Summary of prescribing information for GUDRIL tablets

Active Ingredient: Each film coated tablet of GUDRIL contains: Tramadol Hydrochloride IP 37.5 mg + Paracetamol IP 325 mg. **Indication:** For symptomatic short-term (five days or less) management of acute pain (moderate to severe) in adults. **Dosage:** recommended dose of 1 or 2 tablets every 4 to 6 hours as needed for pain relief up to a maximum of 8 tablets per day, or as prescribed by the physician. Duration of therapy should not exceed 5 days. Individualize dosing based on the severity of pain, patient response, prior analgesic experience, and risk factors for addiction, abuse, and misuse. Do not use with other acetaminophen- or tramadol-containing products. Severe Renal Impairment: Do not exceed 2 tablets every 12 hours. Do not abruptly discontinue in a physically dependent patient because rapid discontinuation of opioid analgesics has resulted in serious withdrawal symptoms, uncontrolled pain, and suicide. **Contraindications:** hypersensitivity to tramadol, paracetamol, any other component of this product or opioids. In any situation where opioids are contraindicated, including acute intoxication with any of the following: alcohol, hypnotics and narcotics, centrally acting analgesics, opioids or psychotropic drugs. In this situation use of this combination may worsen central nervous system and respiratory depression in these patients. Concomitant with MAO inhibitors (or within 14 days following discontinuation of such therapy) is contraindicated. **Warning and precautions:** Serotonin Syndrome: May be life-threatening. Can occur with use of tramadol alone, with concomitant use of serotonergic drugs, with drugs that impair metabolism of serotonin or tramadol. Risk of Seizure: Can occur at the recommended dose of tramadol. Concomitant use with other drugs may increase seizure risk. Risk may increase in patients with epilepsy, a history of seizures, and in patients with a recognized risk for seizures. Risk of Suicide: Do not prescribe for suicidal or addiction-prone patients. Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid. Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients: Monitor closely. Severe Hypotension: Monitor during dosage initiation and titration. Avoid use of in patients with circulatory shock. Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness: Monitor for sedation and respiratory depression. Avoid use in patients with impaired consciousness or coma. **Pregnancy & Lactation:** Pregnancy: May cause fetal harm. Lactation: Breastfeeding not recommended. **Interaction:** Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics: Avoid, because they may reduce analgesic effect or precipitate withdrawal symptoms. **Adverse reactions:** constipation, diarrhea, nausea, somnolence, anorexia, dizziness, and sweating increased. **Overdose:** overdose may include the signs and symptoms of tramadol toxicity, acetaminophen toxicity or both. Tramadol: initial symptoms may include respiratory depression and/or seizures. Serious potential consequences are respiratory depression, lethargy, coma, seizure, cardiac arrest and death. Paracetamol: Serious potential consequences of overdosage are hepatic centrilobular necrosis, leading to hepatic failure and death, renal tubular necrosis, hypoglycemia and coagulation defects. Early symptoms following a potentially hepatotoxic overdose may include: anorexia, nausea, vomiting, malaise, pallor, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post ingestion. Treatment: Primary attention should be given to maintaining adequate ventilation along with general supportive treatment. While naloxone will reverse some, but not all, symptoms caused by overdosage with tramadol, the risk of seizures is also increased with naloxone administration. Hemodialysis is not expected to be helpful in an overdose because it removes less than 7% of the administered dose in a 4-hour dialysis period. Standard recommendations should be followed for the treatment of paracetamol overdose.

Prepared on 24th 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