Cerebromap

100mg & 200 mg Capsules

COMPOSITION:

Each Cerebromap 100 mg capsule contains: 100 mg naftidrofuryl oxalate.

Each Cerebromap 200 mg capsule contains: 200 mg naftidrofuryl oxalate.

PHARMACOLOGICAL ACTION:

Pharmacodynamics:

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 ischemic 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 pro-aggregant 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. Naftidrofuryl enhances the cell energy potential and thus maintains aerobic glucose metabolism. It permits preservation of cellular functions under localized ischemic conditions. Naftidrofuryl also increases arterial oxygen tension.

Pharmacokinetics:

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 AND USAGE:

Peripheral vascular disorders

- Intermittent claudication
- Night cramps
- Rest pain
- Incipient gangrene
- Trophic ulcers
- Raynaud's Syndrome
- Diabetic arteriopathy
- Acrocyanosis

Cerebral vascular disorders

- Cerebral insufficiency
- Cerebral atherosclerosis

Particularly where they manifest themselves as memory impairment and lack of concentration and attention in elderly.

- Post stroke for functional and neurological recovery and shorter hospital stay.

WARNINGS & PRECAUTIONS:

A sufficient amount of liquid should be taken during treatment to maintain an adequate level of diuresis.

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.

Lactation: No information is available.

DRUG INTERACTIONS:

Not known.

CONTRAINDICATIONS:

Hypersensitivity to the drug: Patients with a history of hyperoxaluria or recurrent calcium-containing stones.

SIDE EFFECTS:

Naftidrofuryl oxalate is normally well tolerated in the dosage recommended. Occasionally nausea, epigastric pain and rashes have been noted.

DOSAGE AND ADMINISTRATION:

- ***Peripheral vascular disorders:*** 100 or 200 mg capsule three times daily for a minimum of three months, or at the discretion of the physician.
- ***Cerebral vascular disorders:*** one 100 mg capsule three times daily for a minimum of three months, or at the discretion of the physician.
- There is no recommended use for children.

Administration: For oral administration, the capsules should be swallowed whole during meals with a sufficient amount of water (minimum) of one glass.

PACKAGING AND STORAGE:

Cerebromap 100 mg capsules: Pack of 30 capsules.

Cerebromap 200 mg capsules: Pack of 30 capsules.

Store in a dry place at temperature not exceeding 30° C.

Keep All Medicines Out of Reach of Children

Manufactured by: Apex Pharma - S.A.E - Badr City- Egypt.

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