

GPO-L-ONE TABLET 500MG

Deferiprone (500 mg)

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What GPO-L-One is used for

GPO-L-One is used to treat iron overload caused by frequent blood transfusions in patients with thalassaemia major (a type of anaemia).

How GPO-L-One works

GPO-L-One contains the active ingredient deferiprone. It helps to remove excess iron from the body.

Before you use GPO-L-One

- When you must not use it

Do not take GPO-L-One if you:

- Are allergic to deferiprone or any other ingredients in the formulation.
- Have history of repeated episodes of neutropenia (low white blood cells count).
- Have history of agranulocytosis (very low white blood cell count).
- Are pregnant or breast-feeding.

- Before you start to use it

Tell your doctor if you have allergies to:

- Any other substances, including foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- Neutropenia or agranulocytosis
- Kidney problems
- Liver problems
- HIV positive or any impaired immune system problems
- Low serum ferritin level

Your doctor will also ask you to come in for tests to monitor body iron load. In addition he or she also might ask you to undergo liver biopsies.

- Taking other medicines

Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines and GPO-L-One may interfere with each other. It is important to tell your doctor or pharmacist if you are taking:

- Aluminium-based antacids (relieve heartburn or indigestion caused by excess stomach acid)
- Medicines known to cause neutropenia or agranulocytosis
- Vitamin C

This is not a complete list of medications to be careful with, please ask your doctor or pharmacist for further information.

- Pregnancy and lactation

Do not take this medicine if you are pregnant or plan to become pregnant. This medicine could seriously harm your baby. You must use effective contraception while you are taking this medicine. Ask your doctor which method is best for you. If you become pregnant while taking GPO-L-One, stop taking the medicine immediately and tell your doctor.

Do not take this medicine if you are breast-feeding. It is not known if deferiprone passes into your breast milk. Discuss with your doctor or pharmacist for advice before taking this medicine.

How to use GPO-L-One

Always take GPO-L-One exactly as your doctor has told you. If you are unsure, check with your doctor or pharmacist.

- How much to use

- Adult & Children Over 6 Years

Take 75 mg/kg/body weight daily, in 2 to 4 divided doses.

Dosage Table

| Body weight (kg) | Total daily dose (mg) | Total each dose (divided by 3) | Number of tablets daily |
|------------------|-----------------------|--------------------------------|-------------------------|
| 20 | 1500 | 500 | 1 x 3 times |
| 30 | 2250 | 750 | 1.5 x 3 times |

| | | | |
|----|------|------|---------------|
| 40 | 3000 | 1000 | 2 x 3 times |
| 50 | 3750 | 1250 | 2.5 x 3 times |
| 60 | 4500 | 1500 | 3 x 3 times |
| 70 | 5250 | 1750 | 3.5 x 3 times |
| 80 | 6000 | 2000 | 4 x 3 times |
| 90 | 6750 | 2250 | 4.5 x 3 times |

The dosage can be adjusted up to 100 mg/kg body weight daily, in divided dose. The total daily dose should not exceed 100 mg/kg. Please consult your doctor for the exact dosage to be taken.

- When to use it

GPO-L-One can be taken orally with or without food; however, you may find it easier to remember to take GPO-L-One if you take it with your meals.

- How long to use it

Continue to take your medicine as long as your doctor tells you.

- 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 taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Symptoms of overdose may include neurological disorders such as tremors, double vision, involuntary eye movement, slowing-down of speech or thought and problems with movement coordination.

While you are using it

- Things you must do

- Always take GPO-L-One exactly according to the instructions given to you by your doctor or pharmacists.
- Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription such as supplements or traditional medicines.
- If you are about to be started on any new

medicine, tell your doctor or pharmacist that you are taking this medicine.

- If you become pregnant while taking GPO-L-One, tell your doctor immediately.
- Tell your doctor or pharmacist immediately if you notice any side effects, or if the side effects gets serious or anything else that make you feel unwell.

- Things you must not do

- Do not stop taking your medicines without consulting your doctor.
- Do not use GPO-L-One after the expiry date which is stated on the carton and bottle.
- Do not give this medication to anyone else, even if they have the same condition as you.

- Things to be careful of

GPO-L-One should not affect your ability to drive or use machinery. However, be careful driving, operating machinery or doing jobs that require you to be alert until you know how this medicine affects you.

Side effects

Like all medicines, GPO-L-One can cause side effects, although not everybody gets them.

The most serious side effect is very low white blood cells count. Report immediately to your doctor any symptoms of infection such as: fever, sore throat or flu-like symptoms.

Common side effects:

Abdominal pain, nausea, vomiting, reddish/brown coloured urine, headache, diarrhoea, increase in appetite, fatigue, joint pain, low white blood cells, increase in liver enzymes.

Uncommon side effects:

Allergic reactions including skin rash or hives.

Neurological disorders (such as tremors, walking disorders, double vision, involuntary muscle contractions, problems with movement coordination) have been reported in children who had been voluntarily prescribed more than double the maximum recommended dose of 100 mg/kg/day for several years and have also been observed in children with standard doses of deferiprone. The children recovered from these symptoms after GPO-L-One discontinuation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

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

Storage and Disposal of GPO-L-One

Storage

Do not store above 30°C.
Keep medicines in original packaging and away from direct heat, light and excessive moisture.

Do not leave your medicine in the car. Keep all medicines out of the reach of the children.

- Disposal

The expiry date of GPO-L-One is printed on the carton and bottle. Do not use if after expiry date.

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

GPO-L-One is a dark green, oblong biconvex, film-coated tablet, one side bisected with DFP and 500 marked on each section.

- Ingredients

- Active ingredient
Each tablet contains Deferiprone 500 mg.

- Inactive ingredients
Microcrystalline cellulose, silicified microcrystalline cellulose, colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, talcum, macrogol (PEG), titanium dioxide, hydroxypropyl methylcellulose E5 & E15, copper chlorophyllin.

- Packing

100 tablets in HDPE bottle

- MAL Number

MAL12015002AZ

Manufacturer

The Government Pharmaceutical Organization (GPO)
75/1 Rama VI Road, Ratchathewi, Bangkok 10400, Thailand.

Product Registration Holder

IMEKS Pharma Sdn. Bhd.
No. 5 & 9, Jalan Udang Harimau 2, Medan Niaga Kepong, 51200 Kuala Lumpur, Malaysia.

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