

# MALTOFER® TABLETS, MALTOFER® SYRUP

## MALTOFER® DROPS

### Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

#### 1. Why am I using MALTOFER®

MALTOFER® contains the active ingredient iron as iron polymaltose, an iron carbohydrate compound. MALTOFER® is used to treat iron deficiency in adolescents and adults where the use of ferrous iron supplements is not tolerated, or otherwise inappropriate. MALTOFER® is also used for the prevention of iron deficiency in adults and adolescents at high risk where the use of ferrous iron supplements is not tolerated, or otherwise inappropriate.

For more information, see Section [1. Why am I using MALTOFER®?](#) in the full CMI.

#### 2. What should I know before I use MALTOFER®?

Do not use if you have ever had an allergic reaction to MALTOFER® or any of the ingredients listed at the end of the CMI.

**Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use MALTOFER®?](#) in the full CMI.

#### 3. What if I am taking other medicines?

Some medicines may interfere with MALTOFER® and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

#### 4. How do I use MALTOFER®?

- Always take MALTOFER® exactly as your medical practitioner or pharmacist has told you. You should check with your medical practitioner or pharmacist if you are not sure. More instructions can be found in Section [4. How do I use MALTOFER®?](#) in the full CMI.

#### 5. What should I know while using MALTOFER®?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using MALTOFER®.</li><li>Visit your medical practitioner regularly while you are on this therapy to monitor your iron status.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not stop taking MALTOFER® or change the dose without first checking with your medical practitioner or pharmacist.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Be careful driving or operating machinery until you know how MALTOFER® affects you. However, MALTOFER® has either no or negligible influence on your ability to drive a car or operate machinery.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>No relevant information regarding drinking alcohol while using the medicine is available.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep MALTOFER® tablets or liquid/drops in a cool dry place where the temperature stays below 25° C.</li><li>Keep MALTOFER® out of the reach and sight of children.</li></ul>

For more information, see Section [5. What should I know while using MALTOFER®?](#) in the full CMI.

#### 6. Are there any side effects?

Common side effects include discoloured stool, diarrhoea, nausea, indigestion, gut or stomach pain, discomfort or bloating and constipation.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# MALTOFER® TABLETS

# MALTOFER® SYRUP

# MALTOFER® DROPS

Active ingredient: *iron as iron polymaltose*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using MALTOFER®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MALTOFER®.**

Where to find information in this leaflet:

- [1. Why am I using MALTOFER®?](#)
- [2. What should I know before I use MALTOFER®?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MALTOFER®?](#)
- [5. What should I know while using MALTOFER®?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using MALTOFER®?

MALTOFER® contains the active ingredient iron as iron polymaltose, an iron carbohydrate compound. Iron is an essential element required for the oxygen-carrying capacity of haemoglobin (the red pigment in red blood cells) and of myoglobin (the red pigment in muscle tissue). Moreover, iron plays an important role in many other vital processes in the human body.

MALTOFER® is used for treatment of iron deficiency in adults and adolescents where the use of ferrous iron supplements is not tolerated or otherwise inappropriate.

MALTOFER® is used for the prevention of iron deficiency in adults and adolescents at high risk where the use of ferrous iron supplements is not tolerated, or otherwise inappropriate.

### 2. What should I know before I use MALTOFER®?

#### Warnings

**Do not use MALTOFER®:**

- if you are allergic to iron polymaltose, or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include:
  - rash, itching, hives on the skin
  - shortness of breath
  - wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body

Always check the ingredients to make sure you can use this medicine.

- if you have anaemia not caused by iron deficiency
- if you have iron overload (too much iron in your body) or disturbances in utilisation of iron
- for children under the age of 12 years.

#### Check with your doctor or pharmacist if you:

- you have or have had an infection or tumour
- you have or have had any other health problems
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

The following medicines can affect the absorption of MALTOFER®:

- Injectable iron medicines. If you are treated with injectable iron medicines, you should not take MALTOFER® in addition to that therapy.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MALTOFER®.**

### 4. How do I use MALTOFER®?

#### How much to take

- Always take MALTOFER® exactly as your medical practitioner or pharmacist has told you. You should

check with your medical practitioner or pharmacist if you are not sure.

- MALTOFER® Tablets contain 100 mg iron and should not be divided to take lower doses than 100 mg iron. In cases where lower doses are required, MALTOFER® oral liquid forms (Syrup or Drops) should be used.
- Treatment of iron deficiency in adults and adolescents (Children ≥ 12 years) where the use of ferrous iron supplements is not tolerated, or otherwise inappropriate, take 100 mg to 200 mg iron (1 to 2 tablets, 10 – 20 mL syrup, or 40-80 drops) daily preferably with food, or higher doses as directed by your medical practitioner.
- Prevention of iron deficiency in adults and adolescents (Children ≥ 12 years) at high risk where the use of ferrous iron supplements is not tolerated, or otherwise inappropriate, take 100 mg iron (1 tablet, 10 mL syrup, or 40 drops) daily preferably with food, or higher doses as directed by your medical practitioner.
- You should consult your medical practitioner regularly to monitor your iron status (e.g. serum ferritin levels) during therapy. Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.

#### **When to take MALTOFER®**

- Take MALTOFER® during or immediately after a meal. The daily dose of MALTOFER® can be taken at once or divided into separate doses.

#### **How to take MALTOFER®**

- MALTOFER® Tablets should be taken with a glass of water. MALTOFER® Tablets should be swallowed whole.
- MALTOFER® DROPS and SYRUP: liquid can be mixed with fruit and vegetable juices. Any discolouration of the mixture does not affect the taste of the juices or the effectiveness of MALTOFER®.
- To ensure accurate dosing of MALTOFER® DROPS, the bottle needs to be held upright. The drops should flow immediately. If this does not happen, tap the bottle gently until a drop forms. Do not shake the bottle.

#### **How long to take MALTOFER®**

- This is recommended by the medical practitioner and depends upon the degree of iron deficiency.
- Do not discontinue sooner than recommended as this may reduce the success of therapy.

#### **If you forget to take it**

Take the next dose at the usual time. Do not take a double dose to compensate for the forgotten dose. If you have any further questions on the use of this product, ask your medical practitioner or pharmacist.

#### **If you use too much MALTOFER®**

If you think that you have used too much MALTOFER® you may need urgent medical attention.

#### **You should immediately:**

- phone the Poisons Information Centre  
(in Australia by calling 13 11 26 or in New Zealand by calling The National Poisons Centre 0800 POSION or 0800 764 766), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using MALTOFER®?**

### **Things you should do**

- Remind any doctor, dentist or pharmacist you visit that you are using MALTOFER®.
- Tell your medical practitioner if you become pregnant while taking MALTOFER®.
- Visit your medical practitioner regularly while you are on this therapy to monitor your iron status. If symptoms persist, consult your medical practitioner.

### **Things you should not do**

- Do not stop taking MALTOFER® or change the dose without first checking with your medical practitioner or pharmacist.
- Do not give MALTOFER® to anyone else even if they have the same condition as you.
- Do not use MALTOFER® to treat other complaints unless your medical practitioner or pharmacist says to.
- Do not take any other medicines whether they require a prescription or not without first telling your medical practitioner or consulting a pharmacist.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how MALTOFER® affects you.**

However, MALTOFER® has either no or negligible influence on your ability to drive a car or operate machinery.

### **Drinking alcohol**

**Tell your doctor or pharmacist if you drink alcohol.**

### **Looking after your medicine**

- Keep MALTOFER® tablets or oral liquid/drops in a cool dry place where the temperature stays below 25° C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## When to discard your medicine

If your medical practitioner tells you to stop taking MALTOFER®, or the tablets or adult oral liquid/drops have passed their expiry date, ask your pharmacist what to do with any that is left over.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date. The expiry date refers to the last day of that month.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

### Less serious side effects

Less serious side effects	What to do
<b>Gastro-intestinal related:</b> <ul style="list-style-type: none"><li>discoloured stool</li><li>diarrhoea</li><li>nausea</li><li>indigestion</li><li>gut or stomach pain, discomfort or bloating</li><li>constipation</li><li>vomiting</li><li>inflammation of the stomach</li></ul> <b>Tooth-related:</b> <ul style="list-style-type: none"><li>tooth discolouration</li></ul> <b>Pain-related:</b> <ul style="list-style-type: none"><li>Headache</li></ul> <b>Muscle-related:</b> <ul style="list-style-type: none"><li>muscle spasms</li><li>muscle pain</li></ul>	<b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<b>Allergy related:</b> <ul style="list-style-type: none"><li>skin rash</li><li>itching</li><li>hives</li><li>redness of skin</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) or, in New Zealand, <https://nzphvc.otago.ac.nz/reporting/>. By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

This medicine is available over-the-counter without a doctor's prescription.

### What MALTOFER® Tablets contains

<b>Active ingredient (main ingredient)</b>	100 mg iron as 370 mg iron polymaltose
<b>Other ingredients (inactive ingredients)</b>	crospovidone hypromellose iron oxide red iron oxide yellow macrogol 6000 magnesium stearate microcrystalline cellulose titanium dioxide
<b>Potential allergens</b>	No

### What MALTOFER® Syrup contains

<b>Active ingredient (main ingredient)</b>	50 mg iron/5 mL as 185 mg iron polymaltose
<b>Other ingredients (inactive ingredients)</b>	cream flavour ethanol methyl hydroxybenzoate propyl hydroxybenzoate purified water sodium hydroxide sorbitol solution (70%) non-crystallising sucrose.
<b>Potential allergens</b>	methyl hydroxybenzoate propyl hydroxybenzoate

Maltofer® Syrup contains sorbitol and sucrose/sugar. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

The maximum daily dose of Maltofer® Syrup contains 5.6 g of sorbitol. Products containing sorbitol may have a laxative effect or cause diarrhoea.

Maltofer® Syrup contains small amounts of ethanol/alcohol, 3.25 mg per mL.

What MALTOFER® Drops contains

Active ingredient (main ingredient)	50 mg iron/mL as 185 mg iron polymaltose
Other ingredients (inactive ingredients)	purified water sucrose cream flavour sodium methyl hydroxybenzoate sodium propyl hydroxybenzoate sodium hydroxide
Potential allergens	sodium methylhydroxybenzoate  sodium propyl hydroxybenzoate

Do not take this medicine if you are allergic to any of these ingredients.

What MALTOFER® looks like

MALTOFER® Tablets are reddish brown, round and biconvex. They are supplied in aluminum blister packs of 30 or 100 (AUST R 229647).

MALTOFER® SYRUP, is a dark brown solution in a 150 mL brown glass bottle closed with a child resistant tamper-evident screw cap. A measuring cup for administration covers the screw cap. (AUST R 230643).

MALTOFER® DROPS, is a dark brown solution in a 30 mL brown glass bottle with child resistant tamper-evident screw cap and inserted dropper applicator. (AUST R 230644)

Not all presentations may be marketed.

Who distributes MALTOFER®

Supplied in Australia by:  
Aspen Pharmacare Australia Pty Ltd  
34-36 Chandos St  
St Leonards NSW 2065  
Australia

Supplied in New Zealand by:  
Pharmacy Retailing  
(trading as Healthcare Logistics)  
58 Richard Pearce Drive,  
Airport Oaks, Mangere 2022  
New Zealand  
Tel: 0800 996 312

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