

MALTOFER® SYRUP

Iron (10mg/ml)

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What Maltofer® Syrup is used for

Maltofer® Syrup is used to treat iron deficiency without and with anaemia (lack of red blood cells). It is also used as prevention therapy during pregnancy to avoid iron deficiency

How Maltofer® Syrup works

Maltofer® Syrup contains iron which plays a role in the formation and function of red blood cells.

Before you use Maltofer® Syrup

- When you must not use it

Do not take this medicine

- if you are allergic to iron (III) hydroxide polymaltose complex or to any of the other ingredients (listed in product description)
- have iron overload in the body
- have iron utilisation disorders
- have anaemia which is not caused by iron deficiency

- Before you start to use it

- Your doctor will monitor the progress of your treatment with periodic follow-up examinations and may even carry out blood tests. This is normal and should not alarm you.
- Tell your doctor or pharmacist before taking Maltofer® Syrup if you have an infection or a tumour.
- Tell your doctor if you are

diabetic. One mL of Maltofer® Syrup contains 200 mg of sucrose. Sucrose can be harmful to the teeth.

Pregnancy and lactation

- Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast feeding before using any medicine.
- Before you start taking Maltofer® Syrup, a doctor should confirm the blood's iron and haemoglobin levels using appropriate tests. If the symptoms are not caused by iron deficiency, Maltofer® Syrup will not be effective.

- Taking other medicine

Tell your doctor or pharmacist if you have recently been treated with injectable iron preparations or might be treated with these. Using such iron preparations at the same time as Maltofer® Syrup is not recommended. Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket, or health food shop.

How to use Maltofer® Syrup

Maltofer® Syrup can be mixed with fruit and vegetable juices or with bottle-feed.

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Use the measuring cup from the package to measure the dose.

Syrup:

- Iron deficiency anaemia:
 - Infants aged up to 1 year: 2.5–5 mL.
 - Children (aged 1–12 years): 5–10 mL.
 - Adolescents over 12 years and adults: 10–30 mL.
 - Pregnant women: 20–30 mL.
- Iron deficiency without anaemia:
 - Children (aged 1–12 years): 2.5–5 mL.
 - Adolescents over 12 years and adults: 5–10 mL.
 - Pregnant women: 10 mL.
- Prevention therapy for pregnant women: 5–10 mL.

- When to use it

- To be taken once daily or in divided doses as directed by your doctor or pharmacist.
- Take the syrup during or immediately after a meal.

- How long to use it

- Your doctor will determine the duration of the treatment according to your condition.
- If you have iron deficiency with anaemia, treatment may continue for 3–5 months until blood test values have returned to normal again.
- After that, you need to continue treatment at the dose indicated by your doctor for several weeks or until the end of the pregnancy if you are pregnant, to replenish the iron stores.
- If you have iron deficiency without anaemia, the treatment may last about 1–2 months.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

- Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you

or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

- Use your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are using Maltofer® Syrup
- Tell your doctor immediately if you become pregnant while using this medication.

- Things you must not do

- Do not stop using the medicine unless advised by your doctor.
- Do not use any new medicines without consulting your doctor or pharmacist.
- Do not give Maltofer® Syrup to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

- Maltofer® Syrup contains 0.28 g of sorbitol (sugar) per mL. Tell your doctor if have intolerance for certain sugar.
- Maltofer® Syrup contains small quantities of ethanol (alcohol) of less than 100 mg per 30 mL (maximum daily dose).
- Maltofer® Syrup contains methyl hydroxybenzoate (E218) and propyl hydroxybenzoate (E216). These can cause allergic reactions that may only appear later.
- Maltofer® Syrup contains 1 mg of salt per mL. Tell your doctor if you are on salt restricted diet.
- It is unlikely that Maltofer has any effect on the ability to drive and use machines.

Side effects

- A very common side effect is stool discolouration.
- Common side effects are nausea, constipation, diarrhea and

stomachache.

- Uncommon side effects are, vomiting, teeth discolouration, itchiness, rash, hives, reddening of the skin and headache.
- Rare side effects are muscle cramps and muscle pain.

You may report any side effects adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Maltofer® Syrup

- Storage

Keep medicine out of the reach of children Do not use the product after the expiry date which is stated on the box.

Please store the items in its original packaging and protect from light. Store below 30 °C.

The slight discolouration of the mixture does not affect either the efficacy of the product or the taste of the drink to which it is added.

Discard 2 months after opening.

- Disposal

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.

Product Description

- What it looks like

Brown solution with cream taste in a brown glass bottle. A measuring cup for administration covers the screw cap

- Ingredients

- Active ingredient:
iron as iron (III)-hydroxide polymaltose complex (IPC).
- Inactive ingredients:
purified water, sorbitol solution (70%), sucrose, ethanol (96%), cream essence, methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216) and sodium hydroxide.

- MAL number:

MAL19911911XZ

MAL26056041XCS

Manufacturer

Corden Pharma Friburg SA, Route de Moncor 10 1752 Villars –sur Glane Switzerland.

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Product Registration Holder

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