## **COVAPRIL TABLET®**

Perindopril Erbumine 4mg

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#### What COVAPRIL is used for

This medicine is used to:

- treat high blood pressure (hypertension)
- treat heart failure (a condition where the heart is unable to pump enough blood to meet the body's needs)

## How COVAPRIL works

COVAPRIL tablet belongs to a group of medicines called ACE Inhibitors. These group of medicines works by widening the blood vessels. This makes it easier for your heart to pump blood through the body.

## Before you use COVAPRIL

- When you must not use it
- if you are allergic (hypersensitive) to perindopril or to any of the other ingredients of COVAPRIL tablets or to any other ACE Inhibitor
- if you have in the past suffered from acute swelling of the face, tongue or larynx (angioneuriotic syndrome), regardless of whether or not it has been caused by treatment with similar medicine (ACE Inhibitor).
- if you are more than 3 months pregnant. It is also better to avoid COVAPRIL tablets in early pregnancy.

Children: COVAPRIL tablets are not for use in children.

## - Before you start to use it

If you experience any of the following, please tell your doctor before you start taking COVAPRIL tablet:

- if you have narrowing of the heart valves (aortic or mitral stenosis) or heart muscle disease (hypertrophic cardiomyopathy) or narrowing of the artery supplying the kidney with blood (renal artery stenosis)
- if you have recently had a kidney transplant
- if you have any other heart or liver or kidney problems, or if you are having dialysis
- if you have diabetes which is not well controlled
- if you have been told the limit the salt in your diet or to use a salt-substitute containing potassium
- if you have a collagen disease such as systemic lupus erythematosus or scleroderma
- if you are going to have or are having treatment to reduce the effects of an allergy to bee or wasp stings
- if you are going to have cholesterol removed from your blood by a machine (LDL apheresis)
- you must tell your doctor if you think you are (or might become) pregnant. COVAPRIL tablets are not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after that stage.

In the event of the occurrence of a feeling of tightness in the chest and swelling of the face and tongue (angioneurotic oedema), you should immediately notify your doctor and stop the treatment with COVAPRIL tablet. This applies to all ACE Inhibitors.

Tell the doctor or pharmacist that you are taking COVAPRIL if:

- you are about to have an operation or a general anaesthetic
- you have recently had diarrhoea or vomited
- your blood pressure is not sufficiency lowered due to ethnic affiliation

## - Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular, talk to your doctor before taking COVAPRIL if you are taking:

- medicines for high blood pressure including water tablets (diuretics)
- water tablets (diuretics) which affect potassium, such as spironolactone, triameterene or amiloride
- medicine to increase your level of potassium
- medicines for diabetes (insulin or tablets)
- lithium (for mania or depression)
- medicines for mental illness such as depression, anxiety, schizophrenia or other psychosis
- medicines to treat autoimmune disorders (such as rheumatoid arthritis) or given after transplant surgery. These are called immunosupressants.
- non-steroidal antiinflammatory drugs (NSAIDs such as ibupropen, diclofenac) including aspirin for pain
- medicines for low blood pressure, shock or asthma

(including ephedrine, noradrenaline or adrenaline)

 medicines that make the blood vessels wider (vasodilators, such as nitrates)
Ask your doctor if you are not sure what these medicines are.
Tell the doctor if you have taken any of the medicines listed above in the past, but have now stopped.

#### How to use COVAPRIL

## - How much to use

Your doctor will decide on the amount of COVAPRIL tablet you should start take. This may be increased depending on your condition and other medicines you are taking.

Always take COVAPRIL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Do not change the amount of medicines you take unless your doctor tells you.

## - When to use it

COVAPRIL tablet maybe used on its own, or with other medicines which lower blood pressure.

- take COVAPRIL tablets by mouth only
- take them in the morning, before a meal.
- it is best to take your tablet(s) with a glass of water at the same time each day

## - How long to use it

Continue taking your medicine for as long as your doctor tells you.

Medicines for high blood pressure or heart failure will normally have to be taken for the rest of your life. If you stop taking COVAPRIL tablets your condition may get worse

## - If you forget to use it

Do not take a double dose to make up for a forgotten dose. If you have forgotten to take one or more tablets, you should skip the tablets which you have forgotten. Contact your doctor if in doubt.

## - If you use too much (overdose)

Immediately contact your doctor if you have taken too high a dose.

The following effects may happen: low blood pressure, shock, kidney problems, fast breathing, fast heartbeat, uneven heartbeat (palpitations), slow heartbeat, feeling dizzy or anxious and cough.

## While you are using it

## - Things you must do

Pregnancy:

You must tell your doctor if you think you are (or might become) Your doctor will pregnant. normally advise you to stop taking COVAPRIL tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of COVAPRIL tablets. COVAPRIL tablets are recommended in pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

## Breastfeeding:

Tell your doctor if you are breast-feeding or about to start breast-feeding. COVAPRIL tablets are not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

## - Things you must not do

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Do not take COVAPRIL to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

## - Things to be careful of

Driving and using machines

You may feel dizzy or tired when taking COVAPRIL, just as with other ACE Inhibitors. If this happens, do not drive or use machines. You must talk to your doctor about this.

#### Side effects

Like all medicines, COVAPRIL tablet can cause side effects, although not everyone gets them.

Common (affecting 1 or more than 1 in 100 but less than 1 in 10 patients)

- cough, shortness of breath
- feeling faint due to low blood pressure (especially when you start COVAPRIL, or when the amount is increased, or when you also take water tablets)
- headache, feeling dizzy or tired, feeling dizzy with a spinning sensation (vertigo), pins and needles, muscle cramps, blurred vision, eye pain, sensation of noises in the ears (tinnitus)
- feeling or being sick, stomach pain or indigestion
- changes in your sense of taste, diarrhoea, constipation, skin rash, itching.

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 portal.bpfk.gov.my (Consumers → Reporting).

# **Storage and Disposal of** *COVAPRIL*

## <u>Storage</u>

Keep your tablets in the pack until it is time to take them. If you take your tablets out of the pack they may not keep as well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store COVAPRIL or any other medicine in the bathroom or near a sink.

Do not leave your medicines on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep COVAPRIL where children cannot reach it.

A locked cupboard at least oneand-a-half meters above the ground is a good place to store medicines.

## - <u>Disposal</u>

If your doctor tells you to stop taking COVAPRIL, or the tablets have passed their expiry date, ask your pharmacist what to do with any medicine that is left over.

## **Product Description**

- What it looks like

An oblong, scored, white to offwhite tablet

## - Ingredients

Active ingredient

• Perindopril Erbumine

Inactive ingredients:

- Aerosil 200
- Croscarmellose sodium
- Microcrystalline cellulose
- Magnesium stearate
- Lactose monohydrate

## - <u>MAL number</u>

MAL10080061AC

## Manufacturer

UPHA PHARMACEUTICAL MFG. (M) SDN BHD (53667-M) Lot 2 & 4, Jalan P/7, Section 13. Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

## **Product Registration Holder**

DUOPHARMA (M) SDN. BHD. (42491-M) WHOLLY OWNED BY CCM DUOPHARMA BIOTECH BERHAD (524271-W) Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia.

## **Date of Revision**

28/02/2014