Print Free Areas* | Glue (Hinge) | Glue (Release)

55mm | 55mm | 55mm | 55mm | 55mm | 55mm | 55mm | 55mm | 2.5mm | 57.5mm | 15m

2.5mm

61mm

Package Leaflet: Information for the user
SYTRON® 27.5 mg iron per 5 ml 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.

01

What is in 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)

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- 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 feredetate 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.

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- 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 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 Sytron for a long time or at high doses as this can lead to toxic accumulation in the body.

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Other medicines and Sytron

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

Do not take Sytron if you:

- are currently having iron injections

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)

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- 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)

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.

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Sytron contains:

- **Methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), ponceau 4R (E124)** – may cause allergic reactions (possibly delayed).
- **Sorbitol (sugar)** – this medicine contains 1400 mg sorbitol in each dosage unit (5 ml) which is equivalent to 280 mg/ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) 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.

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- **Ethanol (alcohol)** – this medicinal product contains small amounts of ethanol (alcohol), less than 100 mg in the maximum dose of 10 ml.
- **Sodium (salt)** – this medicine contains approximately 23 mg sodium (main component of cooking/table salt) in the maximum dose of 10 ml (2 x 5 ml spoonfuls). This is equivalent to 1.2% of the recommended daily dietary intake of sodium for an adult. 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 sodium (23 mg) per dose, that is to say 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.

08

66mm

60mm | 60mm | 60mm | 60mm | 60mm | 60mm | 60mm | 75mm

70mm | 16.5mm | 43.5mm | 55mm | 55mm | 55mm | 55mm | 55mm | 55mm | 55mm

2.5mm

61mm

Sytron® 27.5 mg iron per 5 ml Oral Solution
Sodium feredetate trihydrate

Important warning: Contains iron. Keep out of the sight and reach of children, as overdose may be fatal.

For oral use:
Treatment of anaemia: Children: 3 to 6 mg/kg (max 200 mg) of elemental iron daily as given by healthcare professional in 2-3 divided doses. **Adults and elderly:** 1 or 2 x 5ml spoonfuls 3 times a day.
Prevention of anaemia: Babies of low birth-weight who are solely breast-fed: 5mg of elemental iron daily, given by your healthcare professional. A higher dose up to 2 mg/kg of elemental iron daily, given by 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

Peel here but do not remove

500 ml ℮ **Read leaflet before use**

Package Leaflet: Information for the User

GLUE

Treatment of Anaemia:

Adults and 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 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.

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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 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

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- 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.

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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.
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.

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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 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 Sytron

Keep this medicine out of the sight and reach of children.
Do not store above 25°C.
Do not use this medicine after the expiry date which is stated on the label after EXP.

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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).

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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).

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66mm

75mm | 60mm | 60mm | 60mm | 60mm | 60mm | 60mm | 60mm | 60mm

1.5mm

4mm | 75mm | 45mm

63mm

GLUE

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.

The package leaflet for this medicine is also available on the Electronic Medicines Compendium website: https://www.medicines.org.uk/emc/

The leaflet was last revised: 05/2021

LBL-SYT-GB-005

LB006931

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GLUE

SUGAR FREE
Does Not Discolour Teeth

Each 5 ml of Sytron contains 207.5 mg sodium feredetate trihydrate equivalent to 27.5 mg of elemental iron. Elemental iron is iron your body can absorb. Sodium feredetate trihydrate is also known as sodium iron edetate. Also contains methylhydroxybenzoate (E218), propylhydroxybenzoate (E216), sodium, sorbitol, ethanol and ponceau 4R (E124). See pull out leaflet for further information.
MA Holder: Kyowa Kirin Ltd., Galabank Business Park, Galashiels, TD1 1QH, UK
PL 16508/0059
Use within 3 months of opening P

DATE OPENED: _____/_____/____

1.5mm

66mm

18mm | 47mm | 18mm | 39.5mm

124mm