GIS Pharma Part. Ltd.
ห้างหุ้นส่วนจำกัด จีไอเอส ฟาร์มา

NICARDIA-5

1.5 cm.

โปรดอ่านรายละเอียดเพิ่มเติมในเอกสารกำกับยา

ฆศ.842/2561

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COMPOSITION :

Each soft gelatin capsule contains Nifedipine USP 5 mg.

DESCRIPTION :

Calcium Antagonist, Cardiovascular therapeutic agent (Anti-hypertensive and Antianginal)

PHARMACOLOGY :

Absorption

About 90% of the active ingredient Nifedipine is absorbed after oral administration. Speed of absorption depends on the formulation (soft gelatin capsules)

In the case of sublingual administration of the capsules activity in plasma is demonstrable after 3-6 minutes and after a maximum of 20 minutes following oral intake. Maximum concentrations are attained 0.5-1 hour after absorption.

Following oral intake of the capsule plasma determination is possible after 20 minutes. Maximum concentrations are attained after 1-2 hours. Effective plasma levels are still present after 12 hours.

Bioavailability (absorption amount minus firstpass quota) is approximately 65%

Distribution :

The mean steady-state apparent volume of distribution of Nifedipine is 1.32 L/Kg. after oral administration. Nifedipine is highly bound to plasma proteins (92 to 98%) in particular albumin.

Elimination :

The elimination half-life of Nifedipine is 2 hours. No accumulation of unchanged active substance is to be expected in the case of long term medication. Nifedipine is almost totally metabolized and only traces thereof are found in unchanged form (renal dosage fraction Qo = 1) in the Urine. 70-80% of the dosage are excreted in urine in the form of inactive metabolites and the rest is excreted in the faeces.

Clinical situation with possibly changed kinetics

In the case of renal insufficiency the kinetics are not affected although the hypotensive effect is enhanced. Doses of Nifedipine must be reduced in liver cirrhosis.

MECHANISM OF ACTION :

Nifedipine inhibits the influx of Calcium into the heart muscle cell, the smooth muscle cells of the coronary arteries and the peripheral arterioles (resistance vessels). Nifedipine brings about an improvement in the oxygen supply to the heart muscle with simultaneous reduction of oxygen requirements, thereby exerting an antianginal effect. Normalization of elevated blood pressure is brought about by a reduction in peripheral resistance through the dilatation of the arterioles.

INDICATIONS :

Chronic stable angina. Unstable angina pectoris. Prinzmetal's or Vasospastic angina and Systemic hypertension.

USUAL DOSAGE :

ANGINA - Initially 10 mg 3 times daily. Patients with variant angina may require larger dose of more frequent administration i.e. 20 mg 3-4 times daily.

Conversely lower starting doses may be appropriate for the elderly or in combination with other therapy. Titration of dose should usually proceed over 7-14 periods.

SPECIAL DOSAGE INSTRUCTIONS :

In the event of a threatening attack of angina pectoris and of active high blood pressure crisis, a rapid onset of action can be achieved by biting a **Nicardia** capsule. The contents of the capsule are held in the mouth and the active substance is rapidly absorbed via the oral mucosa. The capsule shells may then be swallowed.

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CONTRAINDICATIONS :

Nicardia capsules to be avoided during pregnancy unless the benefits outweighs the risk to the mother than the foetus. No data are available regarding use in Lactation. **Nicardia** capsules should not be used in severe hypotension with danger of collapse.

SIDE EFFECTS :

The most common adverse effects of Nifedipine therapy are headache, flushing dizziness, gastronite intestinal symptoms and lower leg oedema, swelling or fluid retension.

The main vasodilator-related adverse effects of Nifedipine is headache, flushing and dizziness have been reported to necessitate treatment withdrawal in 2 to 6% of patients.

PRECAUTIONS :

Because **Nicardia** has profound peripheral vasodilatory action, careful monitoring of blood pressure during the initial administration and titration of **Nicardia** is suggested, particularly for hypotensive cases.

Close observation is especially recommended for patients already taking medications that are known to lower blood pressure.

Peripheral oedema particularly in lower extremities can occur which responds to diuretic therapy.

PRESENTATION :

Blister packs of 10 x 10 in a carton (10 x 10's).

MANUFACTURED IN INDIA BY :

J.B. CHEMICALS & PHARMACEUTICALS LTD.
215/216, G.I.D.C. Industrial Area, Panoli, 394116,
Gujarat State, India.

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