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Package leaflet: Information for the patient

# Ferrous Sulfate 200mg tablets

### 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.
  If you have any further questions, ask your doctor
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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

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# What Ferrous Sulfate tablets are and what they are used for

Ferrous Sulfate tablets belong to a group of medicines called iron supplements. These medicines work 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.

Ferrous Sulfate tablets are used for the prevention and treatment of iron-deficiency anaemia.

# What you need to know before you take Ferrous Sulfate tablets

#### Do not take Ferrous Sulfate tablets if you:

- are allergic to dried ferrous sulfate 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 haemosiderosis or haemochromatosis
- notice blood in your urine (paroxysmal nocturnal haemoglobinuria)
- have an active stomach ulcer (peptic ulcer)
- suffer from inflammation which causes abdominal pain or diarrhoea (ulcerative colitis) or any other inflammatory condition of the bowels (regional enteritis)

- suffer from **haemolytic anaemia** (anaemia due to destruction of red blood cells)
- · 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)
- history of stomach ulcer
- · diabetes
- · inflammatory bowel disease
- · diverticulicular disease (where pouches form in the bowel wall)
- intestinal strictures (abnormal narrowing of the bowel often caused by inflammation)
- co-existing deficiency of Vitamin B12 or folic acid
- haemoglobinopathies (blood disorders)
- · iron overload
- · difficulty 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.

#### Other medicines and Ferrous Sulfate tablets

**Tell your doctor or pharmacist** if you are taking, have recently taken or might take any other medicines, especially:

- penicilliamine (for rheumatoid arthritis)
- colestyramine (to treat high blood cholesterol)
- dimercaprol (for metal poisoning)
- medicines for Parkinsonism (e.g. co-careldopa, entacapone, levodopa)
- methyldopa (to treat high blood pressure)
- zinc or ascorbic acid (vitamin C) supplements
- mycophenolate mofetil (to suppress the immune system and stop organ rejection after transplant).

It is important not to take the following medicines for two hours before or after taking Ferrous Sulfate tablets:

- medicines to treat infections (e.g. tetracyclines, ciprofloxacin, levofloxacin, norfloxacin, ofloxacin, chloramphenicol, quinolones)
- medicines used to treat bone problems e.g. bisphosphonates
- medicines used to treat indigestion (antacids and mineral supplements containing calcium, magnesium, bicarbonates, carbonates, oxalates and phosphates)
- levothyroxine (for under-active thyroid glands)
- · trientine (for Wilson's disease).

#### Ferrous Sulfate tablets with food and drink

Ferrous Sulfate tablets should not be taken within one hour before or two hours after eating or drinking the following products: tea, 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 Ferrous Sulfate tablets with any of the food or drink listed.

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.

Ferrous Sulfate tablets contain glucose, sucrose and lactose If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## B How to take Ferrous Sulfate tablets

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

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

## The recommended dose is Adults and the elderly

Treatment: one tablet, two to three times daily. Prevention: one tablet a day.

#### Children 6-12 years

Treatment:

Treatment.

Children weighing over 22kg: one tablet a day.

Children weighing over 44kg: one tablet twice a day.

Children weighing over 66kg: one tablet three times a day.

Children under 6 years or weighing less than 22kg Not recommended.

## If you take more Ferrous Sulfate tablets than you should

If you (or someone else) swallow a lot of tablets 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 Ferrous Sulfate tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

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.

**Contact your doctor** at once if you have an allergic reaction e.g. itchy skin rash, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.

**Tell your doctor** if you notice any of the following side effects: **Not known** (frequency cannot be estimated from the available data)

- constipation, diarrhoea, stomach pain, feeling sick, blackened stools, loss of appetite (the link between dose and altered bowel habit is not clear).
- irritation and ulceration of the gullet can occur if the tablets become stuck, so take with water
- increased risk of tooth decay and infections (during prolonged use)
- 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 difficulty swallowing may also be at risk of ulceration of the throat, oesophagus (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.

#### 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: <a href="https://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a> 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. Store below  $25^{\circ}$ C in a dry place.

Do not use this medicine after the expiry date which is stated on the label/carton/bottle. 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 require. These measures will help protect the environment.

# Contents of the pack and other information What Ferrous Sulfate tablets contain

- The active substance (the ingredient that makes the tablets work) is dried ferrous sulfate BP. Each tablet contains 200mg dried ferrous sulfate BP equivalent to 65mg ferrous iron.
- The other ingredients are spray dried liquid glucose, stearic acid, magnesium stearate, microcrystalline cellulose (101) (E460), lactose granules containing lactose, maize starch, pregelatinised maize starch, purified talc (E553), acacia (E414), gelatin, sucrose, titanium dioxide (E171) and yellow carnauba wax.

# What Ferrous Sulfate tablets look like and the contents of the pack

Ferrous Sulfate tablets are white, circular, biconvex, sugarcoated tablets.

Pack size is 28 and 100.

Marketing Authorisation Holder and Manufacturer Accord, Barnstaple, EX32 8NS, UK.

This leaflet was last revised in October 2019.

If you would like a leaflet with larger text, please contact 01271 385257.

