

LIPOPHARM CAPSULE[®]

Phospholipids (300mg)

What is in the leaflet

1. What Lipopharm is used for
2. How Lipopharm works
3. Before you use Lipopharm
4. How to use Lipopharm
5. While you are using it
6. Side effects
7. Storage and Disposal of Lipopharm
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Lipopharm is used for

Lipopharm is used for the treatment of a wide range of liver damage conditions such as liver failure, fatty liver, scarring of liver and toxin induced liver disease.

How Lipopharm works

The liver is the main organ responsible for detoxifying the body. Lipopharm serves to protect the liver cells from any damage from breakdown products of toxins present in liver cells. Furthermore, it also encourages liver cell recovery and regeneration after cell injury. Besides this, Lipopharm also provides the body with ready phospholipids that are essential for our body cells maintenance. Originally, phospholipids are produced by liver cells. A ready supply provided by Lipopharm decreases the effort and workload on the impaired liver.

Before you use Lipopharm*- When you must not use it*

- During pregnancy
- When one is breast feeding
- Those with antiphospholipid syndrome (provokes blood clot)
- Children under age of 12
- Those with known allergy to soya, peanut, and phospholipids (or any other ingredients stated in the product description) and with known hypersensitive tendencies occurring upon consuming or having contact with the above substance.
- Those with hypersensitive reactions such as:
 - cold and red water eyes
 - hives and itching
 - wheezing

- Before you start to use it

If you are currently on any blood thinning drugs, please consult your physician before initiating treatment with Lipopharm.

- 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:

- Coumarin type anticoagulants (blood thinning drugs that include:
 - phenprocoumon
 - warfarin

Pregnancy and lactation

The use of Lipopharm in pregnancy is not recommended. There may be risk induced from the use of this product during breast feeding or pregnancy due to its soya bean derivatives.

How to use Lipopharm

Always take Lipopharm exactly as instructed by your physician. Check with your doctor or pharmacist if you are unsure.

- How much to use

The normal dosage for adults and children above 12 years of age is, 2 capsules of Lipopharm, 3 times daily.

The capsules should be taken before meals, without chewing and with a good amount of water.

- When to use it

Before meals, thrice a day.

- How long to use it

Continue to take your medicine as long as your doctor tells you to. This medicine helps to control your condition but does not cure it. It is important to keep taking this medicine even if you feel well.

- If you forget to use it

Take your dose as soon as you remember and continue to take it as you would normally. If it is time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose you missed.

- If you use too much (overdose)

Lipopharm is not prone to cause an overdose. It is unlikely to cause harm if ingested in excess. However, if you feel sick or any discomfort after excessive intake of the product, seek medical consultation immediately at your nearest hospital.

Be sure to bring along the packaging or remaining capsules with you to the hospital.

While you are using it*- Things you must do*

- Always take Lipopharm in accordance to dosage recommended by your doctor or pharmacist.
- Inform your doctor or pharmacist if you are planning to initiate or are already on any other medication, including those obtained without a prescription such as traditional medicine and supplements or any prescribed by another doctor/pharmacist.
- Be prompt to inform your doctor or pharmacist of any side effects stated in this leaflet or, otherwise, that arise after ingestion of Lipopharm.
- If your pregnant or plan to conceive please inform your doctor or pharmacist.
- Please inform your doctor or pharmacist if your currently breast feeding or planning to start breastfeeding.

- Things you must not do

- Do not stop taking medications without consulting your doctor/ pharmacist
- Do not use Lipopharm after the expiry date stated on the packaging.
- Do not give this medication to anyone else, even if they have the same condition as you.

- Things to be careful of

Be careful of driving or operating heavy machinery while on this medicine, until you know how Lipopharm affects you.

Side effects

Do not hesitate to inform your doctor or pharmacist if any one of the following side effects arises and becomes worrisome:

Side effects:

- More commonly, digestive symptoms include soft stools and diarrhea.
- Rare incidences of allergic skin reactions include itch and hives.
- Very rarely the occurrence of red spots and vaginal bleeding may arise.

LIPOPHARM CAPSULE®

Phospholipids (300mg)

Soya oil content in Lipopharm can cause severe respiratory allergic reaction such as

- Asthma (shortness of breath, or feeling or tightness in the chest)
- Swelling throat (may include the face, lips and tongue)
- Respiratory allergic reactions can be life threatening, thus prompt medical intervention is necessary. Please visit your nearest hospital as soon as any one of these symptoms arise.

Glycerol may cause headache, stomach upset and diarrhoea.

Inform your doctor if you notice any other side effect not listed above. Different individuals react differently to medications due to your unique biological make-up. There may be small instances that side effects not listed above occur in some consumers of this product. Every individual may respond differently to a specific drug.

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 Lipopharm

Storage

Do not store above 25°C.
Keep out of reach and sight of children.

- Disposal

Do not use Lipopharm after the expiry date which is stated on the carton or aluminium foil. If your doctor instructs you to stop taking Lipopharm or if it has passed the expiry date, ask your pharmacist regarding the proper way to dispose the remaining medicines.

Product Description

- What it looks like

Lipopharm is a gold to yellow-brown viscous liquid contained in a colorless, transparent, oblong shaped, long soft gelatin shell.

- Ingredients

- Active ingredient

Each soft gelatin capsule contains 300mg phospholipids from soya beans (73-79% 3-sn-phosphatidylcholine)

- Inactive ingredients

All-rac-alpha tocopherol, soya bean oil refined, glycerol 85%, mono and diglycerides of fatty acids, gelatin, medium chain triglyceride.

- Packing

A push-through package consisting of transparent PVC / PE / PCTFE foil and hard aluminium foil is used as a container.

- MAL Number

MAL10110040XCR

Manufacturer

R.P. Scherer GMBH & CO KG
Gammerlsbacher Strae 2,
Germany.

Product Registration Holder

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

Date of revision

21/09/2017

Serial Number

NPRA(R4/1)280817/00229