tablets are and what they are used for

The name of your medicine is Ferrous sulfate 200 mg film-coated tablets. These tablets contain iron, a mineral essential in the production of red blood cells. Ferrous sulfate tablets are used to treat anaemia caused by lack of iron in the diet or loss of iron from the body.

2. What you need to know before you take Ferrous sulfate tablets

Do not take Ferrous sulfate tablets:

- if you are allergic to ferrous sulfate or any of the other ingredients of this medicine (listed in section 6)
- if you notice blood in your urine (Paroxysmal nocturnal haemoglobinuria)
- if you suffer from iron storage disease, where the body contains more iron than it should (conditions such as haemosiderosis, haemochromatosis)
- if you suffer from an active stomach ulcer (peptic ulcer)
- if you suffer from inflammation which causes abdominal pain or diarrhoea (ulcerative colitis) or any other inflammatory condition of the bowels (regional enteritis)
- if you have had repeated blood transfusion
- If you suffer from haemolytic anaemia (anaemia due to destruction of red blood cells)
- if you are already being treated with iron supplements.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ferrous sulfate tablets:

- if you have had a gastrectomy (operation to remove all or part of the stomach)
- if you have a history of stomach ulcer
- if you suffer from diabetes
- if you have suffered from inflammatory bowel disease
- if you suffer from diverticular disease (where pouches form in the bowel wall)
- if you suffer from iron overload
- if you suffer from intestinal strictures (abnormal narrowing of the bowel often caused by inflammation)
- if you have co-existing deficiency of vitamin B₁₂ or folic acid since combined deficiency produces microcytic blood film
- if you have difficulties swallowing.

Due to the risk of mouth ulceration and tooth

discolouration, tablets 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.

If you accidentally choke on a tablet, please contact your doctor as soon as possible. This is because there is a risk of ulcers and narrowing of the bronchus occurring if the tablet enters the airways. This may result in persistent coughing, coughing up blood and/or feeling out of breath, even if the choking happened days to months before these symptoms occurred. Therefore you need to be urgently assessed to make sure that the tablet doesn't damage your airways.

Children and adolescents

Ferrous sulfate tablets are not recommended for use in children and adolescents.

Other medicines and Ferrous sulfate tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription

The following medicines can affect or be affected by treatment with Ferrous sulfate tablets:

- medicines used to treat indigestion (antacids and mineral supplements e.g. calcium, magnesium, bicarbonates, carbonates, oxalates and phosphates). It is important not to take this medicine for two hours before or after taking Ferrous sulfate tablets.
- medicines used to treat bacterial infections (antibiotics e.g. tetracyclines, quinolones, and chloramphenicol). It is important not to take this medicine for two hours before or after taking Ferrous sulfate tablets.
- zinc supplements
- penicillamine used to treat rheumatoid disease
- trientine used in Wilson's disease, a disorder where your body stores too much copper. It is important not to take this medicine for two hours before or after taking Ferrous sulfate tablets.
- medicines used to treat bone problems e.g. bisphosphonates. It is important not to take this medicine for two hours before or after taking Ferrous sulfate tablets.
- medicines used to treat Parkinsonism (e.g. co-careldopa, entacapone and levodopa)
- levothyroxine used to treat under-active thyroid glands. It is important not to take this medicine for two hours before or after taking Ferrous sulfate tablets.
- methyldopa used to treat high blood pressure
- colestyramine used to treat high blood cholesterol and itching caused by liver disease
- dimercaprol used to treat metal poisoning
- mycophenolate mofetil used to suppress the immune system and stop organ rejection after transplant.

Ferrous sulfate tablets with food and drink

Do not take this medicine with tea, eggs or milk as they reduce its absorption in the stomach.

Pregnancy, breast-feeding and fertility

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.

During the first 12 weeks of pregnancy only take this medicine if your doctor has specifically recommended it. For the remainder of the pregnancy Ferrous sulfate tablets can be taken to prevent iron deficiency.

Ask your doctor or pharmacist before taking any medicine.

Driving and using machines

This medicine does not affect your ability to drive a car or operate machinery.

Ferrous sulfate tablets contains sodium and aspartame

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say it is essentially 'sodium-free'. This medicine contains 0.08 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take Ferrous sulfate tablets

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

Swallow the tablet whole with water. Do not suck, chew or keep the tablet in your mouth.

Adults and Elderly:

Prevention of Iron-deficiency Anaemia: One tablet daily.
Treatment of Iron-deficiency Anaemia: One tablet two to three times daily

- Take Ferrous sulfate tablets by mouth
- Ferrous sulfate tablets should not be taken with tea, milk or eggs

Treatment should not last more than three months after anaemia is controlled.

If you take more Ferrous sulfate tablets than you should

If you take more Ferrous sulfate tablets than you should, contact your doctor or go to the nearest hospital casualty department immediately. Take this leaflet with you so your doctor will know what you have taken.

Symptoms of overdose include abdominal pain, nausea, vomiting and vomiting blood (haematemesis).

If you forget to take Ferrous sulfate tablets

If you forget a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

Serious side effects:

As can happen with any medicine; a few people may develop an allergic reaction. If you experience any of the following, seek medical help immediately:

- rash, itching, or difficulty breathing.

Other side effects:

Other side effects that have been reported are:

- upset stomach
- stomach pain
- feeling or being sick
- diarrhoea
- constipation
- darkening of stools
- loss of appetite.

Irritation and ulceration of the gullet can occur if the tablets become stuck, so take with water.

If you take this medicine for longer than you should, you are at increased risk of tooth decay and infections.

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

Mouth ulceration (in case of incorrect use, when tablets are chewed, sucked or left in the mouth). All patients,

but especially elderly patients and patients with difficulties swallowing may also be at risk of ulceration of the throat or the esophagus (the tube that connects your mouth with your stomach). If the tablet enters the airways, there may be a risk of ulceration of the bronchus (the major air passages of the lungs), resulting in bronchial narrowing.

If you experience any side effects or feel that the medicine is affecting you badly, tell your doctor or pharmacist immediately.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ferrous sulfate tablets

- Keep this medicine out of the sight and reach of children.
- Keep tightly closed, do not store above 25 °C.
- Do not use this medicine after the expiry date which is stated on the outer packaging after 'EXP'. The expiry date refers to the last day of that month.

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 Ferrous sulfate 200 mg film-coated tablets contain:

- The active ingredient is dried ferrous sulfate 200 mg (equivalent to 65 mg Ferrous Iron (Fe II)).
- The other ingredients are microcrystalline cellulose (E460(i)), pregelatinised starch, crospovidone, colloidal anhydrous silica, magnesium stearate (E572), polyvinyl alcohol (E1203), talc (E553B), titanium dioxide (E171), glycerol monocaprylocaprate (E471), sodium lauryl sulfate (E487), macrogol (PEG) polyvinyl alcohol graft-copolymer (E1209), aspartame (E951).

What Ferrous sulfate 200 mg film-coated tablets look like and content of the pack:

- Ferrous sulfate 200 mg film-coated tablets are white round biconvex coated tablets, plain on both sides.
- The tablets are available in packs of 14, 15, 21, 28, 42, 50, 56, 70, 84, 100, 250, 500 or 1000 tablets and in blister strips of 14, 15, 21, 28, 42, 56, 70, 84 and 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Ferrous sulfate 200 mg film-coated tablets

Leaflet size	140 x 255 mm +/-0.5mm
Folded size	-
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Font - Subtitle	Swis Cond. 8pt. Bold
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Font - Color	Black, Pantone 286C
Line Spacing	88%
Paper	OP Medical Print 40g/mp
Pharmacode position	65mm from top/bottom
SAP Code	**
Revision No.	04
Fiber orientation	longitudinal
Pharmacode size	Standard laetus pharmacode

the pharmacodes must be symmetric and the distance between the edge and the pharmacode must be between 1,5 - 2,5 mm.

** - SAP code/Ed.