

Ironorm drops

Ferrous Sulfate

Read all of this leaflet carefully before you start using this medicine. Keep this leaflet; you may need to read it again. If you have any further questions, ask your doctor or pharmacist. You must contact a doctor if your symptoms worsen or do not improve. If any side effect becomes more serious, if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Ironorm Drops are and what do they do?

The name of your medicine is Ironorm Drops. Ironorm Drops contain Ferrous Sulfate. It is used to prevent or treat iron deficiency anaemia.

2. What should I know before using Ironorm Drops?

You should not use this medicine if you:

- ✱ Are sensitive to any of the ingredients (full list provided in Section 6).
- ✱ You suffer from an inherited condition of abnormal iron metabolism.
- ✱ You have an active peptic ulcer.
- ✱ You are undergoing repeated blood transfusions.
- ✱ You suffer from a severe stomach upset or ulcerative colitis.
- ✱ You have been diagnosed with a haemolytic anaemia which are anaemias that cause break down of the red blood cells.

Talk to your doctor or pharmacist before taking this medicine if you:

- ✱ Have had a recent operation on your stomach.
- ✱ Have previously suffered from a peptic ulcer.
- ✱ You are already receiving treatment for other forms of anaemia.
- ✱ You suffer from intestinal blockages.
- ✱ You are elderly (there is an increased risk of intestinal blockage).

If you have recently given birth:

- ✱ Treatment is not normally required more than 1 or 2 months after childbirth.

Is it safe to drive or operate machinery after taking Ironorm Drops?

Ironorm Drops do not affect your ability to drive or operate machinery.

Are there any medicines or foods that interact with Ironorm Drops?

Ironorm Drops may react with other medicines you are taking.

Talk to a pharmacist or doctor if you are taking the following since they will reduce each other's potency:

- ✱ Tetracyclines, a type of antibiotic.
- ✱ Antacids.
- ✱ Cholestyramine, used to remove bile from the gut. It is sometimes used to reduce blood cholesterol levels.
- ✱ Penicillamine, a treatment for rheumatoid arthritis and a few other rare inherited conditions.

Talk to a pharmacist or doctor if you are taking the following since it upsets iron metabolism.

- ✱ Chloramphenicol, a type of antibiotic.

You should also be aware that:

- ✱ Tea, eggs and milk will reduce absorption of the iron.

Can I use Ironorm Drops if I am pregnant or breastfeeding?

Ironorm Drops should only be used during pregnancy, especially during the first trimester, after careful assessment by a medical doctor.

Important Information about some of the ingredients of Ironorm Drops

In addition to the active ingredient, some of the other ingredients in Ironorm Drops may affect some individuals as follows:

- ✱ Metabisulfite can cause allergic reactions (such as skin rash and fluid retention) and bronchospasm (asthma-like difficulty in breathing) in susceptible individuals.
- ✱ Sorbitol, if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

If you experience an allergic reaction then discontinue use of the medicine and consult your doctor.

3. How do I use Ironorm Drops?

Do not exceed the prescribed dose.

PROPHYLACTIC DOSAGE:

Infants 4 – 6 weeks to mixed feeding:

0.2 ml per day (5.0 mg ELEMENTAL IRON).

Higher doses of up to 0.08 ml per kg body weight (2.0 mg ELEMENTAL IRON per kg) might be needed to cover the needs of growing, exclusively breastfed, infants.

Older infants and children to 6 years:

0.5 to 1.2 ml per day (12.5 – 30 mg ELEMENTAL IRON).

Older children:

2.4 ml per day (60 mg ELEMENTAL IRON).

Adults and Elderly:

2.4 to 4.8 ml per day (60 – 120 mg ELEMENTAL IRON).

THERAPEUTIC DOSAGE:

Paediatric:

0.12 ml to 0.24 ml (3 – 6 mg ELEMENTAL IRON) per kg body weight, up to a maximum of 8 ml (200 mg ELEMENTAL IRON) given daily in two or three divided doses.

Adults:

4.0 ml once or twice per day (100 – 200 mg ELEMENTAL IRON).

What should I do if I take or give too large a dose of Ironorm Drops?

If you have taken or given an overdose of Ironorm Drops then you should seek medical attention as soon as possible. When seeking medical advice you should, if possible, take the medicine and this leaflet with you provided it doesn't cause a delay.

What should I do if I miss a dose of Ironorm Drops?

If you have missed a dose then wait until your next dose is due. Do not take a double dose.

4. Do Ironorm Drops have any side effects?

Like all medicines, as well as benefits, Ironorm Drops can cause side effects. The elderly may suffer from severe constipation in which case they should discontinue treatment immediately and seek medical advice.

Ironorm Drops can stain the teeth black during treatment. This can be reduced with regular brushing. The staining is not permanent and will fade when your treatment is over.

The following side effects have also been reported to the ingredients of Ironorm Drops.

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| ❖ Constipation | ❖ Vomiting | ❖ Darkening of stools |
| ❖ Loss of appetite | ❖ Stomach pain | ❖ Allergic reactions |
| ❖ Nausea | ❖ Diarrhoea | |

If you experience any unexpected side effects not mentioned above, or the side effect (as listed) is severe or persists for more than a few days, discontinue use of the medicine and consult your doctor.

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 the package leaflet. You can 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 do I store Ironorm Drops?

Keep all medicines out of the reach and sight of children, preferably in a locked cupboard.

Store below 25°C. Do not use after the expiry date marked on the pack.

6. Further Information

What Ironorm Drops contain:

Each 1.0 ml of syrup contains the active ingredient Ferrous Sulfate 125 mg (equivalent to 25 mg of elemental iron). In addition Ironorm Drops also contain the following ingredients: sorbitol solution, disodium edetate, ascorbic acid, sodium metabisulfite, propylene glycol, orange flavouring and water.

What Ironorm Drops look like and the contents of the pack:

Ironorm Drops are a green to yellow syrup supplied in packs of 15 ml with a calibrated oral syringe. It is normal for the drops to darken slightly on storage.

The Marketing Authorisation holder is:

Wallace Manufacturing Chemists Limited, 51-53 Stert Street, Abingdon, Oxfordshire OX14 3JF, UK.

Manufactured by:

Laleham Health and Beauty Limited, Greenhalgh, Kirkham, Preston, Lancashire PR4 3JA, UK.

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