Approved Patient Information Leaflet for Medicines for Human:

Please note: This application is submitted as a duplicate and hence [PRODUCT NAME] is used to indicate the approved proprietary names as per below:

Master	Duplicate 1	Duplicate 2
PRODUCT NAME 5 mg, 10 mg and 20 mg	Apex Enalapril 5 mg, 10 mg and 20 mg	Camox Enalapril 5 mg, 10 mg and 20 mg

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

PRODUCT NAME 5 mg TABLET

PRODUCT NAME 10 mg TABLET

PRODUCT NAME 20 mg TABLET

Read all of this leaflet carefully before you are given PRODUCT NAME

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

PRODUCT NAME has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT PRODUCT NAME CONTAINS

The active substances are:

PRODUCT NAME 5 contains 5 mg enalapril maleate.

PRODUCT NAME 10 contains 10 mg enalapril maleate.

PRODUCT NAME 20 contains 20 mg enalapril maleate.

The other ingredients are; Maleic acid, lactose monohydrate, hypromellose E 464, croscarmellose sodium, sodium lauryl fumarate.

2. WHAT PRODUCT NAME IS USED FOR

PRODUCT NAME is used:

- To treat high blood pressure (hypertension)
- To treat heart failure (weakening of heart function). It can lower the need to go to the hospital and can help some patients live longer
- For preventing the weakening of heart function in many patients with early stage heart failure prior to the development of symptoms.

PRODUCT NAME is only available on your doctor's prescription.

- **BEFORE YOU TAKE PRODUCT NAME**

Do not take PRODUCT NAME:

- if you are allergic (hypersensitive) to enalapril, or any of the other ingredients of **PRODUCT NAME**
- if you have previously been treated with another medicine in the same class as **PRODUCT NAME** and have had allergic reactions such as swelling of the face, lips, mouth, tongue or throat which caused difficulty in swallowing or breathing (angioedema), or if you have been diagnosed with hereditary or idiopathic angioedema
- if you are pregnant or trying to become pregnant. This medicine may cause harm to your unborn baby
- if you have renal artery stenosis (narrowing of the arteries in your kidneys)
- if you have a problem with your kidney(s), you should not take an antibiotic (medicine used to treat an infection) from the fluoroquinolone class such as moxifloxacin or levofloxacin, while taking **PRODUCT NAME**.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist or professional healthcare provider.

Take special care with PRODUCT NAME:

The presence of other medical problems may affect the use of **PRODUCT NAME**. Talk to your doctor, pharmacist or healthcare professional before taking **PRODUCT NAME** if you:

- Have any of the following risk factors for developing symptomatic hypotension (low blood pressure):
    - Are taking diuretics (water tablets)
    - Are on a sodium (salt) restricted diet
    - Are on dialysis
    - Have recently had diarrhea or vomiting
    - Have heart failure with or without renal insufficiency (kidney failure)
- Have aortic stenosis (narrowing of the opening of one of your heart valves) or hypertrophic cardiomyopathy (when part of your heart muscle is abnormally thickened)
- Have kidney problems. Your doctor may need to adjust your dose
- if you are elderly or have moderate to severe kidney problems, you should not take an antibiotic (medicine used to treat an infection) from the fluoroquinolone class such as moxifloxacin or levofloxacin, while taking **PRODUCT NAME** as it may cause or aggravate kidney problems (see Do not take PRODUCT NAME);
- Have ever had hypersensitivity/angioneurotic oedema (a swelling that is similar to hives but is under the skin) of the face, lips, tongue or throat; whether or not related to treatment with another medicine in the same class as **PRODUCT NAME.** Black people may be at higher risk of this reaction than non-black people
- Have had an allergic reaction during desensitization with hymenoptra venom (the process of reducing allergy to poison from the stings of insects from the class of insects belonging to the order hymenoptra e.g. bees and wasps)
- Are receiving dialysis with high-flux membranes

- Are soon to have a major operation or an operation where you will need anaesthesia

Your doctor may want to monitor your treatment with **PRODUCT NAME** closely in any of the above instances. If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking **PRODUCT NAME**.

Taking PRODUCT NAME with food and drink:

PRODUCT NAME tablets are not affected by food.

Pregnancy and Breast-feeding

PRODUCT NAME should not be used if you are pregnant or breast-feeding.

Driving and using machinery

PRODUCT NAME is unlikely to affect your ability to drive or use machines.

Taking other medicines with PRODUCT NAME:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **PRODUCT NAME** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Tell your doctor, pharmacist or other healthcare professional if you are using or receiving any of the following medicines:

- other medicines for high blood pressure which may lower your blood pressure more than desired, including alcohol
- medicines which may increase the amount of potassium you have in your blood (e.g. spironolactone, triamterene or amiloride), potassium supplements or potassium containing salt substitutes
- lithium

- non-steroidal anti-inflammatories
- fluoroquinolone antibiotics (medicines used to treat infections) such as moxifloxacin or levofloxacin

3. HOW TO TAKE PRODUCT NAME

Do not share medicines prescribed for you with any other person.

Always take **PRODUCT NAME** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with **PRODUCT NAME** will last. Do not stop treatment unless instructed by your doctor

If you have the impression that the effect of **PRODUCT NAME** is too strong or too weak, tell your doctor or pharmacist.

The usual dose for adults is 1 tablet once a day. Swallow your tablets whole with a glass of water. You should take your medicine at the same time each day.

The usual starting dose is **PRODUCT NAME 10** or **PRODUCT NAME 20** once per day but your doctor may change your dose depending on your response.

Your doctor may want to adjust your dose if you have kidney problems, and may need to perform some tests to monitor your response to the dose change.

If you take more PRODUCT NAME than you should:

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken. You may experience low blood pressure which may cause you to feel dizzy, lightheaded, faint or weak. If you have taken too many **PRODUCT NAME** tablets, seek medical attention immediately.

If you forget to take PRODUCT NAME

- If you forget to take a dose, leave that dose out completely. Take your next dose at the right time and continue as before.
- Do not take a double dose to make up for the forgotten dose.

If you stop taking PRODUCT NAME

Do not stop taking **PRODUCT NAME** unless instructed by your doctor. If you do your symptoms could return or 'flare-up'.

5. POSSIBLE SIDE EFFECTS

PRODUCT NAME can have unwanted effects (side effects). Check with your doctor, pharmacist or healthcare professional if any of these unwanted effects persist or become bothersome. Do not be alarmed by the list below, you may not get any of them.

Stop taking **PRODUCT NAME** and contact your doctor immediately if you get any of the following:

- Swelling of the face, lips, mouth, tongue or throat which causes difficulty swallowing and breathing
- A condition called Stevens-Johnson syndrome which begins with flu-like symptoms and a painful red or purplish rash that spreads and blisters with the top layer of the skin eventually peeling off

Contact your doctor as soon as possible for advice if these frequently experienced symptoms cause you problems or last longer than a week:

- Headache, depression, taste abnormality
- Blurred vision
- Dizziness, chest pain, heart rhythm disturbances, temporary loss of consciousness caused by a loss in blood pressure
- Cough, difficulty breathing
- Nausea, diarrhoea, abdominal pain
- Rash
- Tiredness, weakness

Some less frequent side effects which you may experience include:

- Confusion, sleepiness, inability to sleep, nervousness, abnormal dreams, an abnormal skin sensation such as tickling or burning
- Ringing in the ears
- Low blood pressure when standing up, a noticeably rapid or irregular heartbeat
- Runny nose, sore throat, hoarseness, tight chest
- Vomiting, indigestion, constipation, loss of appetite, inflammation of the tongue, inflammation of the mucous membrane of the mouth
- Liver failure, jaundice
- Itchiness, hair loss, hives
- Muscle cramps
- Kidney problems
- Impotence.

Not all side effects reported for **PRODUCT NAME** are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF PRODUCT NAME

KEEP THIS MEDICINE OUT OF THE REACH AND SIGHT OF CHILDREN.

Store in the original packaging until required for use.

Do not store your medicine in the bathroom

Store at or below 25 °C, protected from moisture and light.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF PRODUCT NAME

PRODUCT NAME tablets are packed blister packs (alu-alu blister foil and aluminium foil) of 10 or 14 tablets each. Pack sizes of 30 or 28 tablets in a carton.

8. IDENTIFICATION OF PRODUCT NAME

PRODUCT NAME 5 is a white to off-white, round, flat-face bevelled edge tablet with “5” debossed on the one side and a breakline on the other.

PRODUCT NAME 10 is a white to off-white round, flat-face bevelled edge tablet with “10” debossed on the one side and a breakline on the other.

PRODUCT NAME 20 is a white to off-white round, flat-face bevelled edge tablet with “20” debossed on the one side and a breakline on the other.

9. REGISTRATION NUMBER

PRODUCT NAME 5 mg: 48/7.1.3/0922

PRODUCT NAME 10 mg: 48/7.1.3/0923

PRODUCT NAME 20 mg: 48/7.1.3/0924

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Austell Pharmaceuticals (Pty) Ltd

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11. DATE OF PUBLICATION

Date on the registration certificate: 01 October 2015

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