SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

DIFOSFOCIN "1000 mg/4 ml injectable solution"
DIFOSFOCIN "500 mg/4 ml injectable solution"

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

500 mg/4 ml Injectable solution
Each ampoule contains:
Active substance
Citicoline (Citidine-diphospho-choline) 500 mg

1000 mg/4 ml Injectable solution
Each ampoule contains:
Active substance
Citicoline (Cytidine-diphospho-choline) 1000 mg

For excipients, see 6.1

3. PHARMACEUTICAL FORM

Injectable solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Support treatment for Parkinsonian syndromes.

4.2. Posology and method of administration

Up to 1000 mg of product per day in a single or several administrations, by slow intravenous injection or by intravenous infusion by drops. In Parkinsonian syndromes the product is administered at the dosage of 500-1000 mg per day, by intramuscular injection, slow intravenous injection or by a drip. We recommend therapeutic cycles lasting 3 – 4 weeks, suitably spaced apart.

4.3. Contraindications

Hypersensitivity to the active substance or to any other excipients.

4.4. Special warnings and precautions for use

The product does not replace all those other therapeutic measures that may be advisable in various disease conditions, rather supports and integrates them.
In cases of intravenous administration, inject very slowly.

4.5. Interactions with other medicines and other forms of interaction

Exerts synergy activities with L-Dopa (permitting the dosage to be reduced) in Parkinsons' disease. The product may be used together with anti-haemorrhage substances, with substances that reduce inter-cranial pressure and with perfusion liquids.

4.6. Pregnancy and lactation

In pregnant women and very early infancy, the product should be administered in cases of effective need, under the direct control of a doctor.

4.7. Effects on the ability to drive and on using machines

DIFOSFOCIN does not influence the ability to drive vehicles or to use machinery.

4.8. Undesired effects

No secondary effects correlated to the drug have been reported.

4.9. Overdose

No cases of overdose have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic category: Psycho-stimulants and nootropics, ATC code: N06BX06.
The efficacy of Citicoline in treating Parkinson's disease and Parkinsonian syndromes has been proven; it determines a significant improvement in symptomatalogy above all concerning stiffness, bradycinesis, and some mental symptoms of Parkinsonian syndromes such as apathy and depression.

5.2. Pharmacokinetic properties

Citicoline improves cerebral circulation and therefore oxygen consumption, thus favouring the restoration of normal cerebral metabolism. Finally, it has been experimentally demonstrated that following protective activity on dopaminergic nervous centres it contrasts dopamine depletion at the caudal nucleus level. The product is therefore capable of clearly improving the level of consciousness and the electroencephalograph picture.

5.3. Pre-clinical safety data

The pre-clinical data demonstrate no risks to man on the basis of conventional pharmacological safety studies, no toxicity consequent on repeated administration, genotoxicity, potential cancerigenic potential or reproductive toxicity.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Water for injectable preparations, Sodium hydrate

6.2. Incompatibilities

Not pertinent

6.3. Shelf life

5 years

6.4. Special precautions for storage

No special conservation precautions

6.5. Nature and content of container

Type I neutral, white glass ampoule.
500 mg/4 ml Injectable solution - 5 vials of 4 ml
1000/mg/4 ml Injectable solution - 3 vials of 4 ml
1000/mg/4 ml Injectable solution - 5 vials of 4 ml

6.6. Special precautions for disposal

Unused product and refuse derived from this medicine must be disposed of in conformity with local laws.

7. MARKETING AUTHORISATION HOLDER

MAGIS FARMACEUTICI S.r.l. - Via Cefalonia, 70 - 25124 - BRESCIA.

8. MARKETING AUTHORISATION NUMBERS

500 mg/4 ml Injectable solution – 5 vials of 4 ml	MA no. 024121093
1000/mg/4 ml Injectable solution – 3 vials of 4 ml	MA no. 024121067
1000/mg/4 ml Injectable solution – 5 vials of 4 ml	MA no. 024121129

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal date: June 2010

10. DATE OF REVISION OF THE TEXT

November 2021