

KOPOZGO 2.5MG, 5MG, 10MG, 15MG

CAPSULES

Mavacamten (2.5mg, 5mg, 10mg, 15mg)

What is in this leaflet

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

What KOPOZGO Capsules is used for

KOPOZGO is a prescription medicine used to treat adults with symptomatic obstructive hypertrophic cardiomyopathy (HCM). KOPOZGO may improve your symptoms, improve your ability to be active.

How KOPOZGO Capsules works

KOPOZGO belongs to a group of medicines called cardiac myosin inhibitors. It works by relaxing the muscles in your heart, which improves your heart's ability to pump blood to the rest of your body. This may improve your symptoms and your ability to be active.

Before you use KOPOZGO Capsules

- When you must not use it

Do not use KOPOZGO if:

- you are allergic to mavacamten or any of the other ingredients in KOPOZGO.
- you are taking medicines that are:
 - moderate and strong CYP2C19 inhibitors, or strong CYP3A4 inhibitors (e.g., ticlopidine, itraconazole, ketoconazole)

- moderate and strong CYP2C19 or CYP3A4 inducers (e.g., rifampicin, carbamazepine)

Ask your healthcare professional if you are unsure.

- you are pregnant, planning to become pregnant, or think you might be pregnant.

- Before you start to use it

Tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. KOPOZGO may harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with KOPOZGO.

If you are a female and able to become pregnant:

- Your healthcare provider will do a pregnancy test before you start treatment with KOPOZGO.
- You should use effective birth control (contraception) during treatment with KOPOZGO and for 4 months after your last dose of KOPOZGO.
- KOPOZGO may reduce how well some hormonal birth control works. Talk to your healthcare provider about the use of effective forms of birth control during treatment with KOPOZGO.

- are breastfeeding or plan to breastfeed. It is not known if KOPOZGO passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with KOPOZGO.

- Taking other medicines

Before and during KOPOZGO treatment, tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking KOPOZGO with certain medicines or grapefruit juice may cause heart failure. Do not stop or change the dose of a medicine or start a new medicine without telling your healthcare provider.

Especially tell your healthcare provider if you:

- Take medicines such as omeprazole (for example, Prilosec), esomeprazole (for example, Nexium), or cimetidine (for example, Tagamet).
- Take other medicines to treat your obstructive HCM disease.
- Develop an infection
- Plan to have open heart surgery

How to use KOPOZGO Capsules

- How much to use

- Take KOPOZGO exactly as your healthcare provider tells you to take it.
- Do not change your dose of KOPOZGO without talking to your healthcare provider first.
- Take KOPOZGO 1 time a day.
- Swallow the capsule whole. Do not break, open, or chew the capsule.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop your treatment with KOPOZGO if you have certain side effects.

- When to use it

Take KOPOZGO exactly as your healthcare provider tells you to take it.

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- How long to use it

Take KOPOZGO exactly as your healthcare provider tells you to take it.

- If you forget to use it

If you miss a dose of KOPOZGO, take it as soon as possible and take your next dose at your regularly scheduled time the next day. Do not take 2 doses on the same day to make up for a missed dose.

- If you use too much (overdose)

If you take too much KOPOZGO, call your healthcare provider or go to the nearest hospital emergency room right away.

While you are using KOPOZGO Capsules

- Things you must do

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

- Things you must not do

Do not use KOPOZGO for a condition for which it was not prescribed. Do not give KOPOZGO to other people, even if they have the same symptoms you have. It may harm them. It is not known if KOPOZGO is safe and effective in children. You can ask your healthcare provider or pharmacist for information about KOPOZGO that is written for health professionals.

- Things to be careful of

- The risk of heart failure is also increased when KOPOZGO is taken with certain other medicines. Tell your healthcare provider about the medicines you take, both prescribed and obtained over-the-counter, before and during treatment with KOPOZGO.

Side effects

KOPOZGO may cause serious side effects, including:

- Heart failure, a condition where the heart cannot pump with enough force. Heart failure is a serious condition that can lead to death. You must have echocardiograms before you take your first dose and during your treatment with KOPOZGO to help your healthcare provider understand how your heart is responding to KOPOZGO. People who develop a serious infection or irregular heartbeat have a greater risk of heart failure during treatment with KOPOZGO. People who undergo open heart surgery may have a greater risk of heart failure during treatment with KOPOZGO.
- Tell your healthcare provider or get medical help right away if you develop new or worsening:
 - shortness of breath
 - chest pain
 - fatigue
 - swelling in your legs
 - a racing sensation in your heart (palpitations)
 - rapid weight gain

The most common side effects of KOPOZGO include: dizziness and fainting (syncope).

These are not all of the possible side effects of KOPOZGO.

Call your doctor for medical advice about side effects.

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 KOPOZGO Capsules

- Storage

Do not store above 30°C.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

KOPOZGO is supplied as immediate release Size 2 hard gelatin capsules containing 2.5, 5, 10, or 15 mg of mavacamten. White opaque capsule bodies are imprinted with “Mava”, and the opaque cap is imprinted with the strength. The capsule contains white to off-white powder. KOPOZGO capsules are available in blisters of 14 capsules, as listed in the table below:

Strength	Capsule Cap
2.5 mg	Light purple
5 mg	Yellow
10 mg	Pink
15 mg	Gray

Not all strengths and pack sizes may be marketed.

- Ingredients

- Active ingredients (s)
Mavacamten

- Inactive ingredients
Croscarmellose sodium, hypromellose, magnesium stearate (non-bovine), mannitol, and silicon dioxide. The capsule contains black iron oxide, gelatin, red iron oxide, titanium dioxide, and yellow iron oxide.

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- *MAL number:*

MAL XXXXXXXX

Manufacturer

Patheon Inc.
2100 Syntex Court
Mississauga, Ontario
L5N 7K9, Canada

Product Registration Holder

DKSH Malaysia Sdn Bhd
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