

COMPOSITION

Neurolep ® Tablet: Each tablet contains Piracetam BP 800 mg.

Neurolep ® Solution: Each 5 ml contains Piracetam BP 500 mg.

PHARMACOLOGY

Piracetam is a 'nootrope', that is to say, it is a psychotropic agent which acts directly on the brain to improve the efficacy of the telencephalon in both normal subjects and those suffering from some functional deficit. This area of the brain is involved in cognition and also has a role to play in learning and memory, in alertness and in consciousness. Piracetam does not produce either sedation or stimulation. Piracetam can act on the central nervous system in a variety of ways. It modifies neurotransmission within the brain, and can help to improve the metabolic environment essential for good neuronal function. It is also a haemorrhheological agent and can improve microcirculation without producing vasodilation. When given as acute or long term treatment for patients' suffering from a functional CNS deficit, it heightens alertness and increase cognitive function. This changes can seen as a significant increase in the a-and b-activity, with a reduction in d-activity on an EEG trace. Piracetam protects and restores cognitive functional capacity for cerebral trauma, e.g. hypoxia or intoxication, and after electroshock therapy. Piracetam may be given alone or together with other drugs when treating myoclonia due to anoxia. It reduces the duration of vestibular nystagamus. Piracetam also improves regional oxygen and glucose uptake in the brain in patients suffering from dementia subsequent to multiple infarcts, or in those with cerebral ischaemia. Piracetam inhibits the increased aggregation of activated platelets and, in conditions where there is abnormal rigidity of the RBC, it can restore deformability and the ability to pass through the microvasculature.

INDICATION

Cerebral vascular accidents and cerebral insufficiencies: Ischaemic or even haemorrhagic acute accidents, chronic manifestations of the above accidents or of cerebral atherosclerosis. Mental retardation in children: Ease of resuming individual contact, sociability and learning, improved intellectual performances and school results. Behaviour and psychotic problems in old age: Memory deficits, particularly with regard to fixation and evocation asthenia adaption disorders, disturbed psychomotor reactions.

DOSAGE & ADMINISTRATION

Adults: In cerebro-cortical insufficiency disorders, usual dose is 800 mg 3 times a day.

In myoclonic seizures, a dose of 7.2 gm daily, increasing by 4.8 gm per day every 3 to 4 days up to maximum of 20 gm daily, given in 2 or 3 divided doses.

Children: The daily dosage depends on the weight of the child, 50 mg/kg of body weight in 3 divided doses.

Once the desired results has been obtained, reduce the initial dose by half.

CONTRAINDICATION & PRECAUTION

Piracetam is contra-indicated in patients with severe renal insufficiency (creatinine clearance < 20 ml/min) and hepatic impairment. As the principal route of elimination for Piracetam is via the kidney, special care must be taken when treating patients known to

suffer from renal insufficiency. Monitoring of renal function is recommended in such cases. The increase in half-life is directly related to the decrease in renal function and creatinine clearance. This is also true for the older patient in whom creatinine clearance is dependent on age. When the creatinine clearance is < 60 ml/min, or serum creatinine is >1.25 mg/100 ml, the dosage prescribed should be calculated as following:

Creatinine clearance (ml/min)	Serum clearance (mg/100 ml)	Dosage
60-40	1.25 - 1.7	1/2 of normal dose
40-20	1.70 - 3.0	1/4 of normal dose

SIDE EFFECTS

The side effects reported include nervousness, agitation, irritability, anxiety and sleep disturbances. The incidence of these during clinical trials was (5%) and these were more often noted in the older patients taking > 2.4 gm daily. In the majority of cases, a dose reduction sufficed to make these symptoms disappear. Some patients may complain of fatigue or drowsiness, gastrointestinal problems, e.g. nausea, vomiting, diarrhoea and stomachache have also been reported but their incidence during clinical trials was <_ 2%. Other symptoms e.g. vertigo, headaches, trembling and sexual stimulation have occasionally been reported. Overdose: Piracetam appears to be devoid of toxicity even at very high doses and, therefore, the need for specific measures to be taken in case of an overdose is avoided. Drug Interactions: In a single case, confusion, irritability and sleep disorders were reported in concomitant use with thyroid extract. At present, no interaction has been observed with the following anti-epileptic drugs, clonazepam, carbamazepine, phenyton, phenobarbitone and sodium valporate, based on a small number of studies.

USE IN PREGNANCY AND LACTATION

Piracetam should not be prescribed during pregnancy or when breast feeding, except under exceptional circumstances. Piracetam is able to cross the placenta.

STORAGE

Store in a cool and dry place at a temperature below 300C, Keep away from sunlight. Keep out of the reach of children.

HOW SUPPLIED

Neurolep ® Tablet: Each box contains 10x4's tablets in blister packing.

Neurolep ® Solution: Each PET bottle contains 100 ml solution with a measuring cup.