

xxxxxxx-5343

# ALPRAZOLAM

## ALTROX 250 / ALTROX 500

### 250 mcg and 500 mcg Tablet

#### Anxiolytic

**FORMULATION :**

Each tablet contains :  
Alprazolam, USP ..... 250 mcg and 500 mcg

**PRODUCT DESCRIPTION:**

Alprazolam (Altrox 250) 250 mcg Tablet is a light yellow coloured, round flat beveled edge uncoated tablet with bisecting line on one side.

Alprazolam (Altrox 500) 500 mcg Tablet is a light orange coloured, round flat beveled edge uncoated tablet with bisecting line on one side.

**PHARMACOLOGY / PHARMACOKINETICS :**

Alprazolam is a triazolo analogue of benzodiazepine, which is indicated as an anti-anxiety drug in various disorders associated with anxiety. Alprazolam has a dose related depressant effect on the central nervous system varying from mild to impairment of task performance to hypnosis.

Following oral administration, Alprazolam is readily absorbed and peak concentrations occur within one to two hours. The plasma levels of Alprazolam is proportionate to the dose administered and over the dose range of 0.5 mg to 3 mg, serum levels of 8 to 37 ng/mL are achieved. The elimination half-life of Alprazolam is 12 to 15 hours and it is predominantly metabolized into alphahydroxy alprazolam, which is approximately half in biological activity of Alprazolam.

**INDICATIONS :**

It is indicated for the management of anxiety disorders and short term relief of the symptoms of anxiety, anxiety associated depression and for the treatment of panic disorders.

**CONTRAINDICATIONS:**

Alprazolam is contraindicated in patients with known hypersensitivity to this drug or other benzodiazepines. It is also contraindicated in acute narrow angle glaucoma.

**USE IN PREGNANCY, LACTATION AND CHILDREN:**

Safety of Alprazolam in pregnancy, nursing mothers and children under 18 years has not been established. Its use during first trimester of pregnancy should be avoided.

**ADVERSE EFFECTS :**

Side effects of Alprazolam usually appear at the beginning of therapy and usually disappear upon continued medication. The most frequent side effects are drowsiness and lightheadedness. Abrupt discontinuation of Alprazolam can cause withdrawal seizures. Alprazolam may cause anorexia, transient amnesia or memory impairment, loss of coordination, slurred speech, musculoskeletal weakness, pruritus, diplopia, change in libido, menstrual irregularities, incontinence and urinary retention. Alprazolam on prolonged use may lead to habituation and dependence.

"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:**

Alprazolam produces additive depressant effect on nervous

system when combined with drugs which themselves produce CNS depression. Cimetidine, fluvoxamine, oral contraceptives decrease the clearance of Alprazolam. Co-administration of Alprazolam with azole antifungal agents is not recommended.

**DOSAGE AND ADMINISTRATION:**

The usual starting dose is 250 mcg to 500 mcg three times daily. This may be increased according to the need of the patient to a maximum total daily dose of 3 to 4 mg in divided doses. In elderly patients the usual starting dose is 0.25 mg given twice or thrice daily. Or as prescribed by the physician.

**OVERDOSAGE:**

Alprazolam may cause somnolence, confusion, impaired coordination, diminished reflexes and coma. Treatment consists of supportive measures in the form of gastric lavage, intravenous fluids and ensuring adequate patency of airway.

**CAUTION:**

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription. To be prescribed by PDEA S-2 Licensed Practitioner in a personalized ordinary prescription. It is a habit forming drug.

**STORAGE:**

Store at temperatures not exceeding 30°C, Protect from light and moisture.

**AVAILABILITY**

Alprazolam (Altrox 250) 250 mcg Tablet - Blister Foil Pack of 10's (Box of 100's) - DRP-3132

Alprazolam (Altrox 500) 500 mcg Tablet Alu-Alu Blister Pack of 10's (Box of 100's) - DRP-3180

**DATE OF FIRST AUTHORIZATION**

April 11, 2006 - Altrox 250  
June 26, 2006 - Altrox 500

**DATE OF REVISION**

May 2016



Manufactured by :  
TORRENT PHARMACEUTICALS LTD.  
Intrad-382 721, Dist. Mehsana, INDIA.

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

<b>PRODUCT NAME</b>	: Altrox	<b>COUNTRY</b> : Philippines	<b>LOCATION</b> : Intrad	<b>Supersedes A/W No.:</b>			
<b>ITEM / PACK</b>	: Insert	<b>NO. OF COLORS:</b> 1	<b>REMARK :</b>				
<b>DESIGN STYLE</b>	: Front	<b>PANTONE SHADE NOS.:</b>	<b>SUBSTRATE :</b>				
<b>CODE</b>	: xxxxxxxx-5343		<b>Activities</b>	<b>Department</b>	<b>Name</b>	<b>Signature</b>	<b>Date</b>
<b>DIMENSIONS (MM)</b>	: 150 x 160		Prepared By	<b>Pkg.Dev</b>			
<b>ART WORK SIZE</b>	: S/S		Reviewed By	<b>Pkg.Dev</b>			
<b>DATE</b>	: 22-06-2016	Black	Approved By	<b>Quality</b>			