Package leaflet: Information for the user

Sodium Feredetate 190mg/5ml Oral Solution

Sodium feredetate trihydrate

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.
- 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.

The name of your medicine is Sodium Feredetate 190mg/5ml Oral Solution, but it will be referred to as 'Sodium Feredetate' throughout this leaflet.

What is in this leaflet

1. What Sodium Feredetate is and what it is used for
2. What you need to know before you take Sodium Feredetate
3. How to take Sodium Feredetate
4. Possible side effects
5. How to store Sodium Feredetate
6. Contents of the pack and other information

1. What Sodium Feredetate is and what it is used for

Sodium Feredetate is an oral solution for adults, children and babies to treat iron deficiency anaemia caused by too little iron in the body. The form of iron used in this product means that it is less likely to cause stomach upsets than other iron-containing medicines and will not discolour teeth.
It is taken by:

- People with iron deficiency anaemia (especially children)
- Pregnant women when other forms of oral iron may not be well tolerated
- People who have become anaemic as a result of having rheumatoid arthritis.

2. What you need to know before you take Sodium Feredetate

Do not take Sodium Feredetate if you:

- are **allergic** to sodium feredetate trihydrate or any of the other ingredients of this medicine (listed in section 6, please also see end of section 2: "Sodium Feredetate contains" for important information about some of the ingredients).
- have a history of **sensitivity to iron**-containing preparations.
- have a disorder in which there is **excessive absorption** and **storage** of **iron** such as haemochromatosis or haemosiderosis.
- have repeated **blood transfusions** or have had them in the past.
- are currently having **iron injections.**

Warnings and Precautions

Talk to your doctor or pharmacist before taking Sodium Feredetate if:

- you have haemolytic anaemia
- you have an iron storage or absorption disease
- you have gastrointestinal disease
- you are having tests on your stools as iron preparations colour the faeces black and can interfere with test results

Children and young people

Talk to your doctor or pharmacist if a child has been taking Sodium Feredetate for a long time or at high doses as this can lead to toxic accumulation in the body.

Other medicines and Sodium Feredetate

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

Do not take Sodium feredetate if you:

- are currently having iron injections

Tell your doctor or pharmacist if you are taking any of the following medicines:

- dimercaprol (for metal poisoning)
- iron-containing medicines or tonics
- chloramphenicol, fluoroquinolones or tetracyclines (to treat infections)
- penicillamine (for rheumatoid arthritis)
- methyldopa (for high blood pressure)
- mycophenolate (to prevent organ transplant rejection)
- levodopa, carbidopa or entacapone (for Parkinson's disease)
- bisphosphonates (for osteoporosis)
- thyroxine (for thyroid problems)
- trientine (for Wilson's Disease)
- cholestyramine (for high cholesterol)
- proton-pump-inhibitors e.g. omeprazole (for stomach ulcers)
- bicarbonates, carbonates, calcium, magnesium, zinc and other mineral supplements (indigestion and antacid remedies)

Sodium Feredetate with food and drink

Tea, coffee, eggs, milk, ascorbic acid (vitamin c) and citric acid, may interfere with Sodium Feredetate.

Pregnancy and breast-feeding:

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

Sodium Feredetate is not expected to have an effect on your ability to drive or operate machinery.

Important information about some of the ingredients of Sodium Feredetate

This medicine contains 2000mg **sorbitol** in each 5 ml dosage unit which is equivalent to 400 mg/ml. Sorbitol is a source of fructose. If your doctor has told you (or your child) that you 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. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

This medicine contains 5mg **benzoic acid** in each 5ml dosage unit which is equivalent to 30mg total in the maximum daily dose.
Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

This medicine contains less than 1 mmol **sodium** (23 mg) per 5ml dosage unit, that is to say essentially 'sodium-free'.

3. How to take Sodium Feredetate

The liquid is to be taken by mouth. Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Treatment of Anaemia:

Adults and Elderly (over 65 years)

1 or 2 x 5 ml **3 times a day**

Children

Depends on weight – 3 to 6 mg/kg (max 200 mg) of elemental iron* as given by your healthcare professional in **2-3 divided doses**

Prevention of Anaemia:

Babies of low-birth weight who are solely breast-fed

5 mg of elemental iron* (0.9 ml given in a 1ml syringe. Note: a 1ml syringe is not supplied in the product pack) daily as given by your healthcare professional.

A higher dose – depending on weight – up to 2 mg/kg of elemental iron* daily as given by your healthcare professional may be required for exclusively breast-fed babies.

Babies (6 to 24 months)

1 x 2.5ml daily

Children (2 to 5 years)

1 x 5ml daily

Children (6 to 11 years)

1-2 x 5ml daily

Adolescents

2 x 5ml daily

*Elemental iron is iron your body can absorb.

If you take more Sodium Feredetate than you should

If you accidentally take too much sodium feredetate or give too much to a child, tell your doctor immediately or contact your hospital. Take this leaflet, the container and any remaining Sodium Feredetate with you, if you can.

An overdose may cause:

- sickness (this may have some blood in it) or make you feel sick
- stomach pains
- diarrhoea
- blood in your stools
- tiredness
- cold and sweaty skin
- fast heart beat
- high blood sugar
- high blood acidity (metabolic acidosis).

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you forget to take Sodium Feredetate

If you forget to take a dose, take the next dose at the usual time. **Do not** take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Allergic reactions: e.g. itchy skin rash, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing. If you experience any of the above, **stop taking this medicine and see a doctor immediately**.

You may **feel sick** or have **mild diarrhoea** in the early stages of treatment. These effects should quickly disappear if you stop taking Sodium Feredetate for a short time.

When treatment is restarted, a lower dose of your medicine should be taken.

If your doctor tells you to take Sodium Feredetate at doses higher than is stated in this leaflet, you may experience mild diarrhoea.

Talk to your doctor or pharmacist if a child has been taking the medicine for a long time or at high doses as this can lead to toxic accumulation in the body.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: 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 Sodium Feredetate

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle label. The expiry date refers to the last day of that month.

Do not use your medicine if you notice that the container is damaged.

This medicinal product does not require any special temperature storage conditions.

Store in the original bottle to protect from light.

Once opened the product should be used within 90 days.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Sodium Feredetate contains

The **active substance** is: sodium feredetate trihydrate. Each 5 ml contains 190mg of sodium feredetate (as trihydrate) (equivalent to 27.5 mg of iron).

The **other ingredients** are: benzoic acid (E 210), glycerol (E 422), sorbitol- liquid non crystallizing (E420), saccharin sodium (E 954), citric acid monohydrate (E 330), cherry flavour, sodium citrate trihydrate (E 331) and purified water.

What Sodium Feredetate oral solution looks like and contents of the pack

This medicine is a clear, yellow to brown solution with cherry odour.
This medicine is packed in amber, type III 500 ml glass bottles sealed with a child-resistant, tamper-evident screw cap with Low Density Polyethylene (LDPE) seal. It comes with a 20 ml measuring cup with graduations at 2.5 – 5 –10 – 15– 20ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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Other sources of information

If you would like the leaflet in an alternative format information (braille or large print), for blind and partially sighted patients, please contact marketing authorisation holder listed above.

This leaflet was last revised in July 2026.