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 (P) (*formerly Imodium Plus Caplets*) (loperamide hydrochloride and simeticone) Product Information

Presentation:
White, capsule-shaped uncoated tablet, debossed with “IMO” on one side and a line between “2” and “125” on the other side, which contains loperamide hydrochloride 2mg and simeticone equivalent to 125mg dimeticone.

Uses:
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:
Swallow the correct number of tablets whole with a drink of water. *Adults aged 18 and over:* Take 2 tablets initially, followed by 1 tablet after every loose stool. *Adolescents aged 12–18:* 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:
Imodium Dual Action Relief Tablets (P) should not be used in children under 12 years of age, or by patients with any of the following conditions: 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, or bacterial enterocolitis caused by invasive organisms. This product must not be used when inhibition of peristalsis is to be avoided. Discontinue therapy if constipation, ileus and/or abdominal distension develop. Imodium Dual Action Relief Tablets (P) contains benzyl alcohol (less than 0.026 mg per tablet), which may cause allergic reactions. It also contains maltodextrin (less than 4.4 mg per tablet) which contains glucose; therefore, patients with rare glucose-galactose malabsorption should not take this medicine.

Precautions:
Treatment of diarrhoea with loperamide-simeticone is only symptomatic; give specific treatment when appropriate. 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. Loperamide is an opioid with low bioavailability and limited potential to penetrate the blood brain barrier at therapeutic doses. However, addiction is still observed in this drug class. Cases of drug withdrawal syndrome have been reported upon cessation in individuals who abuse, misuse, and intentionally overdose with excessively large doses of loperamide. Caution is needed in patients with a history of drug abuse. Imodium Dual Action Relief Tablets (P) 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).

Pregnancy and Lactation:

This product is not recommended for use in pregnant and lactating women.

Side effects:

Common: headache, dysgeusia, nausea.

Uncommon: somnolence, dizziness, abdominal pain, abdominal discomfort, abdominal pain upper, vomiting, constipation, abdominal distension, dyspepsia, flatulence, dry mouth, rash, 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, fatigue.

Not known: acute pancreatitis.

Please refer to Summary of Product Characteristics for detailed information.

RRP (ex-VAT): 12’s, £8.33

Legal Category: P

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

PL Number(s): PL 15513/0342

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