PATIENT INFORMATION LEAFLET

Read the entire leaflet correctly before you start taking Gulf Amlodipine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- Gulf Amlodipine has been prescribed for only you and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

Scheduling status: S3

Name of medicines:

GULF AMLODIPINE 5 (tablets)

GULF AMLODIPINE 10 (tablets)

What Gulf Amlodipine contains:

GULF AMLODIPINE 5: Each tablet contains amlodipine besylate equivalent to amlodipine 5 mg

GULF AMLODIPINE 10: Each tablet contains amlodipine besylate equivalent to amlodipine 10 mg

What Gulf Amlodipine is used for:

In the management of angina pectoris and hypertension.

Before taking Gulf Amlodipine:

Do not use Gulf Amlodipine if:

- you are sensitive or ever had a harmful reaction to amlodipine
- you are sensitive or ever had a harmful reaction to dihydropyridines
- you have hypotension (low blood pressure)

Use with caution:

- in patients with renal disorders
- in the elderly
- in patients with hepatic disorders
- in patients with heart failure
- if you suffer from porphyria

If you are pregnant or breast feeding your baby while taking Gulf Amlodipine consult your doctor, pharmacist or other health care professional for advice.

If you are taking medicines on a regular basis, using Gulf Amlodipine at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

How to take Gulf Amlodipine:

Initially 5 mg once daily which may be increased after 10 – 14 days if no improvement is shown.

Do not share medicines prescribed for you with others.

In the event of over dosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre.

Possible Side effects:

The following side effects can occur with use of Gulf Amlodipine:

Gastro-intestinal:

Abdominal pain, nausea, vomiting

Cardiovascular effects:

Peripheral oedema, palpitations, chest pain, hypotension

Central nervous effects:

Dizziness, headache, somnolence, insomnia, tremor

Musculoskeletal:

Fatigue, back pain, muscle cramps

Autonomic nervous system:

Dry mouth, flushing, increased sweating

Not all side effects reported for Gulf Amlodipine are included in this leaflet. Should your general health

worsen while taking Gulf Amlodipine, please consult your doctor, pharmacist or other health care professional for advice.

Storage and disposal information:

Store below 25 °C in a cool, dry place. Protect from light and moisture. Keep tightly closed.

Do not remove from blisters until required for use.

Keep all medicines in a safe place, out of reach of children.

Return all unused or expired medicines to your pharmacist.

Presentation:

Push- through PVC/Al blister strips of 10 tablets in packs of 30 tablets in a unit carton.

White HDPE containers of 30, 100, 500 and 1000 tablets

Identification of Gulf Amlodipine:

Gulf Amlodipine 5 – White to off white, flat, round, bevel edged tablet with a breakline on one side.

Diameter (± 8mm)

Gulf Amlodipine 10 – White to off white, flat, round, bevel edged tablet with a breakline on one side.

Diameter (±11 mm)

Registration number(s):

Gulf Amlodipine 5 – 41/8.1/0812

Gulf Amlodipine 10 – 41/8.1/0813

The Name and the Business Address of the Holder of the Certificate of Registration:

Gulf Drug Company (Pty) Ltd

22 Burnside Drive

Old Mill Industrial Park

Mount Edgecombe, 4300

www.gulfdrug.co.za

Date of publication of the Patient Information Leaflet:

15/08/2008