Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

Adverse events should also be reported to McNeil Products Limited on 0808 238 9999.

IMODIUM® Dual action Relief Tablets (Formerly IMODIUM® Plus Caplets) (loperamide hydrochloride) Product Information

Presentation:
White, capsule-shaped tablet containing loperamide hydrochloride 2mg and simeticone equivalent to 125mg dimeticone.

Indications:
Symptomatic treatment of acute diarrhoea in adults and adolescents over 12 years when acute diarrhoea is associated with gas-related abdominal discomfort including bloating, cramping or flatulence.

Dosage and Administration:
Swallow the correct number of tablets whole with a drink of water. *Adults over 18 years:* Take 2 tablets initially, followed by 1 tablet after every loose stool. *Adolescents aged 12-18 years:* Take 1 tablet initially followed by 1 tablet after each loose stool. Not more than 4 tablets should be taken in 24 hours, limited to no more than 2 days.

Contraindications:
Not to be used in children under 12 years of age, or patients with: hypersensitivity to loperamide or simeticone or to any of the excipients listed in SPC section 6.1; acute dysentery (characterised by blood in stool and high fever); acute ulcerative colitis; pseudomembranous colitis associated with broad spectrum antibiotics; bacterial enterocolitis caused by invasive organisms. Must not be used when inhibition of peristalsis is to be avoided. Therapy must be discontinued if constipation, ileus and/or abdominal distension develop.

Precautions:

Treatment of diarrhoea with loperamide-simeticone is only symptomatic; give specific treatment when appropriate. Upon cessation, cases of drug withdrawal syndrome have been observed in individuals abusing, misusing, or intentionally overdosing with excessively large doses of loperamide. In patients with severe diarrhoea, attention should be paid to appropriate fluid and electrolyte replacement. If clinical improvement is not seen within 48 hours, stop treatment and consult a doctor. Patients with AIDS should stop therapy if abdominal distension develops. Use under medical supervision in patients with hepatic dysfunction. Cardiac events including QT interval and QRS complex prolongation and torsades de pointes have been reported in association with

overdose. Some cases had a fatal outcome. Overdose can unmask existing Brugada syndrome. Imodium Plus contains benzyl alcohol (less than 0.026 mg per tablet), which may cause allergic reactions. Imodium Plus must be used with caution in patients with renal or hepatic impairment, or in patients who are pregnant or breast-feeding, because of the risk of accumulation and toxicity (metabolic acidosis). This medicine contains maltodextrin (less than 4.4 mg per tablet) which contains glucose. Patients with rare glucose-galactose malabsorption should not take this medicine.

Pregnancy and lactation:
Not recommended.

Fertility:
Effect has not been evaluated.

Ability to drive:
Imodium Dual Action Relief has no or negligible influence on the ability to drive and use machines. However, tiredness, dizziness and drowsiness may occur in the setting of diarrheal syndromes treated with loperamide HCl. Therefore, it is advisable to use caution when driving a car or operating machinery.

Side Effects:
The most commonly reported adverse drug reactions in clinical trials were: dysgeusia (2.6%) and nausea (1.6%). Additionally, adverse drug reactions reported with the use of loperamide-simeticone from either clinical trial or post-marketing experience and with the use of loperamide HCl are:

Common: Headache.

Uncommon: Somnolence, dizziness, abdominal pain, abdominal discomfort, abdominal pain upper, vomiting, constipation, abdominal distension, dyspepsia, flatulence, dry mouth, rash and asthenia.

Rare: Hypersensitivity reaction, anaphylactic reaction (including anaphylactic shock), anaphylactoid reaction, loss of consciousness, depressed level of consciousness, stupor, hypertonia, coordination abnormality, miosis, ileus (including paralytic ileus), megacolon (including toxic megacolon), bullous eruption (including Stevens-Johnson syndrome, toxic epidermal necrolysis and erythema multiforme), angioedema, urticaria, pruritus, urinary retention and fatigue.

Not known: Acute pancreatitis.

RRP (ex-VAT): 12 tablets, £6.58

Legal Category: P

PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG UK

PL Number: 15513/0342

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