APO-CAPTO TABLET

Captopril (12.5mg, 25mg)

What is in this leaflet

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

What Apo-Capto is used for

Apo-Capto (Captopril) is an ACE inhibitor. ACE stands for angiotensin converting enzyme.

Captopril is indicated for the treatment of essential hypertension (hypertension with no identifiable cause) or renovascular hypertension (high blood pressure caused by the kidney's hormonal response to narrowing of the blood vessel).

Apo-Capto is indicated for heart failure that has not responded adequately to or cannot be controlled by conventional diuretic and digitalis therapy.

How Apo-Capto works

Captopril works by blocking an enzyme in the body that is necessary to produce a substance that causes blood vessels to tighten. As a result, the blood vessels relax and this lowers the blood pressure.

Before you use Apo-Capto

- When you must not take it

Do not use captopril if you are pregnant. Stop using captopril and tell your doctor right away if you become pregnant. Captopril can cause injury or death to the unborn baby if you take the medicine during your second or third trimester. Use effective birth control while taking this medicine. Captopril can pass into breast milk and may harm a nursing baby. You should not breast-feed while you are using captopril.

- Before you start to use it

You should not use this medication if you are allergic to captopril or to any other ACE inhibitor.

To make sure you can safely take captopril, tell your doctor if you have any of these other conditions:

- kidney disease (or if you are on dialysis);
- liver disease:
- heart disease or congestive heart failure;
- angioedema (swelling under the skin);
- diabetes; or
- a connective tissue disease such as Marfan syndrome, Sjogren's syndrome, lupus, scleroderma, or rheumatoid arthritis.

- Taking other medicines

Tell your doctor about all other medicines you use, especially:

- lithium;
- a potassium supplement;
- salt substitutes that contain potassium;
- drugs that can dilate blood vessels,
- aspirin or other NSAIDs (nonsteroidal anti-inflammatory drugs)
- a diuretic (water pill).

Tell your doctor about all medications you use.

How to use Apo-Capto

- How much to use

The recommended adult dose ranges from 6.25 mg 3 times daily to 150 mg 3 times daily as prescribed by your doctor. Take exactly as directed by your doctor.

- When to use it

Apo-Capto should be taken 1 hour before meals.

- How long to use it

Do not stop taking Apo-Capto without first talking to your doctor. Stopping Apo--Capto abruptly may cause your condition to become worse.

- If you forget to use it

Take the missed dose as soon as you remember.

If it is almost time for the next dose however, skip the missed dose and take only the next regularly scheduled dose. Do not take a double dose of this medication.

- If you take too much (overdose)

If overdosage occurs, in all cases therapy with Apo-Capto should be discontinued and you should immediately contact your doctor or go to your nearest hospital emergency department.

Taking too much of this medication might cause hypotension (low blood pressure)

While you are using it

- 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 Apo-Capto.

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

- 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 Apo-Capto to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Do not use salt substitutes or potassium supplements while taking captopril, unless your doctor has told you to.

Conditions that may cause very low blood pressure include: vomiting, diarrhea, heavy sweating, heart disease, dialysis, a low salt diet, or taking diuretics (water pills). Follow your doctor's instructions about the type and amount of liquids you should drink while taking captopril. Tell your doctor if you have a prolonged illness that causes diarrhea or vomiting.

Side effects

Call your doctor at once if you have a serious side effect while taking captopril such as:

- feeling light-headed, fainting;
- urinating more or less than usual, or not at all;
- fever:
- pale skin, feeling light-headed or short of breath, rapid heart rate, trouble concentrating;
- easy bruising, unusual bleeding (nose, mouth, vagina, or rectum), purple or red pinpoint spots under your skin;
- fast, pounding, or uneven heartbeats;
- chest pain; or
- swelling, rapid weight gain.

Less serious captopril side effects may include:

- cough;
- loss of taste sensation, loss of appetite;
- dizziness, drowsiness, headache;
- sleep problems (insomnia);

- dry mouth, sores inside your mouth or on your lips;
- nausea, diarrhea, constipation; or
- mild skin itching or rash.

This is not a complete list of side effects and others may occur.

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 <u>portal.bpfk.gov.my</u> (Consumers → Reporting).

Storage and Disposal of Apo-Capto

- Storage

Remember to keep APO-CAPTO and all medications safely away from children.

Do not use this medicine after the month and year written after EXP on the container.

Store Apo-Capto at controlled room temperature (15° - 25°C). Protect from moisture.

- Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

Product Description

- What it looks like

Apo-Capto 12.5mg:

Each white, capsule-shaped, flat-faced, bevelled-edged tablets, partial bisect both sides, "APO" on one side, "12.5" on the other side contains captopril 12.5mg.

Apo-Capto 25mg:

Each white, square, biconvex tablets, quadrisect one side, other side

engraved "APO" over "25" contains captopril 25mg.

- Ingredients

Active Ingredient: Captopril

Inactive Ingredients: Lactose monohydrate, microcrystalline cellulose, magnesium stearate, croscarmellose sodium and colloidal silicon dioxide.

- MAL numbers:

Apo-Capto 12.5mg: MAL 19987341AR

Apo-Capto 25mg: MAL 19987340AR

Manufacturer

Apotex Inc. 150 Signet Drive Weston Toronto Ontario M9L 1T9 Canada

Product Registration Holder

Pharmaforte (M) Sdn Bhd 2, Jalan PJU 3/49 Sunway Damansara 47810 Petaling Jaya

Date of revision

4/12/2014

Serial number

BPFK(R4/1)031214/00070