CLONAZEPAM

CLONOTRIL-0.5/CLONOTRIL-2

500 mcg and 2 mg Tablet
Antiepileptic

xxxxxxxx-5343

FORMULATION
Each tablet contains:
Clonazepam, USP ..... 500 mcg and 2 mg

PRODUCT DESCRIPTION
Clonazepam (Clonotril-0.5) 500 mcg is a light orange colored, octagonal, flat uncoated tablet with cross line on one side.
Clonazepam (Clonotril-2) 2 mg is a white, octagonal, flat uncoated tablet with cross line on one side.

PHARMACOKINETICS
Clonazepam is well absorbed following oral administration and peak plasma concentrations have been reported to occur within 4 hours. It is extensively metabolized in the liver, its principal being 7-aminoclonazepam, which has probably has little antiepileptic activity; minor metabolites are the 7-acetamido- and 3-hydroxy derivatives. It is excreted mainly in the urine almost entirely as its metabolites in free or conjugated form. It is about 86% bound to plasma protein and estimations of its plasma half-life range from about 20 to 40 hours, and occasionally more.

INDICATIONS
It is used in the treatment of all types of epilepsy and seizures, myoclonus and associated abnormal movements, panic disorders and status epilepticus.

DOSAGE AND ADMINISTRATION
Treatment should be started with low doses. The dose may be increased progressively until the maintenance dose suited to the individual patient has been found. The maintenance dosage must be determined according to clinical response and tolerance.
INITIAL DOSE - ADULTS: Initial dose of 1 mg by mouth in the evening. **CHILDREN:** Initial dosage should not exceed 0.25 mg/day for infants and small children (1 to 5 years old) and 0.5 mg/day for older children (6 to 12 years old). Or as prescribed by the physician.
MAINTENANCE DOSE - ADULTS: 4 to 8 mg daily in three or four divided doses. **CHILDREN:** 6 to 12 years old: 3 to 6 mg, 1 to 5 years old : 1 to 3 mg, 0 to 1 year old: 0.5 to1 mg, or as prescribed by the physician.
Once the maintenance dose has been reached, the daily amount maybe given as a single dose in the evening. Should several doses be necessary, the largest should be taken in the evening. The maintenance dose level is attained after 1 to 3 weeks of treatment. The maximum daily therapeutic dose for adults is 20 mg while in children is 200mcg/kg body weight.
Combination with other Antiepileptics : Simultaneous administration of more than one antiepileptic drug are a common practice in the treatment of epilepsy, especially in those who can not tolerate high doses of single medication. Clonazepam in such patients can be given in combination. The dosage of each drug may be required to be adjusted to obtain the optimum effect.

CONTRAINDICATIONS
Clonazepam is contraindicated in patients with known hypersensitivity to clonazepam or any of its components, also in patients suffering from acute pulmonary insufficiency, myasthenia gravis, CNS depression or coma, respiratory depression, sleep apnea.

PRECAUTIONS
It should be given with care to elderly or debilitated patients who may be prone to adverse effects. Caution is required in patients with muscle weakness, or those with impaired liver or kidney function, who may require reduced doses; its use should be avoided in severe hepatic impairment. Since Clonazepam produces CNS depression, patients receiving Clonazepam should be cautioned against engaging in hazardous task like operating machinery or driving a vehicle.

USE IN PREGNANCY AND LACTATION
The use of Clonazepam during pregnancy or lactation should be avoided unless there are compelling reasons and clinical situation warrants the risk. Mothers receiving Clonazepam should not breast-feed their infants.

DRUG INTERACTIONS
Hepatic enzyme inducers, such as carbamazepine, phenobarbital, or phenytoin, may accelerate the metabolism of clonazepam. Alcohol may affect the patients response to Clonazepam may be expected to have sedative interactions associated with benzodiapines in general.

ADVERSE EFFECTS
The principal adverse effect of clonazepam is drowsiness, which occurs in about 50% of all patients on starting therapy. Sedation, muscle weakness, ataxia which generally decrease on continued administration and are consequence of CNS depression. Less frequent effects include vertigo, headache, confusion, depression, slurred speech or dysarthia, changes in libido, tremor, visual disturbances, urinary retention or incontinence, gastrointestinal disturbances, changes in salivation and amnesia. Some patients may experience a paradoxical excitation which may lead to hostility, aggression, and disinhibition, Jaundice, blood disorders, and hypersensitivity reactions have been reported rarely. Respiratory depression and hypotension occasionally occur with high dosage and parenteral administration.

"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.

CAUTION
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.
Dangerous Drug to be prescribed by a PDEA S-2 Licensed Practitioner in a Triplicate personalized prescription form. It is a habit forming drug.

STORAGE
Store at temperatures not exceeding 30°C.

AVAILABILITY
Clonazepam (Clonotril-0.5) 500 mcg Tablet - Blister Pack of 10's (Box of 100's) - DRP-2810

DATE OF FIRST AUTHORIZATION
August 29, 2008
Clonazepam (Clonotril-2) 2 mg Tablet - Blister Pack of 10's (Box of 100's) - DRP-2809

DATE OF FIRST AUTHORIZATION
September 2, 2008

DATE OF REVISION
July 2016

torrent PHARMA

Manufactured by :
TORRENT PHARMACEUTICALS LTD.
Indrad-382 721, 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 :	Clonotril	**COUNTRY :** Philippines	**LOCATION :** Indrad		**Supersedes A/W No.:**		
ITEM / PACK :	Insert	**NO. OF COLORS:** 1	**REMARK :**				
DESIGN STYLE :	Front/Back	**PANTONE SHADE NOS.:**	**SUBSTRATE :**				
CODE :	xxxxxxxx-5343		**Activities**	**Department**	**Name**	**Signature**	**Date**
DIMENSIONS (MM) :	150 x 180		Prepared By	**Pkg.Dev**			
ART WORK SIZE :	S/S		Reviewed By	**Pkg.Dev**			
DATE :	21-07-2016	Black	Approved By	**Quality**			