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 Comfort Tablets) (Loperamide & Simeticone) 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 caplets whole with a drink of water. *Adults over 18 years:* Take 2 caplets initially, followed by 1 caplet after every loose stool. *Adolescents aged 12-18 years:* Take 1 caplet initially followed by 1 caplet after each loose stool. Not more than 4 caplets 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 the active substances 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. 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 severe hepatic dysfunction. Use with caution in patients with renal or hepatic impairment. Tiredness, dizziness and drowsiness may occur in the setting of diarrheal syndromes treated with loperamide HCl, therefore use caution when driving a car or operating machinery. Cardiac events including QT interval and QRS complex prolongation and torsades de pointes have been reported in association with overdose. Some cases with extremely high doses had a fatal outcome. Overdose can unmask

existing Brugada syndrome. This medicine contains less than 0.026mg of benzyl alcohol, which may cause allergic reactions and this medicine contains maltodextrin which contains glucose. Patients with rare glucose-galactose malabsorption should not take this medicine. Caution is needed in patients with a history of drug abuse. Abuse and misuse of loperamide, has been described. Upon cessation, cases of drug withdrawal syndrome have been observed in individuals abusing, misusing, or intentionally overdosing with excessively large doses of loperamide. Loperamide is an opioid with low bioavailability and limited potential to penetrate the blood brain barrier at therapeutic doses. However, addiction is observed with opioids as a class.

Fertility, pregnancy and lactation:

Should not be given during pregnancy, especially during the first trimester, unless clinically justified. Not recommended during breast-feeding. The effect on human fertility has not been evaluated.

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): 6 tablets, £4.55

Legal Category: GSL

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

PL Number: 15513/0343

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