

# Ironorm Drops Oral Solution

## Ferrous Sulfate

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

Always 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.
- ◆ 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.

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### 1. What are Ironorm Drops and what are they used for?

The name of your medicine is Ironorm Drops. Ironorm Drops contain **ferrous sulfate**. Ironorm Drops are used to prevent or treat iron deficiency anaemia.

### 2. What you need to know before you use Ironorm Drops?

#### Do not use 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.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Ironorm Drops if:

- ◆ you have had a recent operation on your stomach
- ◆ you 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.

#### Other medicines and Ironorm Drops?

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

Tell your doctor or pharmacist if you are taking any of the following medicines. This is because Ironorm Drops may affect the amount of these medicines in your blood:

- ◆ 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.

Also tell your doctor or pharmacist if you are taking any of the following medicine as 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.

#### Pregnancy and breast-feeding?

If you are pregnant or think you may be pregnant or planning to have a baby, ask your doctor for advice before taking this medicine. Ironorm Drops should only be used during pregnancy, especially during the first trimester, after careful assessment by a medical doctor.

#### Driving and using machines

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

#### Important information about some of the ingredients in Ironorm Drops

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

- ◆ metabisulfite can cause allergic reactions (such as skin rash and fluid retention) and bronchospasm (asthma-like difficulty in breathing) in susceptible individuals
- ◆ sorbitol, this medicine contains 2075 mg sorbitol in each 4.8ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.
- ◆ This medicine contains 623 mg propylene glycol in each 4.8ml. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

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

### 3. How to use Ironorm Drops?

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Read these instructions carefully because the dose depends both on age and the reason for treatment. 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).

#### If you take more Ironorm Drops than you should

If you have taken a possible overdose then you should seek medical advice immediately. If possible you should take any remaining medicine, packaging and this leaflet with you provided it doesn't cause a delay.

#### If you forget to take Ironorm Drops

Do not take a double dose to make up for a forgotten dose. If you have missed a dose then wait until your next dose is due.

### 4. Possible side effects?

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

#### Frequency unknown:

- ◆ constipation
- ◆ loss of appetite
- ◆ nausea
- ◆ vomiting
- ◆ stomach pain
- ◆ diarrhoea
- ◆ darkening of stools
- ◆ allergic reactions.

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](http://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 Ironorm Drops?

Keep this medicine out of the sight and reach of children, preferably in a locked cupboard. Do not use this medicine after the expiry date which is stated on the bottle. Store below 25°C.

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 Ironorm Drops contain:

The active substance is ferrous sulfate. Each 1ml of the syrup contains 125mg of ferrous sulfate which is equivalent to 25mg of elemental iron. The other ingredients are sorbitol solution, disodium edetate, ascorbic acid, sodium metabisulfite, propylene glycol, orange flavouring and purified water.

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

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

#### Marketing Authorisation Holder and Manufacturer:

The marketing authorisation owner is:  
Wallace Manufacturing Chemists Ltd.,  
51-53 Stert Street, Abingdon,  
Oxfordshire OX14 3JF, UK.

The manufacturer is:  
Laleham Health and Beauty Ltd.,  
Bradshaw Lane, Greenhalgh,  
Kirkham, Lancashire PR4 3JA, UK.  
or  
Laleham Health and Beauty Ltd.,  
Sycamore Park, Alton, GU23 2PR, UK.

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