PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

KEYSAL 5 mg (Tablets)

KEYSAL 10 mg (Tablets)

Amlodipine besilate

Read all of this leaflet carefully before you start taking KEYSAL

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or pharmacist.

KEYSAL 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.

WHAT KEYSAL CONTAINS

The active substance is amlodipine.

KEYSAL 5 mg: Each tablet contains amlodipine besilate equivalent to amlodipine 5 mg.

KEYSAL 10 mg: Each tablet contains amlodipine besilate equivalent to amlodipine 10 mg.

The other ingredients are cellulose microcrystalline; sodium starch glycolate; calcium hydrogen phosphate anhydrous and magnesium stearate.

WHAT KEYSAL IS USED FOR

KEYSAL is used for the treatment of:

angina pectoris.

mild-to moderate hypertension, alone or in combination with other antihypertensives.

3. BEFORE YOU TAKE KEYSAL

Do not take KEYSAL:

If you are hypersensitive (allergic) to amlodipine besilate or any of the other ingredients of **KEYSAL**.

If you are hypersensitive (allergic) to dihydropyridines.

Take special care with KEYSAL:

Elderly patients should start **KEYSAL** therapy at a lower dose.

Dosage adjustments may be necessary in patients with kidney and liver disease.

Safety and efficacy in children has not been established.

Safety in porphyria has not been established.

Pregnancy and Breastfeeding:

Safety of **KEYSAL** in pregnant and lactating women has not been established.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking **KEYSAL**.

Taking other medicines with KEYSAL:

KEYSAL interacts with nitroglycerin, long acting nitrates, beta-blockers or other antianginal agents.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

4. HOW TO TAKE KEYSAL

Always take **KEYSAL** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **KEYSAL** is too strong or too weak, talk to your doctor or pharmacist.

Hypertension and Angina Pectoris:

Adults:

An initial dose of 5 mg **KEYSAL** once daily is recommended which may be increased to 10 mg once a day after 10-14 days of therapy if there is no improvement.

No dose reduction is required when adding KEYSAL to thiazide diuretics, beta- blockers, or angiotensin-converting enzyme inhibitors.

If you take more KEYSAL than you should:

There is no documented experience with **KEYSAL** overdosage. Gastric lavage may be of benefit.

Gross overdosage could result in excessive peripheral vasodilation, resulting in marked and probably prolonged systemic hypotension.

Clinically significant hypotension due to **KEYSAL** overdosage requires active cardiovascular support.

Intravenous calcium gluconate may be of benefit in reversing the effects of calcium channel blockade.

Since amlodipine is highly protein-bound, dialysis is not likely to be of benefit.

TREATMENT IS SYMPTOMATIC AND SUPPORTIVE.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take KEYSAL:

Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

KEYSAL can have side effects.

Cardiac disorders

Frequent: peripheral oedema, angioedema, palpitations.

Less frequent: syncope, vasculitis.

The following side effects *have been reported and frequencies are unknown:* hypotension (including orthostatic hypotension), myocardial infarction, arrhythmia (including ventricular tachycardia and atrial fibrillation), chest pain.

Nervous system disorders

Frequent: dizziness, headache, somnolence, flushing.

Less frequent: mood changes, dry mouth, peripheral neuropathy, increased sweating.

The following side effects *have been reported and frequencies are unknown:* hypertonia, hypoesthesia/paresthesia, tremor, insomnia, increased sweating, pain.

Gastrointestinal disorders

Frequent: nausea, abdominal pain, vomiting.

Less frequent: altered bowel habits, dyspepsia, gingival hyperplasia, pancreatitis.

The following side effects have been reported end frequencies are unknown: taste perversion.

Musculoskeletal, connective tissue and bone disorders

Frequent: fatigue.

Less frequent: arthralgia, asthenia, back pain, muscle cramps, myalgia.

Hepato-biliary disorders

The following side effects have been *reported and frequencies are unknown:* hepatitis, jaundice.

Blood and the lymphatic system disorders

Less frequent: leucopenia, thrombocytopenia.

The following side effects have been reported and frequencies are unknown: purpura.

Renal and urinary disorders

Less frequent: increased urinary frequency.

Reproductive system and breast disorders

Less frequent: impotence.

Endocrine disorders

Less frequent: gynaecomastia.

The following side effects *have been reported and frequencies are unknown:* weight increase/decrease.

Investigations

Less frequent: hyperglycemia.

The following side effects *have been reported and frequencies are unknown:* raised liver enzymes (mostly consistent with cholestasis).

Skin and subcutaneous tissue disorders

Less frequent: alopecia.

The following side effects have been reported and frequencies are unknown: allergic reactions with pruritus, rash, and erytherna multiforme.

Respiratory, thoracic and mediastinal disorders

Less frequent: dyspnoea.

The following side effects have been reported and frequencies are unknown: coughing.

Eye disorders

Less frequent: visual disturbances.

Ear and labyrinth disorders

The following side effects have been reported and frequencies are *unknown:* tinnitus.

Not all side effects reported for **KEYSAL** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF KEYSAL

Store all medicines out of reach of children.

Store at or below 30 °C.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF KEYSAL

1. Blisters:

KEYSAL 5 mg:

a) PVC/PE/Aclar - Alu Blister Pack

Tablets are packed in 250 micron white opaque PVC film laminated with 25 micron PE coated with 23 micron Aclar and 25 microns Printed Aluminium foil. Each blister contains 10 tablets.

Pack size: 30's— Each carton contains 3 blisters of 10 tablets each.

b) PVC/PVdC - Alu Blister Pack

Tablets are packed in white opaque 250 micron PVC film laminated with 90 gsm PVdC and 25 microns

Printed Aluminium foil. Each blister contains 10 tablets.

Pack size: 30's — Each carton contains 3 blisters of 10 tablets each.

KEYSAL 10 mg:

a) PVC/PE/Aclar -. Alu Blister Pack

Tablets are packed in 250 micron white opaque PVC film laminated with 25 micron PE coated with 23 micron Aclar and 25 microns Printed Aluminium foil. Each blister contains 10 tablets.

Pack size: 30's — Each carton contains 3 blisters of 10 tablets each.

b) PVC/PVdC - Alu Blister Pack

Tablets are packed in white opaque 250 micron PVC film laminated with 90 gsm PVdC and 25 microns

Printed Aluminium foil. Each blister contains 10 tablets.

Pack size: 30's — Each carton contains 3 blisters of 10 tablets each.

2. HDPE Containers:

KEYSAL 5 mg and **KEYSAL 10 mg:**

Tablets are packed in a HDPE container with a child resistant closure and induction sealing wad, in the following pack sizes:

Pack size: 30's

8. IDENTIFICATION OF KEYSAL

KEYSAL 5 mg:

White to off white, flat, bevel edged, barrel shaped uncoated tablets, debossed with 'C' on one side and '58' on the other side.

KEYSAL 10 mg:

White to off white, flat, bevel edged, round shaped uncoated tablets, debossed with 'C' on one side and '59' on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

KEYSAL 5 mg: 41/7.1/0749

KEYSAL 10 mg: 41/7.1/0750

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Novagen Pharma (Pty) Ltd.

Office 2, 100 Sovereign Drive

Route 21 Corporate Park

Nellmapius Drive

Irene – Pretoria

South Africa

(t) +27 12 345 3175

11. DATE OF PUBLICATION

Date of registration: 5 March 2009

Date of latest revision of the text as approved by Council: 5 March 2009

Date of notification with regard to amended Reg. 9 and 10: 16 January 2015

FOR NAMIBIA ONLY:

Schedule: NS2

Registration Numbers:

KEYSAL 5 mg: 14/7.1/0644

KEYSAL 10 mg: 14/7.1/0643