Summary of prescribing information for CLOBA tablets, CLOBA MT tablets, CLOBA suspension

Active Ingredient: each tablet of CLOBA contains: clobazam 5 mg, 10 mg, & 20 mg. Each mouth-dissolving tablet of CLOBA MT contains: clobazam 5 mg, 10 mg, CLOBA oral suspension contains: clobazam 2.5 mg/ml in 120 ml bottle. **Indication:** adjunctive therapy in patients with refractory epilepsy; Acute and chronic anxiety states. **Dosage:** Treatment of anxiety: Adults: 20-30 mg daily in divided doses or as a single dose given at night; maximum 60 mg daily. Elderly: 10-20 mg daily; treatment requires low initial doses and gradual dose increments under careful observation. Treatment of epilepsy: For doses above 5 mg/day administer in two divided doses, Adults: 20-30 mg daily; 60 mg daily. Pediatric patients aged 2 years and above: Patients ≤30 kg body weight: initiate at 5 mg daily; titrate as tolerated up to 20 mg daily, Patients >30 kg body weight: initiate at 10 mg daily; titrate as tolerated up to 40 mg daily. Maintenance dose of 0.3 to 1mg/kg body weight daily is usually sufficient. **Contraindications:** Hypersensitivity to clobazam or any of its excipients, Myasthenia gravis (risk of aggravation of muscle weakness), Narrow angle glaucoma, Any history of drug or alcohol dependence (increased risk of development of dependence), Severe respiratory insufficiency, Sleep apnoea syndrome (risk of deterioration), Severe impairment of liver function (risk of precipitating encephalopathy), During first trimester of pregnancy and breast-feeding. **Warning and precautions:** Somnolence or sedation: monitor for central nervous system (CNS) depression. Risk may be increased with concomitant use of other CNS depressants. Withdrawal: symptoms may occur with rapid dose reduction or discontinuation. Discontinue clobazam gradually. Physical and psychological dependence: monitor patients with a history of substance abuse for signs of habituation and dependence. Serious dermatological reactions (including Stevens-Johnson syndrome and toxic epidermal necrolysis): discontinue clobazam at first sign of rash unless the rash is clearly not drug-related. Suicidal behavior and ideation: monitor for suicidal thoughts or behaviors. **Pregnancy & Lactation:** Pregnancy: Based on animal data, may cause fetal harm. Since benzodiazepines are found in the breast milk, benzodiazepines should not be given to breast feeding mothers. **Interaction:** Drugs metabolized by CYP2D6: lower doses of these drugs may be required when used concomitantly with clobazam. Strong or Moderate CYP2C19 Inhibitors: dosage adjustment of clobazam may be necessary. Alcohol: Increases blood levels of clobazam by about 50%. **Adverse reactions:** common: constipation, somnolence or sedation, pyrexia, lethargy, and drooling. **Overdose:** Symptoms: CNS depression, associated with drowsiness, confusion and lethargy, possibly progressing to ataxia, respiratory depression, hypotension, and, rarely, coma or death. The risk of a fatal outcome is increased in cases of combined poisoning with other CNS depressants, including alcohol. Management: may include gastric lavage and/or administration of activated charcoal, intravenous fluid replenishment, early control of airway and general supportive measures, monitoring level of consciousness and vital signs. Hypotension can be treated by replenishment with plasma substitutes and, if necessary, with sympathomimetic agents. The efficacy of supplementary administration of physostigmine (a cholinergic agent) or of flumazenil (a benzodiazepine antagonist) in clobazam overdose has not been assessed. The administration of flumazenil in cases of benzodiazepine overdose can lead to withdrawal and adverse reactions. Its use in patients with epilepsy is typically not recommended.

Prepared on 21st Feb 2020.

It is recommended to refer full prescribing information before prescription.

For further medical information, please write to: Intas Pharmaceuticals Ltd., Corporate House, Near Sola Bridge, SG highway, Thaltej, Ahmedabad-380054, Gujarat, India. productqueries@intaspharma.com