

## **DYCOTIAM**

**For the use of a Registered Medical Practitioner or Hospital or a Laboratory only**

Abbreviated Prescribing information for **DYCOTIAM** [Acotiamide Tablets 100 mg] [Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

**PHARMACOLOGICAL PROPERTIES:** Acotiamide is a novel gastroprokinetic drug that exerts its activity via muscarinic receptor inhibition, which results in enhanced acetylcholine release, and via inhibition of acetylcholinesterase (AChE) activity in the stomach.

**INDICATION:** For the treatment of bloating after meals, epigastric bloating and early satiety in functional dyspepsia.

**DOSAGE AND ADMINISTRATION:** The usual adult dosage of Acotiamide is 100 mg orally three times a day before meals.

**CONTRAINDICATION:** Hypersensitivity to the active substance or to any of the excipients.

**WARNINGS & PRECAUTIONS:** Acotiamide should not be co-administered with other cholinergic drugs. Acotiamide is an acetylcholinesterase inhibitor (AChE inhibitor), and since the action of acetylcholine increases, Acotiamide should be used carefully considering this. The safety of Acotiamide when combined with other prokinetic agents commonly used for this condition is not known. As reported in literature, in the carcinogenicity test in rats for 24 months, an endometrial adenocarcinoma was noted in 5/50 cases, 8/50 cases, and 5/50 cases in 200 mg/kg/day group, 600 mg/kg/day group, and 2,000 mg/kg/day group, respectively. There is little evidence to suspect that Acotiamide increased the incidence of endometrial adenocarcinomas observed in the carcinogenicity study in rats, and that it is more appropriate to consider that the cancer occurs spontaneously, as observed usually in rat strain.

**DRUG INTERACTIONS:** Drugs having anticholinergic effect such as atropine, butylscopolammonium bromide and choline activator and cholinesterase inhibitor such as acetylcholine chloride and neostigmine bromide.

**ADVERSE REACTIONS:** Diarrhoea, constipation, nausea, vomiting, rash, hives. The laboratory test value abnormalities showed increase in serum prolactin ALT (GPT) (1.8%), Y-GTP, serum triglycerides, AST (GOT), serum bilirubin, neutrophil count, ALP, increased blood prolactin and increased blood triglycerides.

**MARKETED BY:**



**TORRENT PHARMACEUTICALS LTD.**

Torrent House, Off Ashram Road,  
Ahmedabad-380 009, INDIA

**IN/DYCOTIAM 100mg /NOV-16/01/ABPI**

(Additional information is available on request)