NICARDIPINE MEDIS® 10 mg/10ml

Nicardipine hydrochloride

1. WHAT NICARDIPINE MEDIS® 10 mg / 10 ml?

Pharmaceutical form:

NICARDIPINE MEDIS 10 mg/10 ml: Dci: injectable solution I.V. (direct administration or infusion), box of 5 ampoules of 10 ml.

Pharmacological class:

Selective calcium channel blockers with vascular effects.

Nicardipine is an inhibitor of the slow calcium channels, belonging to the family of phenyl-dihydropyridines.

Administered by systemic route, nicardipine is a potent vasodilator which reduces the total peripheral resistance and lowers blood pressure.

The vasodilator action of nicardipine also occurs in the coronary and cerebral vessels.

Composition: per 10 ml ampoule

Active ingredient: Nicardipine (as hydrochloride) ….....…… 10 mg
List of excipients: sorbitol, hydrochloric acid……...…….s.q.f
Water for injections…….....… s.q.f ampoule of 10 ml
Active excipients : sorbitol

2. What NICARDIPINE MEDIS 10 mg/10 ml is used for?

- Hypertension accompanied with a visceral involvement threatening the prognosis at a very short-term (hypertensive emergency), in particular when:
• Malignant hypertension (with stage III hypertensive retinopathy),
• Hypertensive encephalopathy,
• Aortic dissection,
• Decompensation of left ventricular with pulmonary edema,
• Severe pre-eclampsia involving the maternal prognosis,
- In anesthesia
• Controlled hypotension,
• Perioperative Hypertension.

3. WHAT ARE THE NECESSARY INFORMATION BEFORE YOU TAKE NICARDIPINE MEDIS 10 mg/10 ml?

Contraindications:

• Hypersensitivity to nicardipine.
• Fructose intolerance, due to the presence of sorbitol in the composition.

Warning and precautions for use:

Warning:

• Hypertension during pregnancy : due to the threat risk, even foetal death, the decrease in blood pressure should be progressive and always closely monitored.
• A hypertensive episode which often accompanies a stoke is not an indication for emergency antihypertensive therapy. The decision must be made according to the presence of visceral complication threatening the prognosis in the short term.
• take into account the presence of sorbitol in case of fructose intolerance

Precautions for use:

• In coronary patients, it may be necessary to involve a beta-blocker
• To minimize the risk of infusion site irritation, it is recommended to change the injection site every 12 hours

Use during pregnancy and lactation:

• Pregnancy

The use of nicardipine should be considered during the first two trimesters of pregnancy only if necessary.

The use of nicardipine during the third trimester of pregnancy could potentially produce an undesirable tocolytic effect which could potentially interfere with the spontaneous induction of labor, but didn't reveal no specific foetotoxic effect of this molecule.

• Lactation:

Nicardipine and its metabolites are excreted in human milk at very low concentrations. The brief use (less than 1 week) of this treatment in postpartum authorizes the lactation subject to surveillance of neonatal blood pressure.

In other cases, it should as far as possible to avoid the lactation during treatment with this drug.

Interactions with other drugs:

• Not recommended combinations:

Dantrolene (infusion): in animal, cases of mortal ventricular fibrillation are constantly observed during administration of verapamil and dantrolene by IV route. The combination of a calcium antagonist and dantrolene is therefore potentially dangerous. However, some patients received the association of nifedipine and dantrolene without inconvenience.

• Combinations requiring precautions for use:

-Anticonvulsants enzymatic inducer (carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone): reduction of plasma concentrations of nicardipine by increasing its hepatic metabolism by the inductor. Clinical monitoring and possible adaptation of nicardipine posology during the treatment with the inducer and after its withdrawal.

-Baclofen: increased in the risk of hypertension, in particular orthostatic. Monitoring of blood pressure and dosage adaptation of the antihypertensive if necessary.

-Immunosuppressants (ciclosporin, everolimus, tacrolimus, sirolimus): increased blood concentrations of the immunosuppressant by inhibiting its metabolism. Dosage of blood concentrations of the immunosuppressant,monitoring of renal function and adaptation of its posology during the treatment and after its withdrawal.

-Itraconazole, Ketoconazole: increased risk of adverse effects, in particular the edema by decreased hepatic metabolism of nicardipine.

Clinical monitoring and possible adaptation of nicardipine posology during the treatment with itraconazole and after its withdrawal.

-Rifampicin: decreased plasma concentrations of nicardipine by increasing its hepatic metabolism. Clinical monitoring and possible adaptation of nicardipine posology during the treatment with rifampicin and after its withdrawal.

• Associations to be taken into account:

-Alpha-blockers used in the treatment of urologic disease (alfuzosin, doxazosin, prazosin, tamsulosin, terazosin), antihypertensive alpha-blocker (prazosin, trimazosin, urapidil): increase the hypotensive effect, increased risk of orthostatic hypotension.

-Amifostine: Increase the risk of hypotension,in particular orthostatic.

-Tricyclic antidepressants, neuroleptics: Increased the risk of hypotension, in particular orthostatic.

-Beta-blockers (except ESMOLOL): hypotension, heart failure in patients with latent or uncontrolled cardiac insufficiency(addition of negative inotropic effects). Beta-blockers may also reduce the sympathetic reflex reaction which happens in the case of excessive hemodynamic repercussion.

-Beta-blockers in cardiac insufficiency (bisoprolol, carvedilol, metoprolol, nebivolol):hypotension, heart failure in patients with latent or uncontrolled cardiac insufficiency (negative inotropic effect in vitro dihydropyridine,more or less marked depending on the products and may be added to the negative inotropic effects of beta-blockers). The presence of a beta-blocker treatment may also minimize the sympathetic reflex reaction which happens in the in case of excessive hemodynamic effect.

-nitrated and related derivatives (isosorbide dinitrate, isosorbide linsidomine, molsidomine, nicorandil, nitroglycerin): Increase the risk of orthostatic hypotension

-Glucocorticoids (except hydrocortisone replacement therapy) and Mineralocorticoids: Decreased antihypertensive effect (hydrosodic retention of corticoides).

• Major incompatibilities:

-Precipitation with products presenting in solution pH> 6(for example: bicarbonate solution, Ringer solution,diazepam, furosemide,sodium methohexital, thiopental).

-Risk of adsorption of nicardipine on plastic materials of infusion devices due to the presence of salt solutions.

4. HOW TO TAKE NICARDIPINE MEDIS 10 mg / ml?

Dosage and mode of administration:

In the treatment of hypertensive emergency, the dose will be adapted so that the drop in blood pressure does not exceed 25% of the initial level within one hour after the institution of the injectable treatment, in fact, a abrupt decrease in blood pressure may lead to myocardial ischemia, brain or kidney.

The antihypertensive effect is dependent of the administered dose.

• For a quick effect:

-Direct intravenous administration after dilution in 5% glucose solution at a rate of 1 mg / min until a cumulative dose of 10 mg.

-Or direct intravenous administration of a dose of 2.5 mg renewable after 10 minutes until a cumulative dose of 10 mg.

• For a more gradual effect:

-Intravenous infusion diluted in a 5% glucose solution at a rate of 8 to 15 mg / h over 30 minutes.

-The relay in either case is possible by continuous infusion at a rate of 2 to 4 mg / h, with dosage adaptation by increments of 0.5 mg / h.

- A switch can also be made to oral nicardipine 20mg capsules at dosage of 60 mg/ day in 3 daily doses, or to nicardipine 50 mg extended-release tablets, at dosage of 100mg/day, in 2 daily doses.

• Dosage in infants: 1-2 mg/m2 of body surface area in 5 minutes

Overdose:

Nicardipine is not dialyzable. It should ensure the maintaining of sinus rhythm and cardiac output. Major hypotension can be treated by IV infusion of any plasma volume expander.

5. WHAT ARE THE POSSIBLE SIDE EFFECTS?

Side effects reported are generally mild and may require occasionally a dose adjustment or rarely the stopping of the treatment.

Most are the result of the vasodilator effect of nicardipine.

The most common are: dizziness, lower limb edema, headache, flushing, palpitation. More rarely,there are tachycardia, BAV, sinus bradycardia, hypotension may be symptomatic: syncope, nausea and vomiting, thrombocytopenia, polyuria.

Very rare cases of elevation of hepatic enzymes, isolated cases of hepatitis. Exceptional cases of extrapyramidal syndrome have been reported. Local reaction at the injection site (thrombophlebitis, phlebitis), specially during infusion whose duration is greater than 16 hours.

6. HOW TO STORE NICARDIPINE MEDIS® 10 mg/10 ml?

Store at a temperature not exceeding 25°C in the outer carton. Protected from light

7. WHAT ARE THE CONDITIONS OF ISSUE?

LISTE I

8. PRESENTATION AND MA NUMBER:

Specialty	Presentation	N° MA
NICARDIPINE MEDIS 10 mg/10 ml	**box of 5 ampoules of 10 ml.**	**923 364 1**

DATE OF LAST REVISION: January 2014

This is a drug

- A drug is a specific product agent.
- A drug is a product acting on your health and its use, contrary to prescriptions may be dangerous for you.
- Strictly respect the doctor's prescription and the instructions of use he has prescribed.
- Follow your pharmacist's know this drug ; its indications and contra-indications.
- Do not discontinue the drug intake by yourself during the prescription period.
- Do not repeat the prescription or increase the dosage without consulting your doctor.

KEEP ANY DRUG OUT OF THE REACH OF CHILDREN.

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