Naftiprax®

Naftidrofuryl Hydrogen Oxalate

FORMS AND PRESENTATION
Naftiprax®: Film Coated Tablets. Box of 30.

COMPOSITION
Naftiprax®: Each film coated tablet contains Naftidrofuryl Hydrogen Oxalate 200mg.
Excipients: ammonio methacrylate copolymer Type B, glycerol dibehenate, lactose monohydrate, talc, magnesium stearate, polyacrylate dispersion 30 %, hypromellose, macrogol 4000.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Pharmacotherapeutic group: peripheral vasodilator,
ATC code: C04AX21.

Mechanism of action
Naftidrofuryl oxalate has been shown to exert a direct effect on intracellular metabolism. Thus, it has been shown in man and animals that it produces an increase of ATP levels and a decrease of lactic acid levels in ischaemic conditions, evidence for an enhancement of cellular oxidative capacity. Furthermore, naftidrofuryl oxalate is a powerful spasmolytic agent.
At vascular level: Naftidrofuryl, an antivasoconstrictor (not a vasodilator) agent, increases blood flow by lowering arteriolar tone.
At tissue level: Naftidrofuryl locally opposes the vasoconstricting and platelet proaggregant actions of serotonin by blocking 5 HT2 receptors, explaining the clinical antivasoconstrictor effect and the improvement of blood flow in ischemic areas without including systemic hypotension.

Pharmacokinetic properties
Naftidrofuryl oxalate is well absorbed when given orally. Peak plasma levels occur about 30 minutes after dosing and the half-life is about an hour, although inter subject variation is relatively high. Accumulation does not occur at a dose level of 200mg three times daily.
The drug becomes extensively bound to plasma proteins and is excreted principally via the urine, all in the form of metabolites.

INDICATIONS
Naftiprax® is indicated for the treatment of peripheral vascular disorders: intermittent claudication, night cramps, rest pain, incipient gangrene, trophic ulcers, Raynaud's Syndrome, diabetic arteriopathy and acrocyanosis.
Naftiprax® is indicated for the treatment of cerebral vascular disorders: cerebral insufficiency, cerebral atherosclerosis.

CONTRAINDICATIONS
-Hypersensitivity to the active substance or to any of the excipients listed.
-Patients with a history of hyperoxaluria or recurrent calcium-containing kidney stones.

PRECAUTIONS
The administration of Naftiprax® may modify the composition of the urine, promoting the formation of calcium oxalate kidney stones.
A sufficient amount of liquid should be taken during treatment to maintain an adequate level of diuresis.
The administration of Naftiprax® without liquid before going to bed may cause local oesophagitis. Therefore, it is essential to always take the tablet with a sufficient amount of water.
Cases of liver damage have been reported. In the event of symptoms suggesting liver damage, Naftiprax® must be discontinued.

Effects on ability to drive and use machines
None known.

PREGNANCY AND LACTATION
Pregnancy
There is no, or inadequate, evidence of the safety of naftidrofuryl oxalate in human pregnancy, but it has been in wide use for many years without apparent ill consequence, animal studies having shown no hazard. If drug therapy is needed in pregnancy, this drug can be used if there is no safer alternative.
Breast-feeding
In the absence of specific data concerning the excretion of the drug in human milk, Naftiprax® should not be used by breast-feeding women.

DRUG INTERACTIONS
None known.

ADVERSE EFFECTS
Adverse effects are listed below by system organ class and frequency. Frequencies are defined as: very common (> 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1000 to < 1/100); rare (≥ 1/10000 to < 1/1000); very rare (<1/10,000); not known (cannot be estimated from the available data).
Gastrointestinal disorders: diarrhea, nausea, vomiting, epigastric pain (uncommon); in some patients who took the medicinal product without liquid before going to bed, the tablet being stuck in the throat led to local oesophagitis (not known).
Renal and urinary disorders: calcium oxalate kidney stones (very rare).
Skin and subcutaneous tissue disorders: skin rash (uncommon).
Hepatobiliary disorders: liver damage (rare).

DOSAGE AND ADMINISTRATION
Posology
One tablet three times daily for a minimum of three months, or at the discretion of the physician.

Method of administration
For oral administration. The tablet should be swallowed whole during meals with a sufficient amount of water (minimum of one glass).

Paediatric population
The safety and efficacy of Naftiprax® in the paediatric population have not been established. This drug is not indicated for use in children.

OVERDOSAGE
Signs and symptoms
Depression of cardiac conduction and convulsions may occur.

Treatment
The stomach should be emptied by gastric lavage and emesis. Activated charcoal may be employed if necessary. Cardiovascular function and respiration should be monitored and, in severe cases, electrical pacemaking or the use of isoprenaline should be considered. Convulsions may be managed by diazepam.

STORAGE CONDITIONS
Store below 30ºC.
Keep in original pack in intact conditions.

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Marketing Authorization Holder
Benta S.A.L. - Lebanon

Manufacturer
Manufactured by Benta Lyon S.A.S Saint Genis Laval, France
For Benta S.A.L. – Lebanon

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