

Product Information for IMODIUM® Original 2mg Capsules (Loperamide Hydrochloride), IMODIUM® Instants (Loperamide Hydrochloride) and IMODIUM® IBS Relief 2mg Capsules Soft, (Loperamide Hydrochloride)

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® Original 2mg Capsules (loperamide hydrochloride) Product Information:

Presentation:

Opaque green cap and grey body, hard gelatine capsule imprinted with 'Imodium' on cap and 'Janssen' on body containing loperamide hydrochloride 2mg.

Uses:

Symptomatic treatment of acute diarrhoea in adults and children aged 12 years and over. For the symptomatic treatment of acute episodes of diarrhoea associated with irritable bowel syndrome in adults following initial diagnosis by a doctor.

Dosage:

Capsules should be taken with liquid. Acute Diarrhoea: Adults and children over 12 years old: 2 capsules initially followed by 1 capsule after every loose stool. The maximum daily dose should not exceed 6 capsules. Symptomatic treatment of acute episodes of diarrhoea associated with irritable bowel syndrome (IBS) in adults aged 18 years and over: Two capsules to be taken initially, followed by 1 capsule after every loose stool, or as previously advised by your doctor. The maximum daily dose should not exceed 6 capsules.

Contraindications:

Hypersensitivity to loperamide or any excipient. Children under 12 years of age. Acute dysentery, characterized by blood in stools and high fever. Acute ulcerative colitis. Bacterial enterocolitis caused by invasive organisms. Pseudomembranous colitis associated with broad spectrum antibiotics. Conditions when inhibition of peristalsis is to be avoided due to the possible risk of ileus, megacolon or toxic megacolon. Discontinue promptly when ileus, constipation or abdominal distension develop.

Precautions:

Treatment with IMODIUM® capsules is symptomatic; give specific treatment when appropriate. The priority in acute diarrhoea is the prevention or reversal of fluid and electrolyte depletion, particularly in young children and in frail and elderly patients. Use

of IMODIUM® capsules does not preclude the administration of appropriate fluid and electrolyte replacement therapy. Since persistent diarrhoea can be an indicator of potentially more serious conditions, IMODIUM® capsules should not be used for prolonged periods until the underlying cause of the diarrhoea has been investigated. If symptoms persist for more than 48 hours, consult a doctor. Patients with AIDS should stop therapy with IMODIUM® capsules if abdominal distension develops. Use with caution in hepatic impairment. Patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine as it contains lactose. If IMODIUM® capsules are being used to control episodes of diarrhoea associated with irritable bowel syndrome, consult a doctor if clinical improvement is not seen within 48 hours, for any changes in the pattern of symptoms or if there is a need for continuous treatment of more than 2 weeks. Consult a doctor if patients have recently travelled abroad, are vomiting, having difficulty or pain passing urine, or have a loss of appetite. Cardiac events have been reported in association with overdose. Some cases with extremely high doses had a fatal outcome. Loss of consciousness, depressed level of consciousness, tiredness, dizziness, or drowsiness may occur when diarrhoea is treated with this medicine. Therefore, it is advisable to 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. Overdose can unmask existing Brugada syndrome. Patients should not exceed the recommended dose and/or the recommended duration of treatment. 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.

Pregnancy and lactation:

Not recommended.

Side Effects:

Common: headache, constipation, nausea and flatulence.

Uncommon: dizziness, somnolence, abdominal pain, abdominal discomfort, dry mouth, abdominal pain upper, vomiting, dyspepsia and rash.

Rare: hypersensitivity reaction, anaphylactic reaction (including anaphylactic shock), anaphylactoid reaction, loss of consciousness, stupor, depressed level of consciousness, hypertonia, coordination abnormality, miosis, ileus (including paralytic ileus), megacolon (including toxic megacolon), abdominal distension, 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): 6 capsules, £3.48

Legal Category: GSL

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

PL Number: 15513/0310

Date of Prep: 16 Oct 2024

IMODIUM® Instants (loperamide hydrochloride) Product Information:

Presentation:

White to off-white, circular, orodispersible tablet containing loperamide hydrochloride 2mg. Excipients with known effect: Each tablet contains 0.750 mg of aspartame (E951), which is equivalent to 0.055 mg/mg, and mint flavour, which contains less than 0.00066mg of benzyl alcohol, less than 0.24 mg of maltodextrin (which contains glucose), and traces of sulphites.

Uses:

Symptomatic treatment of acute diarrhoea in adults and children aged 12 years and over. Symptomatic treatment of acute episodes of diarrhoea associated with irritable bowel syndrome in adults aged 18 years and over following initial diagnosis by a doctor.

Dosage:

Acute diarrhoea in adults and children over 12 years old: two tablets initially followed by one tablet after every loose stool. The total daily dose should not exceed 6 tablets.

Symptomatic treatment of acute episodes of diarrhoea associated with irritable bowel syndrome in adults aged 18 years and over: two tablets to be taken initially, followed by one tablet after every loose stool, or as previously advised by your doctor. The total daily dose should not exceed 6 tablets.

Method of administration: allow the tablet to disintegrate on the tongue and swallow; no liquid is needed.

Contraindications:

IMODIUM® Instants is contraindicated in children under 12 years of age, in individuals with hypersensitivity to loperamide hydrochloride or any of the excipients. This product should not be used in the following conditions: acute dysentery, which is characterised by blood in stools and high fever, acute ulcerative colitis, bacterial enterocolitis caused by invasive organisms such as *Salmonella*, *Shigella*, and *Campylobacter*, and pseudomembranous colitis associated with broad spectrum antibiotics. Do not use this product in conditions wherein the inhibition of peristalsis must be avoided, due to the possible risk of ileus, megacolon, or toxic megacolon. Discontinue this product immediately when ileus, constipation, or abdominal distension develop.

Precautions:

Treatment with IMODIUM® Instants is symptomatic; give specific treatment when appropriate. The priority in acute diarrhoea is the prevention or reversal of fluid and electrolyte depletion, particularly in young children and in frail and elderly patients. Use of IMODIUM® Instants does not preclude the administration of appropriate fluid and electrolyte replacement therapy. Since persistent diarrhoea can be an indicator of potentially more serious conditions, IMODIUM® Instants should not be used for prolonged periods until the underlying cause of the diarrhoea has been investigated. If symptoms persist for more than 48 hours, consult a doctor. Use with caution in hepatic or renal impairment, or in patients who are pregnant or breast feeding, because of the

risk of accumulation and toxicity (metabolic acidosis). Patients with AIDS should stop therapy with IMODIUM® Instants if abdominal distension develops. This product contains maltodextrin which contains glucose; therefore, patients with rare glucose-galactose malabsorption should not take this medicine. It also contains benzyl alcohol, which may cause allergic reactions. If IMODIUM® Instants are being used to control episodes of diarrhoea associated with irritable bowel syndrome, consult a doctor if clinical improvement is not seen within 48 hours, for any changes in the pattern of symptoms or if there is a need for continuous treatment of more than 2 weeks. Patients should consult a doctor if aged 40 or over where it is some time since their last IBS attack or if symptoms differ to previous episodes, in cases of severe constipation, weight loss or loss of appetite, pain passing urine, presence of blood in stools, and if the episode occurs after recent travel abroad. Cardiac events have been reported in association with overdose. Some cases with extremely high doses had a fatal outcome. Loss of consciousness, depressed level of consciousness, tiredness, dizziness, or drowsiness may occur when diarrhoea is treated with loperamide. Therefore, it is advisable to 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. Overdose can unmask existing Brugada syndrome. Patients should not exceed the recommended dose and/or the recommended duration of treatment. 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.

Pregnancy and lactation:

This product is not recommended in pregnant and lactating women.

Side Effects:

Common: constipation, flatulence, headache, nausea.

Uncommon: dizziness, somnolence, abdominal pain, abdominal discomfort, dry mouth, abdominal pain upper, vomiting, dyspepsia, and rash.

Rare: hypersensitivity reaction, anaphylactic reaction (including anaphylactic shock), anaphylactoid reaction, loss of consciousness, stupor, depressed level of consciousness, hypertonia, coordination abnormality, miosis, ileus (including paralytic ileus), megacolon (including toxic megacolon), abdominal distension, 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): 6 tablets £4.60; 12 tablets £7.03

Legal Category: GSL

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

PL Number: 15513/0345

Date of Preparation: 04 June 2024

IMODIUM® IBS Relief 2mg Capsules Soft (loperamide hydrochloride) Product Information:

Presentation:

Clear blue, oval, soft gelatine capsule containing loperamide hydrochloride 2mg.
Excipient with known effect: each capsule contains 115.31 mg propylene glycol which is equivalent to 0.65 mg/mg, also contains 0.06 micrograms of soya lecithin.

Uses:

Symptomatic treatment of acute diarrhoea in adults and children aged 12 years and over. Symptomatic treatment of acute episodes of diarrhoea associated with irritable bowel syndrome in adults aged 18 years and over following initial diagnosis by a doctor.

Dosage:

Acute diarrhoea in adults and children over 12 years old: two capsules initially followed by one capsule after every loose stool. The total daily dose should not exceed 6 capsules.

Symptomatic treatment of acute episodes of diarrhoea associated with irritable bowel syndrome in adults aged 18 years and over: two capsules to be taken initially, followed by one capsule after every loose stool, or as previously advised by your doctor. The total daily dose should not exceed 6 capsules.

Contraindications:

IMODIUM® IBS Relief 2mg Capsules Soft is contraindicated in children under 12 years of age, in individuals with hypersensitivity to loperamide hydrochloride, any of the excipients, soya, or peanuts. This product should not be used in the following conditions: acute dysentery, which is characterised by blood in stools and high fever, acute ulcerative colitis, bacterial enterocolitis caused by invasive organisms such as Salmonella, Shigella, and Campylobacter, and pseudomembranous colitis associated with broad spectrum antibiotics. Do not use this product in conditions wherein the inhibition of peristalsis must be avoided, due to the possible risk of ileus, megacolon, or toxic megacolon. Discontinue this product immediately when ileus, constipation, or abdominal distension develop.

Precautions:

Treatment with IMODIUM® IBS Relief 2mg Capsules Soft is symptomatic; give specific treatment when appropriate. The priority in acute diarrhoea is the prevention or reversal of fluid and electrolyte depletion, particularly in young children and in frail and elderly patients. Use of this product does not preclude the administration of appropriate fluid and electrolyte replacement therapy. Since persistent diarrhoea can be an indicator of potentially more serious conditions, IMODIUM® IBS Relief 2mg Capsules Soft should not be used for prolonged periods until the underlying cause of the diarrhoea has been investigated. If symptoms persist for more than 48 hours, consult a doctor. Use with caution in patients with hepatic impairment. Patients with AIDS should stop therapy with IMODIUM® IBS Relief 2mg Capsules Soft if abdominal distension develops. If this product is being used to control episodes of diarrhoea associated with irritable bowel syndrome, consult a doctor if clinical improvement is not seen within 48 hours, for any

changes in the pattern of symptoms, or if there is a need for continuous treatment of more than 2 weeks. Cardiac events have been reported in association with overdose. Some cases with extremely high doses had a fatal outcome. Loss of consciousness, depressed level of consciousness, tiredness, dizziness, or drowsiness may occur when diarrhoea is treated with this medicine. Therefore, it is advisable to 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. Overdose can unmask existing Brugada syndrome. Patients should not exceed the recommended dose and/or the recommended duration of treatment. 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.

Pregnancy and lactation:

This product is not recommended in pregnant and lactating women.

Side Effects:

Common: constipation, flatulence, headache, nausea.

Uncommon: dizziness, somnolence, abdominal pain, abdominal discomfort, dry mouth, abdominal pain upper, vomiting, dyspepsia, and rash.

Rare: hypersensitivity reaction, anaphylactic reaction (including anaphylactic shock), anaphylactoid reaction, loss of consciousness, stupor, depressed level of consciousness, hypertonia, coordination abnormality, miosis, ileus (including paralytic ileus), megacolon (including toxic megacolon), abdominal distension, 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): 6's: £4.08

Legal Category: GSL

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

PL Number: 15513/0367

Date of Preparation: 31 October 2023