

Sodium feredetate liquid 190 mg/5 ml (equivalent to 27.5 mg of iron/5 ml)

Read all of this leaflet carefully before you start taking this medicine.

- Please keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you suffer from any side effect that gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Sytron is and what it is used for
2. Before you take Sytron
3. How to take Sytron
4. Possible side effects
5. How to store Sytron
6. Further information

1. WHAT SYTRON IS AND WHAT IT IS USED FOR

Sytron is an oral solution for treating anaemia caused by too little iron in the body (iron deficiency anaemia). 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:

- pregnant women when other forms of oral iron may not be well tolerated
- children and adults who have become anaemic as a result of having rheumatoid arthritis.

2. BEFORE YOU TAKE SYTRON

DO NOT TAKE Sytron if you:

- are **allergic** to any of the ingredients in the product (see end of section 2: Important information about some of the ingredients and section 6: Further information).
- 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**.

Talk to your doctor or pharmacist before taking Sytron:

- if you have haemolytic anaemia
- if you have an iron storage or absorption disease
- if you have gastrointestinal disease
- if a child has been taking Sytron for a long time or at high doses as this can lead to toxic accumulation in the body

- if you are having tests on your stools as iron preparations colour the faeces black and can interfere with test results

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicine obtained without a prescription.

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

- 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)
- tea, coffee, eggs, milk, ascorbic acid (vitamin c) and citric acid, these may interfere with Sytron

Pregnancy and breast-feeding

Tell your doctor before taking Sytron if you are pregnant, planning to become pregnant or breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machines

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

Important information about some of the ingredients of Sytron

This product contains the following:

- **Methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), ponceau 4R (E124)** - which may cause allergic reactions.
- **Sorbitol** - consult your doctor before taking this medicinal product if you have an intolerance to some sugars.
- **Ethanol (alcohol)** - Sytron contains less than 100 mg of ethanol per 5 ml.

3. HOW TO TAKE SYTRON

The liquid is to be taken by mouth. Always take Sytron exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Take the following doses as given in the table:

Age	Dose
Treatment of anaemia:	
Adults	1 or 2 x 5 ml spoonfuls 3 times a day
Elderly (over 65 years)	1 or 2 x 5 ml spoonfuls 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 1 ml syringe) 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 2.5 ml spoonful daily
Children (2 to 5 years)	1 x 5 ml spoonful daily
Children (6 to 11 years)	1 - 2 x 5 ml spoonfuls daily
Adolescents	2 x 5 ml spoonfuls daily

*Elemental iron is iron your body can absorb.

If you take more Sytron than you should

If you accidentally take too much Sytron or give too much to a child, tell your doctor immediately or contact your hospital. Take this leaflet, the container and any remaining Sytron 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 Sytron

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, Sytron 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 Sytron for a short time.

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

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

If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell 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 this leaflet. You can also report side effects directly via the Yellow Card Scheme.

Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SYTRON

Keep out of the sight and reach of children.

The product should be stored below 30°C.

Do not use Sytron after the expiry date printed on the label. Once opened the product should be used **within 3 months** (there is a space on the label to record the date it was first opened).

If the product shows any signs of deterioration please return it to your pharmacist.

Medicines should not be disposed of 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. FURTHER INFORMATION

What Sytron contains

The **active substance** is: sodium feredetate (also known as sodium iron edetate) 190 mg/5 ml.

The **other ingredients** are: methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), citric acid monohydrate, saccharin sodium, glycerol, sorbitol, ethanol, ponceau 4R (E124), black cherry flavouring, water (*see end of section 2: Important information about some of the ingredients of Sytron*).

What Sytron looks like and contents of the pack

Sytron is a red, sugar free, cherry-flavoured liquid supplied in amber coloured glass bottles containing either 125 ml, 500 ml or 2250 ml of oral solution (not all pack sizes may be marketed).

Marketing Authorisation Holder

Archimedes Pharma UK Limited,
Galabank Business Park, Galashiels,
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Manufacturer

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