

Nidipro

PRESENTATION

Nidipro ® Capsule - Each capsule contains Nifedipine USP 20 mg as sustained release pellets and Atenolol USP 50 mg.

PHARMACOLOGY

Atenolol belongs to a group of medicines called beta-blockers. It has an effect on the heart by blocking the action of chemicals called noradrenaline and adrenaline on beta receptor and control its rate and rhythm of beating. By reducing the heart rate and the force of muscle contraction, atenolol reduces the need of heart muscle for oxygen (demand). Because angina occurs when oxygen demand of the heart exceeds supply, atenolol is helpful in treating angina.

Nifedipine belongs to a group of medicines called calcium-channel blockers. These medicines block the transport of calcium, via holes called channels, into the smooth muscle cells lining the heart blood vessels and other blood vessels of the body. Blocking calcium transport relaxes the muscles of the blood vessels and makes them wider.

Absorption of atenolol following oral dosing is consistent but incomplete (approximately 40 to 50%) with peak plasma concentrations occurring 2 to 4 hours after dosing. There is no significant hepatic metabolism of atenolol and more than 90% of that absorbed reaches the systemic circulation unaltered. The plasma half-life is about 6 hours and kidney is the major route of elimination.

Absorption of nifedipine following oral dosing is complete with peak plasma concentrations occurring about 3 hours after dosing. Nifedipine is >90% plasma protein bound. There is significant hepatic metabolism of nifedipine. The plasma half-life is between 6 and 11 hours for the sustained formulation of nifedipine.

Co-administration of atenolol and nifedipine has little effect on the pharmacokinetics of either. In the elderly, the systemic bioavailability and elimination half-life of both components are increased.

INDICATIONS AND USES

Management of hypertension where therapy with either a calcium channel blocker or a beta-blocking drug proves inadequate.

Management of chronic stable angina pectoris where therapy with a calcium channel blocker or a beta-adrenoceptor blocking drug proves inadequate.

DOSAGE & ADMINISTRATION

Adults

Hypertension: One capsule daily swallowed with water. If necessary, the dosage may be increased to 1 capsule dosed every 12 hours.

Angina: One capsule every 12 hours swallowed with water. Where additional efficacy is necessary, prophylactic nitrate therapy or additional nifedipine may be of benefit.

Elderly

Dosage should not exceed 1 capsule daily in hypertension or 1 capsule twice daily in angina.

CONTRAINDICATIONS

This combination should not be used in patients with any of the following conditions: known hypersensitivity to either active component, or any other excipient or other dihydropyridines. Bradycardia; cardiogenic shock; hypotension; metabolic acidosis; severe peripheral arterial circulatory disturbances; second or third degree heart block; sick sinus syndrome; untreated phaeochromocytoma; uncontrolled heart failure; women capable of childbearing or during pregnancy or during lactation; patients with clinically significant aortic stenosis; patients with marked renal impairment. This combination should not be used for secondary prevention of myocardial infarction.

SIDE EFFECTS

The following undesired events have been reported: Cardiovascular: flushing, edema. CNS: dizziness, headache. Gastrointestinal: gastrointestinal disturbance. Haematological: purpura. Reproductive: impotence. Others: fatigue.

PRECAUTION

Due to its beta-blocker component this combination may increase the number and duration of angina attacks in patients with Prinzmetal's angina due to unopposed alpha receptor mediated coronary artery vasoconstriction. Due to its negative effect on conduction time, caution must be exercised if it is given to patients with first degree heart block.

DRUG INTERACTION

This combination must not be used in conjunction with calcium channel blockers with negative inotropic effects. eg. verapamil, diltiazem. Concomitant therapy with additional dihydropyridines eg. nifedipine, may increase the risk of hypotension, and cardiac failure may occur in patients with latent cardiac insufficiency.

USE IN PREGNANCY AND LACTATION

This combination is contraindicated in women capable of childbearing or during pregnancy or during lactation.

USE IN PEDIATRIC PATIENTS

Safety and effectiveness in pediatric patients have not been established.

STORAGE CONDITION

Store in a cool and dry place protected from light and moisture.

PACKAGE QUANTITIES

Nidipro ® Capsule- Each box contains 5x10 capsules in blister pack.

