

Vifor (International) Inc.
PATIENT INFORMATION LEAFLET
Iron (III) hydroxide-polymaltose-complex
Film-Coated Tablet 100 mg

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 have 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

Name of Product

Maltofer® (Iron Hydroxide Polymaltose Complex) Film-coated Tablets 100mg

What is Maltofer®?

Maltofer® is a medicine containing iron.

Maltofer® film-coated tablets are brown-maroon, round biconvex film-coated tablets.

Packages contain 30 (3 packs of 10) or 100 (10 packs of 10) film-coated tablets packed in aluminium strips. Not all package sizes may be marketed.

Each film-coated tablet contains:

- 100 mg iron as iron(III)-hydroxide polymaltose complex

The other ingredients are:

- crospovidone
- hydroxypropyl cellulose
- hydroxypropyl methylcellulose
- iron oxide red (E172)
- iron oxide yellow (E172)
- macrogol 6000
- magnesium stearate
- microcrystalline cellulose
- titanium dioxide (E171)

What is Maltofer® used for?

Maltofer® is used to:

- treat iron deficiency
- prevent iron deficiency, during pregnancy

How to use Maltofer®?

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose

- Treatment of iron deficiency with reduced number of red blood cells in children over 12 years and adults
1 to 3 tablets once daily or divided into separate doses for about 3 to 5 months

After normalisation of the red blood pigment (haemoglobin) value, continue with 1 tablet once daily for several weeks. This will replenish the iron stores.

- Treatment of iron deficiency with reduced number of red blood cells in pregnancy
2 to 3 tablets once daily or divided into separate dose

After normalisation of the red blood pigment value, continue with 1 tablet once daily until, at least, the end of pregnancy. This will replenish the iron stores and provide the increased amount of iron required during pregnancy.

- Treatment of iron deficiency with normal number of red blood cells in children over 12 years, adults and pregnancy, and prevention of iron deficiency in pregnancy

1 tablet once daily for 1 to 2 months

Method of use:

The daily dose can be divided into separate doses or can be taken at once. Take Maltofer® during or immediately after a meal. Maltofer® film-coated tablets should be swallowed whole.

Duration of use:

This depends upon the degree of iron deficiency.

If you stop taking Maltofer®:

Do not discontinue sooner than recommended as this may reduce the success of therapy.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

When should you not take Maltofer®?

Do not take Maltofer®, if you are/have

- allergic to iron(III)-hydroxide polymaltose complex or any of the other ingredients of Maltofer®
- an iron overload in the body
- disturbed use of iron by the body
- reduced number of red blood cells (anaemia), not caused by iron deficiency, such as due to
 - increased red blood cell breakdown
 - vitamin B12 deficiency

Check with your doctor before use if:

Talk to your doctor or pharmacist before taking Maltofer® if you have

- an infection or tumour

Undesirable effects/side effects

Like all medicines, this medicine 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
- constipation
- Stomach ache

Uncommon, may affect up to 1 in 100 people

- vomiting
- inflammation of the stomach (gastritis)

- hives
- reddening of the skin (erythema)
-
- • tooth discolouration
- skin rash
- itching
- headache

Rare, may affect up to 1 in 1000 people

- cramps
- muscle pain (myalgia)

These side effects are usually temporary.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

What other medicine should be avoided whilst taking Maltofer®?

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

The following medicines can affect Maltofer®:

- injectable iron medicines

Additional injectable iron medicines are not recommended.

What should you do if you miss a dose?

Just take the next dose at the usual time. Do not take a double dose to compensate the forgotten dose.

How should you keep Maltofer®?

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

Keep the tablets in the outer carton to protect from light.

Do not use this medicine after the expiry date which is stated on the label and carton after “Exp.:”. The expiry date refers to the last day of that month.

What to do when you have taken more than the recommended dosage (overdose)?

Contact your doctor or pharmacist if this occurs.

Care that should be taken when taking Maltofer®?

This medicinal product contains 12 mg of sodium (main component of table salt) in each tablet. This corresponds to 0.6% of the recommended maximum daily sodium allowance that adults should take through nutrition.

Treatment with Maltofer may cause dark discolouration of the stools but this is harmless.

Children 12 years and younger:

Maltofer® tablets are not recommended for this age group. Other iron medicines are more suitable, such as Maltofer® oral drops and Maltofer® syrup.

Pregnancy and breast-feeding:

Based on the available data, negative influence on the foetus or the woman during pregnancy or breast-feeding is unlikely.

However, as a precaution: If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines:

Maltofer® has no or negligible influence on the ability to drive and use machines.

Name of product licence holder

Vifor Pharma Asia Pacific Pte. Ltd.