

**Composition:**

**Motelity™ 1 Tablet:** Each film coated tablet contains Prucalopride Succinate INN equivalent to Prucalopride 1 mg.

**Motelity™ 2 Tablet:** Each film coated tablet contains Prucalopride Succinate INN equivalent to Prucalopride 2 mg.

**Description:**

**Motelity™** (Prucalopride) is a dihydrobenzofurancarboxamide derivative from the benzofurane family that selectively stimulates 5-HT<sub>4</sub> receptors and thus, it presents enterokinetic properties. The high selectivity of prucalopride allowed further development as it prevented the cardiac adverse reactions observed due to non-target effects of precedent therapies.

**Indications:**

**Motelity™** is indicated for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief.

**Dosage & Administration:****Chronic Constipation****Adults**

2 mg once daily with or without food, at any time of the day. Due to the specific mode of action of Prucalopride (stimulation of propulsive motility), exceeding the daily dose of 2 mg is not expected to increase efficacy.

**Older people (> 65 Years)**

Start with 1 mg once daily; if needed the dose can be increased to 2 mg once daily.

**Children**

Prucalopride should not be used in children and adolescents younger than 18 years.

**Patients with renal Impairment**

The dose for patients with severe renal impairment (GFR < 30 ml/min/1.73 m<sup>2</sup>) is 1 mg once daily. No dose adjustment is required for patients with mild to moderate renal impairment.

**Patients with hepatic Impairment**

Patients with severe hepatic impairment (Child-Pugh class C) start with 1 mg once daily which may be increased to 2 mg if required to improve efficacy and if the 1 mg dose is well tolerated. No dose adjustment is required for patients with mild to moderate hepatic impairment.

**Contraindications:**

Prucalopride is contraindicated in those people who are hypersensitive to the active substance or to any of the excipients, people with renal impairment requiring dialysis, Intestinal perforation or obstruction due to structural or functional disorder of gut wall, obstructive ileus, severe inflammatory conditions of the intestinal tract (eg, Crohn disease, ulcerative colitis, toxic megacolon/megarectum)

**Warnings:**

Renal excretion is the main route of elimination of Prucalopride. A dose of 1 mg is recommended in subjects with severe renal impairment. Caution should be exercised when prescribing Prucalopride (**Motelity™**) to patients with severe hepatic impairment (Child-Pugh class C) due to limited data in patients with severe hepatic impairment. In case of severe diarrhoea, the efficacy of oral contraceptives may be reduced and the use of an additional contraceptive method is recommended to prevent possible failure of oral contraception. The tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

**Adverse Reactions:**

The most frequently reported adverse reactions associated with **Motelity™** therapy are headache (17.8%) and gastrointestinal symptoms (abdominal pain), nausea and diarrhoea. The adverse reactions occur predominantly at the start of therapy and usually disappear within a few days with continued treatment. Other adverse reactions have been reported occasionally. The majority of adverse events were mild to moderate in intensity.

**Use in Pregnancy:**

Prucalopride is not recommended during pregnancy and women of childbearing potential should use effective contraception during treatment. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

**Use in Lactation:**

In the absence of human data, it is not recommended to use Prucalopride during breast feeding.

**Overdosage:**

Treatment with prucalopride was well tolerated when given in an up-titrating scheme up to 20 mg once daily (10 times the recommended therapeutic dose). An overdose may result in symptoms resulting from an exaggeration of prucalopride's known pharmacodynamic effects and include headache, nausea and diarrhoea. Specific treatment is not available for Resolor overdose. Should an overdose occur, the patient should be treated symptomatically and supportive measures instituted, as required. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances

**Storage:**

Store below 30°C & dry place. Keep away from light. Keep out of the reach of the children.

**Commercial Pack:**

Motelity™ 1 tablet: Each box contains in 2 X 10's tablets in alu-alu blister pack.

Motelity™ 2 tablet: Each box contains in 2 X 10's tablets in alu-alu blister pack.



Manufactured by:  
**Nuvista Pharma Limited**  
48 Tongi Industrial Area, Gazipur, Bangladesh  
A subsidiary of Beximco Pharmaceuticals Ltd.

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