xxxxxxxxxx-5343

PIRACETAM

NORMABRAIN-800

800 mg Film-Coated Tablet **Psychostimulant / Nootropic**

FORMULATION

Each film coated tablet contains:

. 800 ma

PRODUCT DESCRIPTION

Piracetam (NORMABRAIN - 800) 800 mg film-coated tablet is a light orange coloured, oval shaped, biconvex film-coated tablets, with

CLINICAL PHARMACOLOGY

Piracetam is a nootropic agent, which improves directly the efficiency of the higher functions of the brain involved in cognitive processes such as those related to learning, memory though and consciousness, both in normal and deficient situations. Piracetam modulates brain neurotransmission, promotes metabolic conditions for learning and memory retention.

Effects on cerebral neurotransmisssion:Piracetam increases synthesis of neurotransmitters in the brain.

Piracetam improves microcirculation by various rheological properties such as: enhanced red blood cell elasticity, reduced red blood adhesivity and agrregability, reduced platelet aggregation, enhanced phagacytosis and respiratory burst of neutrophils, prevention and inhibition of cerebral vasospsams.

Controlled studies in children presenting with developmental dyslexia have shown that Piracetam improves reading fluency and the capacity to comprehend the read matter

Piracetam improves the ability to execute tasks after different brain aggressions such as hypoxia, intoxications, electroshock therapy.

Piracetam reduces the duration of a provoked vestibular nystagmus.

Piracetam improves cerebral flow and cerebral metabolic rates of oxygen and glucose in multi-dementia patients.

Piracetam improves the regional cerebral blood flow as well as the regional glucose consumption, without affecting blood flow and glucose consumption in the regions with normal perfusion, and inhibits hyperaggregability of activated platelets in patients presenting with acute cerebral ischemia.

Following oral dose, the peak plasma concentrations of Piracetam are achieved within 45 to 60 minutes. It is not metabolized and is excreted unchange in urine. Half-life is 4 to 5 hours. Renal clearance of Piracetam is 80mL/minute.

INDICATIONS

For cerebral vascular accidents and cerebral insufficiencies: ischemic or even hemorrhagic acute accidents and chronic manifestations of the above accident of cerebral atherosclerosis; mental retardation in children; behavior and psychotic problems in old age **PRECAUTIONS**

Caution should be exercised when Piracetam is administered in patients with renal insufficiency

(creatinine clearance 60 mL/minute or serum creatinine 1.25 mg/100 mL)

No significant adverse effects have been noticed in patients taking Piracetam.

For suspected adverse drug reaction, report to FDA: www.fda.gov.ph or to TORRENT: www.torrentpharma.com".

Patient to seek medical attention immediately at the first sign of any adverse drug reaction shall appear

DRUG INTERACTIONS

Prothrombin time was increased in one patient stabilized on warfarin when treatment with Piracetam was started.

DOSAGE AND ADMINISTRATION

Adults: The average dosage is 800 mg three times a day. When the desired effect has been obtained, gradually reduce to 400 mg three times a day. Or as prescribed by the physician.

Children: The daily dose depends on the weight of the child and the dose range is 40 - 50 mg/kg of body weight given in 3 separate

doses. Once the desired result has been obtained, reduce the initial dose by half. Or as prescribed by the physician STORAGE

Store at temperatures not exceeding 30°C.

CAUTION

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

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Piracetam (NORMABRAIN - 800) 800 mg Film-Coated Tablet - Strip Pack of 5x10's (Box of 50's) - DRP-2764 DATE OF FIRST AUTHORIZATION

November 17 .2006

DATE OF REVISION

May 2016



Manufactured by : TORRENT PHARMACEUTICALS LTD. Indrad-382 721, Tal: Kadi, City: Indrad, Dist.: Mehsana, INDIA.

Imported and Distributed by : TORRENT PHARMA PHILIPPINES INC. Units 3 & 4, 34th Floor, Zuellig Building Makati Avenue corner Paseo de Roxas Makati City, PHILIPPINES



PRODUCT NAME :	Normabrain-800	COUNTRY: Philippines	LOCATION : Chhatral		Supersedes A/W No.:		
ITEM / PACK :	Insert	NO. OF COLORS: 1	REMARK:				
DESIGN STYLE :	Front	PANTONE SHADE NOS.:	SUBSTRATE:				
CODE :	xxxxxxxxx-5343	Black	Activities	Department	Name	Signature	Date
DIMENSIONS (MM) :	150 x 190		Prepared By	Pkg.Dev			
ART WORK SIZE :	S/S		Reviewed By	Pkg.Dev			
DATE :	27-09-2017		Approved By	Quality			