

LINTIDE

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only
Abbreviated Prescribing information for LINTIDE [Linaclotide Capsules 72 mcg and 145 mcg]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Linaclotide and its active metabolite bind to the Guanylate Cyclase-C receptor (GC-C) receptor, on the luminal surface of the intestinal epithelium. Through its action at GC-C, linaclotide has been shown to reduce visceral pain and increase GI transit in animal models and increase colonic transit in humans. Activation of GC-C results in an increase in concentrations of cyclic guanosine monophosphate (cGMP), both extracellularly and intracellularly. Extracellular cGMP decreases pain-fiber activity, resulting in reduced visceral pain in animal models. Intracellular cGMP causes secretion of chloride and bicarbonate into the intestinal lumen, through activation of the cystic fibrosis transmembrane conductance regulator (CFTR), which results in increased intestinal fluid and accelerated transit.

INDICATIONS: Linaclotide is indicated in adults for the treatment of Chronic idiopathic constipation.

DOSAGE AND ADMINISTRATION: The recommended dosage of Linaclotide is 72 mcg orally once daily or 145 mcg orally once daily based on individual presentation or tolerability. The capsule should be taken on an empty stomach, at least 30 minutes prior to the meal at approximately the same time each day.

CONTRAINDICATION: • Hypersensitivity to linaclotide or to any of the excipients. • Patients with known or suspected mechanical gastrointestinal obstruction. • Linaclotide is contraindicated in patients less than 2 years of age.

WARNINGS & PRECAUTIONS: Linaclotide is contraindicated in patients less than 2 years of age. Linaclotide should be used after organic diseases have been ruled out. Patients should be aware of the possible occurrence of diarrhoea and lower gastrointestinal bleeding during treatment. They should be instructed to inform their physician if severe or prolonged diarrhoea or lower gastrointestinal bleeding occurs. Additional caution should be exercised in patients who are prone to a disturbance of water or electrolyte balance (e.g. elderly, patients with cardiovascular (CV) diseases, diabetes, hypertension), and electrolyte control should be considered. Linaclotide has not been studied in patients with chronic inflammatory conditions of the intestinal tract, such as Crohn's disease and ulcerative colitis; therefore it is not recommended to use Linaclotide in these patients. Special attention should be given to elderly patients and the treatment benefit-risk ratio should be carefully and periodically assessed. Linaclotide should not be used in children and adolescents as it has not been studied in this population.

DRUG INTERACTIONS: Concomitant treatment with proton pump inhibitors, laxatives or NSAIDs may increase the risk of diarrhoea. The efficacy of oral contraceptives may be reduced. Caution should be exercised when prescribing medicinal products absorbed in the intestinal tract with a narrow therapeutic index such as levothyroxine as their efficacy may be reduced.

ADVERSE REACTIONS: Diarrhea, abdominal pain, flatulence, abdominal distension, gastritis, hypochlorhydria, nausea, vomiting, asthenia, pain, pyrexia, upper respiratory tract infection sinusitis, nasopharyngitis, vertigo, diabetes mellitus, back pain, wrist fracture, headache, amenorrhoea, cough, productive cough, hypersensitivity reactions: anaphylaxis, angioedema, rash (including hives or urticaria) gastrointestinal reactions: hematochezia, rectal haemorrhage.

MARKETED BY:



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(Additional information is available on request)