

GOOFICE® 5mg Film Coated Tablets

Elobixibat 5mg

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What *GOOFICE*® is used for

GOOFICE® contains a medicine called elobixibat hydrate. It belongs to a group of medicines called laxative. These medicines are used to treat constipation. *GOOFICE*® is used to treat chronic constipation (except for constipation associated with organic diseases).

How *GOOFICE*® works

Elobixibat suppresses reabsorption of bile acids and increases the flow of bile acids to the colon. It consequently promotes moisture/electrolyte secretion to the colon, enhances bowel movement. Therefore, *GOOFICE*® induces the therapeutic effect on constipation.

Before you use *GOOFICE*®

- When you must not use it

Do not take *GOOFICE*® if you are allergic to elobixibat hydrate or any of the other ingredients of this medicine as listed in Ingredients (Product Description).

Do not take *GOOFICE*® if you have a documented intestinal obstruction associated with a tumor or hernia, or with the suspicion of such conditions.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

Do not stop the treatment without first discussing it with your doctor.

GOOFICE® should be used in pregnant women and women who may possibly be pregnant only if the expected therapeutic benefits outweigh the possible risks associated with the

treatment.

It is advised that lactating women should avoid *GOOFICE*®. If treatment with *GOOFICE*® is essential, breastfeeding must be discontinued during treatment. Transfer of elobixibat into milk has been reported in animal studies.

The doctor will weigh the benefits and risks to your baby of taking *GOOFICE*® while you are breastfeeding.

- Before you start to use it

Talk to your doctor or pharmacist before taking *GOOFICE*® if you have serious liver problems.

Children

No clinical studies to investigate the efficacy and safety of *GOOFICE*® in children have been conducted.

The Elderly

GOOFICE® should be administered carefully to the elderly. The elderly generally has reduced physiological functions, therefore reducing the dose may be necessary.

- Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. Taking *GOOFICE*® with certain other medicines may cause side effects or affect how they work. Do not start or stop other medicines without consulting your doctor or pharmacist.

Inform your doctor or pharmacist if you are taking:

- Bile acid preparations such as ursodeoxycholic acid (a medicine used to treat disease of biliary system and liver disease resulting from bile flow retention, improve dyspepsia after small intestine resection and that in inflammatory disease of small intestine, dissolve cholesterol gallstones, and improve liver function in chronic liver disease, primary biliary cirrhosis and chronic liver disease due to hepatitis C virus.) and chenodeoxycholic acid (a medicine used to treat cholelithiasis)

may be affected by *GOOFICE*®. Tell your doctor if you are taking or have recently taken these medicines as your dose may need to be adjusted.

- Aluminium-containing antacids such as sucralfate hydrate (a medicine used to treat gastric/duodenal ulcer and improve gastric mucosal lesion (erosion, bleeding, redness, edema) in acute gastritis and in acute exacerbation phase of chronic gastritis), aldioxa (a medicine used to improve subjective symptoms or objective of gastric/duodenal ulcer and gastritis), etc. may affect *GOOFICE*®. Tell your doctor if you are taking or have recently taken these medicines as your dose may need to be adjusted.

- Cholestyramine (a medicine used to treat high cholesterol levels) and colestimide (a medicine used to treat high cholesterol levels and familial high cholesterol levels) may affect *GOOFICE*®. Tell your doctor if you are taking or have recently taken these medicines as your dose may need to be adjusted.

- Digoxin (a medicine used to treat heart failure and very fast heartbeat) and dabigatran etexilate methanesulfonate (a medicine used to prevent blockage of blood supply to the brain and systemic embolism in patients with erratic heart rhythm not relating to heart valve) may be affected by *GOOFICE*®. Tell your doctor if you are taking or have recently taken these medicines as your dose may need to be adjusted.

- Midazolam (a medicine used as pre-anesthetic medication, to induce/maintain general anesthesia, for sedation during artificial respiration in intensive care, and for sedation during dental/oral surgery or treatment, and to treat prolonged seizures) may be affected by *GOOFICE*®. Tell your doctor if you are taking or have recently taken these medicines as your dose may need to be adjusted.

How to use *GOOFICE*®

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

GOOFICE® 5mg Film Coated Tablets

Elobixibat 5mg

The usual adult dose for oral use is 10 mg once daily as elobixibat before meal. The dosage may be adjusted depending on your symptoms but must not exceed the maximum dose of 15 mg per day.

Swallow the whole tablet with a glass of water. Do not chew, crush or split the tablet. The tablets cannot be split accurately as there is no break line in the middle. To ensure you get the entire dose, the tablets should be swallowed whole without chewing or crushing.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Take GOOFICE® for as long as your doctor recommends. Do not stop unless your doctor advises you to. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

If you forget to take a tablet, wait until your next dose and then carry on as usual. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

There are no data on overdose of the drug. Do not exceed the recommended dose. Actively monitor for timely response.

While you are using it GOOFICE®

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking GOOFICE®.

Tell your doctor immediately if you become pregnant while taking this medication.

Take GOOFICE® only with a doctor's prescription.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give GOOFICE® to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

There is no evidence of drug effects on the ability to drive or operate machinery.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Possible side effects are:

Very common (may affect more than 1 in 10) are:

- abdominal pain
- diarrhea

Common (may affect more than 1 in 100) are:

- abnormal hepatic function (increased liver enzymes)
- dizziness
- lower abdominal pain
- abdominal distension
- nausea
- upper abdominal pain
- abdominal discomfort
- soft feces
- anemia
- increased Creatinine Kinase (enzyme indicating muscle damage)

Uncommon (may affect more than 1 in 1000) are:

- stomatitis
- thirst
- skin rash with red, raised, itchy bumps
- increased vitamin E

Not known (the frequency of this side effect cannot be estimated from the

available data) are:

- increased LDH (a marker for cell damage)
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- headache
- hot flush
- flatulence
- defecation urgency
- vomiting
- abnormal gastrointestinal sounds
- constipation
- inflammation of the large intestine caused by temporarily reduced blood flow
- red blood in stool
- frequent bowel movements
- discolored feces
- unable to control bowel moment
- decreased appetite
- rash
- increased eosinophil (a type of white blood cell) count
- menstrual pain

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.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of GOOFICE®

- Storage

Keep out of the reach and sight of children.

Store GOOFICE® below 30°C.

- 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

GOOFICE® is a light-yellow round-shaped film-coated tablet, printed with EA1 on one side.

- Ingredients

- Active ingredient
 - Elobixibat hydrate

GOOFICE[®] 5mg Film Coated Tablets

Elobixibat 5mg

- Inactive ingredients

- Microcrystalline cellulose
- D-mannitol
- Hypromellose
- Croscarmellose sodium
- Light anhydrous silicic acid
- Magnesium stearate
- Macrogol 6000
- Titanium oxide,
- Yellow ferric oxide
- Carnauba wax

- MAL numbers:

MAL25046003AZ

Manufacturer

EA Pharma Co., Ltd.
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Product Registration Holder

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