Summary of prescribing information for BACLOF OD tablets

Active Ingredient: each extended release (GRS) tablet of BACLOF OD contains: baclofen 20 & 30 mg respectively. **Indication:** For the symptomatic treatment of neuronal spasticity due to multiple sclerosis, spinal cord, pathology & injury. **Dosage:** Initial dosage regimen should begin with Baclofen once daily 20 mg tablet administered once daily. The dosage can be gradually increased over a period of every 3 days, until optimum effect is achieved and as per the tolerability of patient. Maximum dose should not exceed 100 mg once daily. P*atients being transferred from baclofen immediate release (IR) formulation to Baclofen OD*: begin with the strength of Baclofen OD that is closest to the total daily dose of the IR regimen. The dosage should be increased gradually over an interval of every 3 days upto a maximum of 100 mg once daily. Pediatric use: There is no data available. Elderly: no sufficient clinical data. **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