

LOWRAC®

DESCRIPTION

LOWRAC® is the trade name of Amlodipine Besylate, a calcium channel blocking agent, indicated as an antianginal and antihypertensive.

Each **LOWRAC®** 5mg Capsule contains Amlodipine Besylate equivalent to Amlodipine 5mg.

CHEMISTRY

Amlodipine Besylate is: 3-Ethyl 5-methyl 2-(2-aminoethoxymethyl)-4-(2-chlorophenyl)-1,4-dihydro-6-methylpyridine-3,5-dicarboxylate monobenzene-sulphonate.

SITE AND MODE OF ACTION

LOWRAC® is a calcium channel blocking agent which selectively inhibits calcium influx across cell membranes in cardiac and vascular smooth muscles, with a greater effect on vascular smooth muscle. **LOWRAC®** is a peripheral arteriolar vasodilator, which leads to a reduction in the afterload.

Amlodipine is slowly and almost completely absorbed from the gastrointestinal tract; bioavailability is approximately 65%. Its protein binding is very high. The extended half-life of Amlodipine allows for an easy once daily dosage regimen.

INDICATIONS

- LOWRAC®** is indicated for the treatment of chronic stable angina; alone or in combination with other antianginal agents.
- LOWRAC®** is indicated for the treatment of confirmed or suspected vasospastic angina; alone or in combination with other antianginal agents.
- LOWRAC®** is indicated for the treatment of hypertension; alone or in combination with other antihypertensive agents.

DOSAGE

Usual adult dose

Antianginal or antihypertensive: 5 to 10mg **LOWRAC®** once a day.

Usual pediatric dose

Safety and efficacy have not been established.

Notes

- A lower initial antihypertensive dose is recommended for small, fragile or elderly patients, and patients with hepatic function impairment, or when adding **LOWRAC®** to other antihypertensive therapy.
- For the elderly, and for patients with hepatic function impairment, an initial antianginal dose of 5mg of **LOWRAC®** is recommended.

ADVERSE EFFECTS

- More frequent effects: peripheral edema, flushing, headache.
- Less frequent effects: dizziness; palpitations, fatigue, nausea.

USE IN PREGNANCY

Studies on the use of Amlodipine in pregnant women have not been done. No evidence of teratogenicity or other embryo/fetal toxicity was observed in animal studies; however, the number of intrauterine deaths increased in rats. Accordingly, Amlodipine should not be used in pregnant women, unless deemed essential by the physician. FDA Pregnancy Category C.

USE IN LACTATION

It is not known whether Amlodipine is distributed into breast milk. Therefore, Amlodipine should not be used during lactation.

INTERFERENCE WITH CLINICAL AND LABORATORY TESTS

Not documented.

DRUG INTERACTIONS

No drug reactions of major clinical significance have been reported with Amlodipine, however, caution is recommended upon concurrent use with other highly protein-bound medications because Amlodipine is highly protein bound.

CONTRAINDICATIONS

Amlodipine should not be used in case of severe hypotension.

WARNINGS

Risk-benefit should be considered when the following medical problems exist:

- Aortic stenosis: because of increased risk of heart failure.
- Congestive heart failure: because of the slight risk for negative inotropic effect.
- Hepatic function impairment: because Amlodipine clearance may be reduced.

OVERDOSE

Limited information is available on the acute toxicity of Amlodipine in humans. Acute dilatation of blood vessels with marked fall in blood pressure may occur. Recommended treatment consists of the administration of intravenous fluids, dopamine or dobutamine, calcium chloride, isoproterenol, metaraminol or norepinephrine for hypotension; direct-current cardioversion, intravenous lidocaine, or procainamide for tachycardia; and intravenous atropine, isoproterenol, norepinephrine or calcium chloride, or the use of electronic pacemaker for bradycardia.

PRECAUTIONS

- The half-life of Amlodipine may be increased in the elderly. These patients may be more sensitive to the hypotensive effects of Amlodipine and may require a lower initial dose.
- In case of surgery, the anesthesiologist must be aware of hypotensive therapy.
- Gingival hyperplasia has been rarely reported with Amlodipine. Periodontal surgery may be indicated in some cases, and should be followed by careful plaque control to inhibit recurrence.
- Blood pressure determinations, ECG readings, and heart rate determinations are recommended primarily during dosage titration or when a dosage is increased, and also when other medications are added that affect cardiac conduction or blood pressure.

PRESENTATIONS

- Boxes of 14 or 28 blistered capsules of **LOWRAC®** 5mg Capsules.
- Hospital packs of different presentations.

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicaments out of the reach of children

COUNCIL OF ARAB HEALTH MINISTERS
UNION OF ARAB PHARMACISTS

Prescribing Information Available Upon Request

THE JORDANIAN PHARMACEUTICAL MANUFACTURING CO. LTD.
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