Abridged prescribing information (VIBY)

Active Ingredient: Each pouch packet contains Vigabatrin 500 mg. **Indication:** Refractory Complex Partial Seizures as adjunctive therapy in patients 2 years of age and older who have responded inadequately to several alternative treatments; Vigabatrin is not indicated as a first line agent. Infantile Spasms - monotherapy in infants 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss. **Dosage:** Use the lowest dosage and shortest exposure to Vigabatrin consistent with clinical objectives. *Refractory Complex Partial Seizures:* Adults (Patients 17 Years of Age and Older) - initiate at 1000 mg/day (500 mg twice daily), increase in 500 mg/day increments at weekly intervals, depending on response to the recommended dose of 3000 mg/day (1500 mg twice daily). Pediatric (10 to 16 years of age) - Initiate at 500 mg/day (250 mg twice daily); increase total daily dose weekly in 500 mg/day increments, to recommended maintenance dose of 2000 mg/day (1000 mg twice daily); dose patients weighing more than 60 kg according to adult recommendations. *Infantile Spasms:* Initiate at a daily dose of 50 mg/kg (25 mg/kg twice daily); increase total daily dose every 3 days, in increments of 25 mg/kg/day to 50 mg/kg/day, up to a maximum daily dose of 150 mg/kg (75 mg/kg twice daily). *Renal Impairment:* Dose adjustment recommended. **Contraindications:** patients who have hypersensitivity to vigabatrin. **Warning and precautions:** *Permanent Vision Loss:* Vigabatrin can cause permanent bilateral concentric visual field constriction, including tunnel vision that can result in disability. In some cases, Vigabatrin also can damage the central retina and may decrease visual acuity. The onset of vision loss from Vigabatrin is unpredictable, and can occur within weeks of starting treatment or sooner, or at any time after starting treatment, even after months or years. Symptoms of vision loss from Vigabatrin are unlikely to be recognized by patients or caregivers before vision loss is severe. Vision loss of milder severity, while often unrecognized by the patient or caregiver, can still adversely affect function. The risk of vision loss increases with increasing dose and cumulative exposure, but there is no dose or exposure known to be free of risk of vision loss. Vision assessment is recommended at baseline (no later than 4 weeks after starting Vigabatrin), at least every 3 months during therapy, and about 3 to 6 months after the discontinuation of therapy. Once detected, vision loss due to Vigabatrin is not reversible. It is expected that, even with frequent monitoring, some patients will develop severe vision loss. Consider drug discontinuation, balancing benefit and risk, if vision loss is documented. Risk of new or worsening vision loss continues as long as Vigabatrin is used. It is possible that vision loss can worsen despite discontinuation of Vigabatrin. Because of the risk of vision loss, Vigabatrin should be withdrawn from patients with refractory complex partial seizures who fail to show substantial clinical benefit within 3 months of initiation and within 2-4 weeks of initiation for patients with infantile spasms, or sooner if treatment failure becomes obvious. Patient response to and continued need for Vigabatrin should be periodically reassessed. Vigabatrin should not be used in patients with, or at high risk of, other types of irreversible vision loss unless the benefits of treatment clearly outweigh the risks. Vigabatrin should not be used with other drugs associated with serious adverse ophthalmic effects such as retinopathy or glaucoma unless the benefits clearly outweigh the risks. Use the lowest dosage and shortest exposure to Vigabatrin consistent with clinical objectives. *Abnormal MRI signal changes* have been reported in some infants with Infantile Spasms receiving vigabatrin. *Suicidal behavior and ideation:* Antiepileptic drugs, including vigabatrin, increase the risk of suicidal thoughts and behaviour. *Withdrawal of AEDs:* Taper dose to avoid withdrawal seizures. *Anemia:* Monitor for symptoms of anemia. *Somnolence and fatigue:* Advise patients not to drive or operate machinery until they have gained sufficient experience on vigabatrin. **Pregnancy & Lactation:** Pregnancy: Based on animal data, may cause fetal harm. Nursing Mothers: vigabatrin is excreted in human milk. **Interaction:** Decreased phenytoin plasma levels: dosage adjustment may be needed. **Adverse reactions:** *Refractory Complex Partial Seizures* - Most common adverse reactions in controlled studies include (incidence ≥5% over placebo): Adults: in addition to permanent vision loss, fatigue, somnolence, nystagmus, tremor, blurred vision, memory impairment, weight gain, arthralgia, abnormal coordination, and confusional state. Pediatric patients (10 to 16 years of age): weight gain, upper respiratory tract infection, tremor, fatigue, aggression, and diplopia. *Infantile Spasms* (incidence >5% and greater than on placebo) Somnolence, bronchitis, ear infection, and acute otitis media. **Overdose:** Coma, unconsciousness, and/or drowsiness were described in the majority of cases of Vigabatrin overdose. Other less commonly reported symptoms included vertigo, psychosis, apnea or respiratory depression, bradycardia, agitation, irritability, confusion, headache, hypotension, abnormal behavior, increased seizure activity, status epilepticus, and speech disorder. These symptoms resolved with supportive care. There is no specific antidote for Vigabatrin overdose. Standard measures to remove unabsorbed drug should be used, including elimination by emesis or gastric lavage. Supportive measures should be employed, including monitoring of vital signs and observation of the clinical status of the patient. In an *in vitro* study, activated charcoal did not significantly adsorb Vigabatrin. The effectiveness of hemodialysis in the treatment of Vigabatrin overdose is unknown. In isolated case reports in renal failure patients receiving therapeutic doses of vigabatrin, hemodialysis reduced Vigabatrin plasma concentrations by 40% to 60%.

(Prepared on 26th Aug 2021. 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)