NUCLEO CMP FORTE

Summary Product Characteristics

1. Name of the medicinal product:

NUCLEO CMP FORTE capsules

2. Qualitative and quantitative composition.

Composition per capsule:

- Cytidine-5'-disodium monophosphate (CMP disodium salt)… 5 mg
- Uridine-5'-trisodium triphosphate (UTP trisodium salt), Uridine-5'-disodium diphosphate (UDP disodium salt), Uridine-5'-disodium monophosphate (UMP disodium salt), on the whole 3 mg (equivalent to 1.330 mg of Uridine)

For a full list of excipients see section 6.1.

3. Pharmaceutical form:

Hard capsule.

4. Clinical particulars:

4.1. Therapeutical indications:

Treatment of neuropathies of osteoarticular (sciatica, radiculitis), metabolic (diabetic, alcoholic polyneuritis), infectious (herpes zoster) origin and a frigore.

It is also prescribed for the treatment of neuralgias (facial, trigeminal, intercostals) and for lumbalgias.

4.2. Posology and method of administration:

Nucleo CMP Forte capsules is administered by oral route.

Adults: 1 or 2 capsules 2 times daily

Children: 1 capsule 2 times daily. As prescribed by physician.

4.3. Contraindications:

Hypersensitivity to the active substances or to any of the excipients.

4.4. Special warnings and precautions for use:

Food has no influence over the action of NUCLEO CMP Forte therefore it can be taken before, during or after the meals.

If there is any kind of gastric disorder, it is recommended to take NUCLEO CMP Forte during the meals.

4.5. Interactions with other medicinal products and other forms of interaction:

Not known.

4.6. Pregnancy and lactation:

The safety of the medicinal product during pregnancy and lactation has not been established. In pregnant women or women that can become pregnant or during the lactation period, it should only be administered in case the expected therapeutic benefit is considered to outweigh any possible risk.

4.7. Effects on the ability to drive and use machines

There is no evidence of effects on the ability to drive or use machines.

4.8. Undesirable effects:

No undesirable effects have been described.

4.9. Overdose:

Given the limited toxicity of the product, intoxication is not foreseen, even in those cases when therapeutic doses have been accidentally surpassed.

In case of accidental overdose, institute symptomatic treatment.

5. Pharmacological properties

5.1. Pharmacodynamic properties:

Pharmacotherapeutic group: Other drugs for disorders of muscle-skeleton system

ATC Code: M09AX91

The activity of NUCLEO CMP Forte derives from the incorporation of its active substances into specific metabolic pathways. NUCLEO CMP Forte provides the phosphate groups needed for the metabolism of cerebrosides and phosphatidic acids that constitute the sphingomyelin and the glycerophospholipids, the main components of the myelin sheath. This confers the product with trophic properties for the axonal development and regeneration of the nerve tissue.

Experimental studies in animals with and induced neuropathy showed that the administration of NUCLEP CMP Forte exerts a preventive and healing action. After the administration, an increase of the density of the damaged nerve fibre is confirmed as well as of the diameter. This is translated into an activation of the axonal regeneration mechanism and an increase of the axonal flow rate.

5.2. Pharmacokinetic properties:

There are no available data regarding its pharmacokinetic properties in humans. The pharmaceutical product NUCLEO CMP Forte is an association of two nucleotides: CMP and UTP. These nucleotides are present in the organism. This is the reason why it is difficult to conduct a typical pharmacokinetic assay, with the administration of the product and the analysis of the content corresponding to outer contribution in biological fluids by means of the usual analytical techniques as this would require the administration of radiolabeled product enabling to differentiate the organic content from the outer contribution and this is questioned ethically and legally.

Experimental assays in animals showed that the maximum plasma concentration, both for CMP and UTP, is reached 20 minutes after the administration by oral route. The half life ranges from 1.5 to 5 hours in the alpha distribution phase. With respect to beta distribution phase (elimination), the half life is about 8 hours. UTP is mainly eliminated in the form of uridine. CMP is eliminated in a first phase as cytosine and later also in the form of uridine. Nevertheless, there were found radioactive traces even 72 hours after the administration, which confirms its contribution to the metabolic processes of the body.

5.3. Preclinical safety data:

As this is a product composed of two nucleotides that occur physiologically in the body, no preclinical safety studies were conducted.

6. Pharmaceutical particulars:

6.1. List of excipients:

Citric acid, Sodium citrate $2H_2O$, Aerosil 200, Magnesium stearate and Mannitol.

The capsule contains: Gelatin, Titanium dioxide, Indigotine and Iron oxide.

6.2. Incompatibilities:

None are described.

6.3. Shelf life:

2 years.

6.4. Special precautions for storage

Store in a dry place at temperature below 30 ºC

6.5. Nature and contents of container

Aluminium/PVDC blister.

Each package contains 30 hard gelatine capsules of grey/blue colour.

6.6. Special precautions for disposal

No special precaution

7. Marketing Authorization Holder

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