Summary of prescribing information for BACLOF tablets, BACLOF liquid

Active Ingredient: each tablet of BACLOF contains: baclofen 10, 25 mg, BACLOF liquid contains baclofen 5mg/5ml, 100 ml bottle. **Indication:** treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. **Dosage:** Tablets: Initiate with a low dosage, preferably in divided doses, administered orally. Increase gradually based on clinical response and tolerability. The maximum dosage is 80 mg daily (20 mg four times a day). When discontinuing, reduce the dosage slowly. Liquid: adults: One 5ml spoonful (5mg) 3 times a day for 3 days; Two 5ml spoonfuls (10mg) 3 times a day for 3 days; Three 5ml spoonfuls (15mg) 3 times a day for 3 days; Four 5ml spoonfuls (20mg) 3 times a day for 3 days. Elderly: Small doses should be used at the start of treatment, the dose being titrated gradually against the response, under careful supervision. Paediatric population (0 to <18 years): A dosage of 0.75-2mg/kg body weight should be used. In children over ten years of age, however a maximum daily dosage of 2.5mg/kg body weight may be given. Treatment is usually started with half a 5ml spoonful (2.5mg) given 4 times daily. The recommended daily dosages for maintenance therapy are as: 12 months – 2 years: Two to four 5ml spoonfuls (10-20mg), 2 years – 6 years: Four to six 5ml spoonfuls (20-30mg); 6 years – 10 years: Six to twelve 5ml spoonfuls (30-60mg). **Contraindications:** hypersensitivity to baclofen or any component of this product. **Warning and precautions:** Abrupt discontinuation of baclofen has resulted in serious adverse reactions including death; therefore, reduce the dosage slowly when baclofen is discontinued. Neonatal withdrawal symptoms can occur; gradually reduce the dosage and discontinue baclofen before delivery. Baclofen can cause drowsiness and sedation. Patients should avoid the operation of automobiles or other dangerous machinery until they know how the drug affects them. Advise patients that the central nervous system effects of baclofen may be additive to those of alcohol and other CNS depressants. Baclofen can cause exacerbation of the following: psychotic disorders, schizophrenia, or confusional states; autonomic dysreflexia; epilepsy. Use with caution in patients with these condition. **Pregnancy & Lactation:** Pregnancy: Based on animal data, may cause fetal harm. At recommended oral doses, baclofen is present in human milk. There are no human data on the effects of baclofen on milk production and on breastfed infant. **Interaction:** CNS depressants like benzodiazepines, antihistamine, antipsychotic, and alcohol etc., may cause increased sedative effects. Morphine (epidural) may cause hypotension and dyspnea. Laboratory Test Interactions may cause false elevation of AST (aspartate aminotransferase), alkaline phosphatase, or blood glucose. **Adverse reactions:** most common drowsiness, dizziness, and weakness. **Overdose:** Symptoms: Patients may present in coma or with progressive drowsiness, lightheadedness, dizziness, somnolence, accommodation disorders, respiratory depression, seizures, or hypotonia progressing to loss of consciousness. Treatment: includes gastric decontamination, maintaining an adequate airway and respirations.

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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