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

1. WHAT SYTRON IS AND WHAT IT IS USED FOR

Sytron 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 SYTRON

DO NOT TAKE Sytron if you:
- are allergic to sodium ferpedetate trihydrate or any of the other ingredients of this medicine (listed in section 6, please also see end of section 2: "Sytron 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 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

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

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)
- cholestryramine (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)

**Sytron with food and drink**
Tea, coffee, eggs, milk, ascorbic acid (vitamin c) and citric acid, may interfere with Sytron.

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

**Sytron contains:**
- **Methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), ponceau 4R (E124)** - which may cause allergic reactions (possibly delayed).
- **Sorbitol** - if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- **Ethanol** - this medicinal product contains small amounts of ethanol (alcohol), less than 100 mg in the maximum dose of 10 ml.
- **Sodium** – this medicinal product contains approximately 1.04 mmol (24.00 mg) sodium in the maximum dose of 10 ml (2 x 5 ml spoonfuls), and should be taken into consideration by patients on a controlled sodium diet. However, if you are taking smaller doses e.g. 1 x 5 ml spoonful at a time or less then it contains less than 1 mmol (23 mg) sodium per dose and is essentially sodium free.

**3. HOW TO TAKE SYTRON**
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.

Take the following doses as given in the table below:
### Treatment of anaemia:

<table>
<thead>
<tr>
<th>Age</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>1 or 2 x 5 ml spoonfuls 3 times a day</td>
</tr>
<tr>
<td>Elderly (over 65 years)</td>
<td>1 or 2 x 5 ml spoonfuls 3 times a day</td>
</tr>
<tr>
<td>Children</td>
<td>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</td>
</tr>
</tbody>
</table>

### Prevention of anaemia:

<table>
<thead>
<tr>
<th>Age</th>
<th>Dose</th>
</tr>
</thead>
</table>
| Babies of low-birth weight who are solely breast-fed | 5 mg of elemental iron* (0.9 ml given in a 1ml 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 5ml spoonful daily                                              |
| Children (6 to 11 years)                 | 1-2 x 5ml 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, 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 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.

**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](http://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 this medicine out of the sight and reach of children.**

The product should be stored below 30°C.

Do not use this medicine after the expiry date which is stated on the label after EXP. 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.**

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 Sytron contains**
The **active substance** is: sodium feredetate trihydrate (also known as sodium iron edetate) 207.5 mg/5 ml (equivalent to 27.5 mg/5 ml of elemental iron).

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 (please see end of section 2: "Sytron contains” for important information about some of the ingredients).

**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 125 ml, 500 ml or 2250 ml of oral solution (not all pack sizes may be marketed).

**Marketing Authorisation Holder**
Kyowa Kirin Limited,
Galabank Business Park,
Galashiels,
TD1 1QH,
United Kingdom.

**Manufacturer**
Laleham Health and Beauty Limited,
Fairfield,
Bradshaw Lane,
Greenhalgh,
Kirkham,
Preston,
Lancashire,
PR4 3JA,
United Kingdom.

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