

## ZICAM

### **For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only**

Abbreviated Prescribing information for ZICAM (Clonazepam Dispersible Tablets.) [Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

**PHARMACOLOGICAL PROPERTIES:** Clonazepam exhibits pharmacological properties which are common to benzodiazepines and include anticonvulsive, sedative, muscle relaxing and anxiolytic effects. Animal data and electroencephalographic investigations in man have shown that clonazepam rapidly suppresses many types of paroxysmal activity including the spike and wave discharge in absence seizures (petit mal), slow spike wave, generalised spike wave, spikes with temporal or other locations as well as irregular spikes and waves.

**INDICATIONS:** In the treatment of petitmal and its variant, akinetic and myoclonic seizures.

**DOSAGE AND ADMINISTRATION:** Dosage: As directed by the Physician.

**CONTRAINDICATION:** Hypersensitivity to the active substance, to other rapamycin derivatives or to any of the excipient Acute pulmonary insufficiency; severe respiratory insufficiency, sleep apnoea syndrome, myasthenia gravis, severe hepatic insufficiency. Clonazepam must not be used in patients in a coma, or in patients known to be abusing pharmaceuticals, drugs or alcohol. **WARNINGS & PRECAUTION *Suicidal behaviour:*** Suicidal ideation and behaviour have been reported in patients treated with antiepileptic agents in several indications. **Dependence Use** of benzodiazepines may lead to the development of physical and psychological dependence upon these products (see 4.8). In particular, long-term or high-dose treatment, may lead to reversible disorders such as dysarthria, reduced coordination of movements and gait disorder (ataxia), nystagmus and double vision (diplopia):

**DRUG INTERACTIONS: *Coadministration with alcohol*** in combination with clonazepam may modify the effects of the drug, compromise the success of therapy or give rise to unpredictable side-effects. ***Antiepileptic drugs*** When used in conjunction with other antiepileptic drugs, side-effects such as sedation and apathy, and toxicity may be more evident, particularly with hydantoins or phenobarbital and combinations including them. ***Special Precautions*** The plasma concentration of clonazepam is often reduced by carbamazepine, phenobarbital, phenytoin or primidone, and possibly by theophylline. Concurrent treatment with phenytoin or primidone can change the plasma concentration of phenytoin or primidone (usually increases). **ADVERSE REACTIONS MARKETED BY:** • Memory loss (amnesia) after a traumatic event which may be linked with some strange behaviour (more likely with higher doses). • Depression. • Loss of sex drive, impotence. • Dependence on clonazepam – this is more of a risk when the dose is high or the treatment is for a long time, and is especially likely to occur in patients with a history of alcoholism or drug abuse. • Dizziness, light-headedness, sleepiness, tiredness, lack of co-ordination, poor concentration, restlessness, confusion, disorientation, floppiness and weakness of the muscles, headache. Particularly at the start of treatment. The side effects are usually short-lived and may disappear by adjusting the dose. • Breathlessness, swelling of the ankles, cough, tiredness and a racing heart. • Chest pain which may spread to your neck and shoulders and down your left arm. • Feeling unsteady when walking. • Platelet count bruising easily, being short of breath and nose bleeds. • Slurring of speech, lack of co-ordination of movement, double vision, rapid eye movements are all reversible effects that may occur particularly if on long-term or high-dose treatment. • Increase in number of fits (epileptic seizures) may occur during long-term treatment or in patients with a rare condition called porphyria. • Infants and small children may start to dribble or drool because of increased production of saliva and secretions from the airways. Children should therefore be watched carefully as this might cause problems in breathing and/or severe choking and coughing.

• Rarely, nausea and stomach problems can occur. • Rarely there may be hives, rashes, short-term hair loss or change in skin colouring. • Rarely, urinary incontinence (not being able to control when to pass water) may occur. There have been some isolated reports of: • changes to your blood or liver function (seen in test results). • early development of puberty in children. This effect is reversible. **Withdrawal symptoms** Stopping Clonazepam suddenly may cause withdrawal symptoms. These include, shakes (tremors), sweating, agitation, problems sleeping, anxiety (sometimes severe), headaches, muscle pain, tension, restlessness, confusion, irritability and fits (epileptic seizures). In severe cases the following effects may happen: a feeling of being unreal, oversensitivity to noise, light and touch, numbness and tingling of the hands and feet or hallucinations. Gradual withdrawal of Clonazepam will help to reduce these effects.



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**IN/ ZICAM 0.25,0.5,1 and 2 mg Tablets /JUN-19/01//AbPI**

(Additional information is available on request)