

Abridged Prescribing Information:

Active Ingredient: Blonitas 2 / 4 / 8 tablets contain blonanserin 2 mg / 4 mg / 8 mg. **Indication:** For the treatment of Schizophrenia in adult patients when first line treatment is ineffective. **Dosage:** Schizophrenia in adult patients-Starting dose: 4 mg twice daily (BID), gradually increased upto maximum 24 mg/day. Dose is adjusted according to patient's age, disease condition and response to therapy. Maintenance dose is: 8-16 mg/day. **Administration:** Twice a day, always take after meals **Contraindications:** Not to be given if patient is taking a protease inhibitor (e.g. nelfinavir – for HIV infection), azole antifungals, adrenaline, taking a CNS depressant drug, patient is comatose, patient is hypersensitive (allergic) to Blonanserin **Warnings & Precautions:** Neuroleptic malignant syndrome, Diabetes mellitus / hyperglycemia, Cardiovascular diseases, hypotension, tendency to develop hypotension, Parkinson's disease, Epilepsy, convulsive disorder, History of suicidal ideation / suicide attempts, Elderly, Hostility / positive symptoms, Liver dysfunction, Driving, riding, operating machinery, Intestinal paralysis/pseudo-ileus (loss of appetite, nausea, vomiting, symptoms of stasis of intestinal contents like abdominal distention, severe constipation, etc.) Syndrome of inappropriate antidiuretic hormone secretion (SIADH). **Pregnancy & Lactation:** Pregnancy: No studies; to be used only if the potential therapeutic benefit justifies the potential risk to the fetus *Pregnancy category:* Not mentioned. Lactation: discontinue nursing if taking the drug. **Interaction:** CYP3A4 inhibitors -HIV protease inhibitors (ritonavir, saquinavir), azole antifungals (ketoconazole, itraconazole), adrenaline, CNS depressants (alcohol, barbiturates, Benzodiazepines etc.), dopamine agonists (levodopa, bromocriptine), antihypertensive drugs, CYP3A4 inhibitors (erythromycin, clarithromycin, cyclosporine, diltiazem, grapefruit juice), CYP3A4 inducers (rifampicin, barbiturates, phenytoin, carbamazepine). **Adverse Reactions:** Parkinsonism (EPS) (tremor, muscle rigidity, excessive salivation, hypokinesia, gait disturbances, mask-like face), Akathisia, Dyskinesias (dysarthria, dysphagia, involuntary limb movements, abnormal movements of the mouth) Constipation, loss of appetite, nausea, elevated prolactin, insomnia, agitation, anxiety, drowsiness, dizziness, headache, excitement, fatigue, dry mouth, weakness. **Overdose:** Akathisia at overdose is seen. Data is Limited (*For details, please refer full prescribing information*)

Version date: 10/03/21. If you require any further information, please reply us on productqueries@intaspharma.com