MALTOFER® TABLETS
MALTOFER® SYRUP
MALTOFER® DROPS

Consumer Medicine Information

MALTOFER® products contain iron as iron polymaltose, an iron carbohydrate compound.

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about MALTOFER®. It does not contain all the available information. This does not replace talking with your medical practitioner or pharmacist.

All medicines have risks and benefits. Your medical practitioner or pharmacist has weighed the risks of you taking MALTOFER® against the benefits this medicine is expected to have for you.

If you have any concerns about this medicine, ask your medical practitioner or pharmacist.

Keep this leaflet.
You may need to read it again.

WHAT IS MALTOFER®

MALTOFER is a medicine that is used in the treatment of iron deficiency in adolescents and adults where the use of ferrous iron supplements is not tolerated, or otherwise inappropriate.

It contains iron in the form of 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.

WHAT MALTOFER IS USED FOR

MALTOFER® is used for the 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.

BEFORE YOU TAKE MALTOFER®

When you must not take it

- if you are hypersensitive (allergic) to iron polymaltose or any of the other ingredients in MALTOFER® tablets or oral liquid.
  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
- 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.
- if you are under the age of 12 years
- **if the package is torn or shows signs of tampering.**
- **if the expiry date (EXP) printed on the pack has passed.** If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be taking MALTOFER®, talk to your medical practitioner or pharmacist.

BEFORE YOU START TO TAKE MALTOFER®

You must tell your medical practitioner or pharmacist if

- you have or have had an infection or tumour
- you are pregnant, plan to become pregnant or you are breastfeeding
- you have or have had any other health problems.

Taking other medicines

Tell your medical practitioner or pharmacist if you are taking any other medicines, including any that you have bought with a prescription or any without a prescription from a pharmacy, supermarket or health food shop.

The following medicine 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.

HOW TO TAKE 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.

When to take it

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 it

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 it

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 take too much (overdose)

Immediately telephone your medical practitioner, or:

- **In Australia - Poisons Information Centre (telephone 13 11 26)**
- **In New Zealand - The National Poisons Centre (telephone 0800 POISON or 0800 764 766),**

or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much MALTOFER®. Do this even if there are no signs of discomfort or poisoning.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your medical practitioner or pharmacist.

WHILE YOU ARE TAKING MALTOFER®

Things you must do

Tell all medical practitioners, dentists and pharmacists who are treating you that you are taking 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 must 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.

Things to be careful of

Be careful driving or operating machinery until you know how MALTOFER® affects you. However, MALTOFER® has no or negligible influence on your ability to drive a car or operate machinery.

POSSIBLE SIDE EFFECTS

Like all medicines, MALTOFER® can cause side effects, although not everybody gets them.

Side effects can occur with the following frequency:

Very common, may affect more than 1 in 10 people

- discoloured stool

Common, may affect up to 1 in 10 people

- diarrhoea
- nausea
- indigestion
- abdominal pain, discomfort or bloating
- constipation

Uncommon, may affect up to 1 in 100 people

- vomiting
- tooth discolouration
- gastritis
- skin rash
- itching
- hives
- redness of skin
- headache

Rare, may affect up to 1 in 1000 people

- muscle spasms
- muscle pain

If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your medical practitioner or pharmacist.

AFTER TAKING MALTOFER®

Storage

Keep MALTOFER® out of the reach and sight of children.

Do not use MALTOFER® after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

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

Do not store MALTOFER® tablets or oral liquid/drops or any other medicine, in a bathroom or near a sink.

Do not leave your medicine in the car or on window sills.

Disposal

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.

PRODUCT DESCRIPTION

What it 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, oral liquid is a dark brown solution in a 150 mL Type III 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, oral liquid is a dark brown solution in a 30 mL Type III brown glass bottle with child resistant tamper-evident screw cap and inserted dropper applicator. (AUST R 230644)

Not all presentations may be marketed.

Active ingredient

MALTOFER® Tablets: 100 mg iron as 370 mg iron polymaltose

MALTOFER® SYRUP, Oral liquid: 50 mg iron/5 mL as 185 mg iron polymaltose

MALTOFER® DROPS, Oral liquid: 50 mg iron/mL as 185 mg iron polymaltose

Inactive ingredients

MALTOFER® Tablets: crospovidone, hydroxypropyl cellulose, hypromellose, iron oxide red, iron oxide yellow, macrogol 6000, magnesium stearate, cellulose - microcrystalline and titanium dioxide.

MALTOFER® SYRUP, Oral liquid: cream flavour, ethanol, methyl hydroxybenzoate, propyl hydroxybenzoate, water-purified, sodium hydroxide, sorbitol solution (70%) non-crystallising and sucrose.

MALTOFER® DROPS, Oral liquid: water-purified, sucrose, cream flavour, sodium methyl hydroxybenzoate, sodium propyl hydroxybenzoate and sodium hydroxide.

Supplied in Australia by:

Vifor Pharma Pty Ltd
Level 9, 140 William Street
Melbourne VIC 3000
Australia
Tel: 1800 202 674

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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