

GPO-L-ONE TABLET[®]

Deferiprone (500mg)

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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 thalassemia major (a type of anaemia).

How GPO-L-One works

GPO-L-One contains active ingredient, deferiprone. It helps to get rid of the 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 the active ingredient deferiprone or any ingredients in the formulation.
- Have history of low white blood cells count
- Are pregnant or breastfeeding

If you are not sure whether you should start taking this medicine, consult your doctor.

- Before you start to use it

Tell your doctor if you have allergies to:

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

Please be informed that there may be discolouration of urine when taking this medicine.

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

- Kidney problems
- Liver problems
- HIV positive or any impaired immune system problems
- Low iron 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

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription. You may need to use different amounts of these medicines, or you may need to take different medicines. Your doctor will advise you. In particular, tell your doctor if you take any of the following:

- Aluminium-based antacids (relieve heartburn or indigestion caused by excess stomach acid)
- Medicines known to cause low white blood cells
- Vitamin C

Pregnancy and lactation

Please consult your doctor before start to use GPO-L-One if you are pregnant, plan to become pregnant, breast-feeding or intend to breast-feed. Your doctor will have weighed the risks of you taking GPO-L-One against the benefits they expect it will have for you.

How to use GPO-L-One

Always use GPO-L-One exactly according to the instruction given to you by your doctor or pharmacist. If you are unsure, check with your doctor or pharmacist.

- How much to use

- Adult & Children Over 6 Years

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

The dosage can be adjusted up to 100mg/kg body weight daily, in divided dose.

The total daily dose should not exceed 100mg/kg.

Please consult your doctor for the exact dosage to be taken.

- When to use it

Take GPO-L-One at the same time every day. The tablet should be taken orally and preferably with meal.

- How long to use it

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

- If you forget to use it

Take your dose as soon as you remember and continue to take it as you would normally. Do not take double dose to make up for the dose you missed.

- If you use too much (overdose)

If you or anyone else take too many tablets, you should immediately go to your nearest hospital emergency department or tell your doctor. Do this even if there are no signs of discomfort or poisoning. Take the carton or remaining tablets you have with you.

Symptoms of overdose may include neurological disorders such as tremors, double vision, involuntary eye movement, slowing-down of speech or thought, problems with movement coordination.

While you are using it

- Things you must do

- Always take your GPO-L-One exactly according to the instructions given to you by your doctor or pharmacist.
- Inform your doctor or your 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, remind your doctor and pharmacist that you are taking GPO-L-One.
- If you are pregnant or plan to be pregnant, get advice from your doctor.
- Tell your doctor or pharmacist immediately if you notice any side effects, or if the side effects get 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

Be careful driving or operating machinery until you know how this drug affects you.

Taking GPO-L-One may cause dizziness or headaches. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

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

The most serious side effects 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, diarrhoea, increase in appetite, headache, fatigue, flu syndrome, swelling, low white blood cells, joint pain, increase in liver enzymes

Uncommon side effects:

Fever, bacterial infection, feeling of discomfort, cyst formation (abnormal closed-sac in the body), depletion of minerals, dizziness, sleepiness, decrease in muscle activity, deafness, ear pain, sore throat, liver tenderness, jaundice, inflammation of liver and stomach, excess gas, skin reactions (rash, itchiness, redness), bone pain, muscle pain, leg cramps, painful inflammation of the tendons of the elbow, loss of menstruation, frequent urination.

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 calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (*Public -> Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety*)

Storage and Disposal of GPO-L-One

Storage

Keep medicines in original packaging. Store in a cool dry place, below 30°C. 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

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 500mg.

- Inactive ingredients
Cellulose microcrystalline, silicified microcrystalline cellulose, colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, talcum USP, PEG 6000/Macrogol 6000, titanium dioxide, hydroxypropyl methylcellulose E5, hydroxypropyl methylcellulose E15, copper chlorophyllin, propylene glycol

- Packing

100 tablets in HDPE bottle

- MAL Number

MAL12015002AZ

Manufacturer

The Government Pharmaceutical Organization (GPO)
75/1 Rama 6 Road, Rajtevi,
Bangkok 10400, Thailand.

Product Registration Holder

IMEKS Pharma Sdn. Bhd.
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