

FERROSIG INJECTION

(Iron polymaltose injection)

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about FERROSIG INJECTION.

It does not contain all the available information.

It does not take place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

Your doctor has weighed the risks of using FERROSIG INJECTION 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 is FERROSIG INJECTION?

The name of your medicine is FERROSIG Injection.

FERROSIG injection is an iron supplement.

It contains iron in a form that can be used by your body to build up iron reserves that are needed for your system to operate properly.

What is FERROSIG INJECTION used for?

FERROSIG INJECTION is used in cases of iron deficiency (too little iron in the system).

FERROSIG INJECTION is used when dosage by mouth is impractical, the anaemia is severe or disturbances in the gastro-intestinal tract make absorption difficult or uncertain.

FERROSIG INJECTION is also used for treating iron deficiency states discovered in the third trimester of pregnancy and in circumstances where contact between patient and doctor only occurs at irregular intervals.

Your doctor however, may have prescribed and used FERROSIG INJECTION for another reason.

Ask your doctor if you have any questions about why FERROSIG INJECTION has been prescribed for you.

A doctor's prescription is required for FERROSIG INJECTION.

Before you are given FERROSIG INJECTION

When you must not be given it:

Do not use FERROSIG INJECTION if you have ever had an allergic reaction to:

1. FERROSIG INJECTION or other iron preparations.
2. any of the other ingredients in FERROSIG.

You must tell your doctor if:

1. **You have had an allergic reaction to iron supplements.**
Some of the symptoms of an allergic reaction may include

skin rash and itching. Other reactions may include nausea, vomiting and diarrhoea.

There have been reports of hypersensitivity reactions which progressed to Kounis syndrome (acute coronary arteriospasm that can result in myocardial infarction).

2. **You are allergic to any other medicines or any foods, dyes or preservatives.**
3. **You have any other medical conditions or health problems including:**
Liver and/or kidney problems, Bronchial asthma, arthritis, heart disease
 - Allergies
 - Infections
4. **you are pregnant or intend to become pregnant.**

Foetal bradycardia may occur following administration of parenteral irons. It is usually transient and a consequence of a hypersensitivity reaction in the mother. The unborn baby should be carefully monitored during administration of parenteral irons to pregnant women.

Like most medicines, FERROSIG INJECTION is not recommended in the first trimester of pregnancy. Your doctor will discuss the possible risks and benefits of using FERROSIG INJECTION during pregnancy.

If you have not told your doctor about any of the above, tell them before you are given any FERROSIG INJECTION.

When you must not be given FERROSIG INJECTION

- 1. If the ampoule contents are discoloured or show signs of visible sedimentation.**
- 2. After the expiry date printed on the pack has passed.**

The medication may have no effect at all, or worse, it may give an entirely unexpected effect if you use it after the expiry date.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interact with FERROSIG INJECTION.

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).
- Oral iron supplements.

Your doctor or pharmacist has more information on medicines to avoid while taking FERROSIG INJECTION.

How FERROSIG INJECTION is given

FERROSIG INJECTION 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.

FERROSIG INJECTION should never be injected into the arm or other exposed areas.

Your doctor has detailed information on the correct injection technique.

FERROSIG INJECTION may also be administered intravenously. This should only be done by a doctor in a hospital.

How much to inject

The dose of FERROSIG INJECTION is determined by the amount of iron found in your system using a blood test.

Your doctor has information on the correct dosage requirement for different haemoglobin or iron levels.

Your doctor will decide what dose and how you are administered FERROSIG INJECTION.

How long to use it

Your doctor will tell you how long the course of FERROSIG INJECTION will last.

While you are using FERROSIG INJECTION

Things you must do

Tell your doctor if:

- Your symptoms do not improve within a few days, or if they become worse.
- **You develop any form of skin rash and/or itching or difficulty in breathing while using FERROSIG INJECTION.**
- You become pregnant while using FERROSIG INJECTION.

If you have to get any blood or urine tests done tell your doctor and nurse that you are using FERROSIG INJECTION.

Tell any doctor, dentist and pharmacist who are treating you that you are on a course of FERROSIG INJECTION.

Tell your doctor if you feel that FERROSIG INJECTION is not helping your condition.

Tell your doctor if, for any reason, FERROSIG INJECTION has not been used exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not take any oral iron supplements while using FERROSIG INJECTION.

Side Effects or Adverse Reactions

Tell your doctor or pharmacist if you do not feel well while you are using FERROSIG INJECTION.

FERROSIG INJECTION helps most people with low haemoglobin (or iron) but it may have some unwanted side effects in a few people.

Side effects that have been reported by people using FERROSIG INJECTION include:

- Kounis syndrome - frequency not known.
- In pregnancy, associated foetal bradycardia may occur with parenteral iron preparations.
- Pain at site of injection
- Local redness or swelling at the injection site
- Lower quadrant abdominal pain
- Headache
- Nausea, vomiting
- Joint and muscle pains
- Faintness, sweating, flushing
- Difficulty breathing
- Dizziness on standing from a sitting position.

Some adverse reactions can be delayed and these may include:

- Sensation of stiffening of the arms, legs or face
- Chest and back pain
- Faintness
- Chills, fever, rash

- hypophosphataemia including hypophosphataemic osteomalacia

Incorrect injection technique could result in staining of the skin.

FERROSIG INJECTION may cause other side effects. If you have any other side effects, check with your doctor.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using FERROSIG INJECTION

Storage

Keep FERROSIG INJECTION where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Store FERROSIG INJECTION at below 25°C. Do not freeze. Protect from light.

Do not leave FERROSIG INJECTION in the car or on windowsills. Heat can destroy some medicines.

Disposal

If your doctor tells you to stop using FERROSIG INJECTION or it has passed its expiry date, ask your pharmacist what to do with any FERROSIG INJECTION left over.

Further Information

This is not all the information that is available on FERROSIG INJECTION. If you need more information, ask a doctor or pharmacist.

Product Description

What it looks like

FERROSIG INJECTION is a slightly viscous, dark reddish-brown liquid and is supplied in 2mL ampoules for injection. Each ampoule contains 318 mg iron polymaltose equivalent to 100 mg iron III (50 mg per mL).

Active ingredient

Iron polymaltose complex is the active ingredient in *FERROSIG INJECTION*.

List of inactive ingredients

Water for injections and hydrochloric acid or sodium hydroxide (for pH adjustment of the formulation).

The Australian Product Registration number for FERROSIG INJECTION is AUSTR 82435.

SPONSOR

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