

FERRUM H®

Iron Polymaltose

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about FERRUM H. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of using FERRUM H against the benefits this medicine is expected to have for you.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What FERRUM H is used for

FERRUM H provides a source of iron that can help to replenish a shortage of iron in patients with iron deficiency.

FERRUM H is used when dosage by mouth is impractical or contraindicated and when disturbances in the gastrointestinal tract make absorption difficult or uncertain.

Before you are given FERRUM H

When you must not be given it

Do not use FERRUM H if:

- You are known to be sensitive (allergic) to any of the ingredients of FERRUM H
- Your anaemia is not due to a shortage of iron
- You have a condition known as haemochromatosis (an excess of iron in the body)
- You have any medical conditions or health problems including arthritis, bronchial asthma, hepatitis
- You are in the 1st trimester of a pregnancy

FERRUM H should not be used after the expiry date printed on the label.

If you are not sure whether you should be given FERRUM H please talk to your doctor.

Before you are given it

You should be aware that:

- A blood test should have been carried out to ensure treatment with this medicine is appropriate
- If you have a history of asthma, eczema or other atopic allergies you are more susceptible to experience allergic reactions

You must tell your doctor if:

- You are pregnant or breastfeeding
- You or a blood relative have the condition haemochromatosis
- You have a history of liver disease

If you have not told your doctor about any of the above, please do so before you are given FERRUM H.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a

prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with FERRUM H.

These include:

- Drugs that are used to treat heart disease and high blood pressure known as ACE inhibitors (e.g. captopril, enalapril, fosinopril, lisinopril or quinalapril)
- Iron preparations taken by mouth

Your doctor or pharmacist has more information on medicines to avoid while taking FERRUM H.

How FERRUM H is given

FERRUM H is given in a prescribed manner into the muscle. The injection technique is well defined and must be adhered to.

Failure to inject as recommended could result in persistent staining of the skin.

FERRUM H should never be injected into the arm or other exposed areas.

Your doctor has detailed information on the correct injection technique.

Your doctor will decide what dose and how long you will receive FERRUM H.

FERRUM H will be administered in a setting where possible allergic reactions can receive appropriate and prompt treatment.

You will be observed for about 30 minutes by your doctor or nurse after each administration.

If you are given too much (overdose)

As FERRUM H is given to you under the supervision of your doctor, it is very unlikely that you will be given an overdose. However, if you experience several side effects, tell your doctor immediately. The symptoms of an overdose may include the side effects listed in the side effects section but are usually of a more severe nature.

Side effects

Tell your doctor, nurse or pharmacist if you do not feel well while you are using FERRUM H.

FERRUM H helps most people with low iron levels but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Ask your doctor to answer any question you may have.

Side effects that have been reported by people using FERRUM H include:

- Flushing, sweating, chills and fever
- Chest and back pain
- Pain at site of injection
- Local redness or swelling at the injection site
- Abdominal pain
- Nausea, vomiting
- Headache, dizziness
- Joint and muscle pains
- Sensation of stiffening of the arms, legs or face
- Fainting
- Hypotension
- Difficulty in breathing
- Rash

Adverse reactions can be delayed by 1-2 days after treatment with FERRUM H.

Incorrect injection technique could result in staining of the skin.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice any other effects.

After using Ferrum H

Storage

FERRUM H will be stored in the pharmacy or on the ward.

The ampoules should be stored below 25°C in the original cartons.

The product should not be frozen.

Protect from light. Once the ampoules have been opened they should be used immediately.

FERRUM H is to be kept out of the reach and sight of children.

Product description

What it looks like

FERRUM H comes in a glass ampoule containing 2 mL of solution.

The product is supplied in cardboard boxes each containing 5 ampoules.

Ingredients

Active ingredient:

- Iron polymaltose complex

Inactive ingredients:

- Water for injections
- Sodium hydroxide
- Hydrochloric acid

Medicine classification

Prescription Only Medicine

Sponsor

FERRUM H is supplied in Australia by:

Vifor Pharma Pty Ltd Level 8, 80 Dorcas Street South Bank, Melbourne VIC 3006 Australia

Exclusive New Zealand distributor:

Pharmacy Retailing (NZ)
Limited trading as Healthcare
Logistics Auckland, New Zealand

Australian Registration
Number AUST R 68110

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