



Research reveals disconnect in the management of acute diarrhoea

Experts create acute diarrhoea algorithm for GPs to help turn current guidelines into practice

5th November 2009, Glasgow: Guidelines on the management of acute diarrhoea are not always being followed by GPs. There is also a disconnect between what patients with acute diarrhoea want and how GPs are currently managing the condition.^{1,2} These were the findings from new research unveiled at a satellite symposium entitled 'Acute Diarrhoea – Turning Guidelines into Practice' held at the third RCGP Annual National Primary Care Conference, in Glasgow on 5th November 2009.

Survey results suggest more than more than 20 million UK adults have suffered from diarrhoea in the last 6 months³ making it the subject of many GP consultations. Practice guidelines for acute diarrhoea published by the World Gastroenterology Organisation (WGO) recommend loperamide for self medication in otherwise healthy adults⁴ but the research findings showed that half (48%) of GPs said they would rather patients use oral rehydration therapy alone and let diarrhoea 'run its course'.² The research also showed that the majority (69%) of diarrhoea sufferers wanted a treatment that is fast acting.¹

Commenting on the research sponsored by McNeil Products Ltd, the makers of IMODIUM® (loperamide hydrochloride), Dr Jamie Dalrymple, Chair of the Primary Care Society for Gastroenterology and Honorary Senior Lecturer, Schools of Medicine, Health Policy and Practice, University of East Anglia, said: "In times of economic uncertainty, people want to be productive in their working life, not have to take time off work, and carry on with their lives as normal. 76% of people agreed that diarrhoea stops them from doing things they would normally do,¹ so clearly, letting the diarrhoea run its course is not always an option for many people."

The findings presented today have led to the development of the new 'Treating Acute Diarrhoea in Healthy Adults' Algorithm which is being made available in *GP* in November 2009.

The algorithm which was also presented today, was created by a panel of experts in

gastroenterology, to provide guidance for UK GPs on how to treat acute diarrhoea in healthy adults.

One of the algorithm's authors, Dr Stephen Lewis, Consultant Gastroenterologist, Derriford Hospital, Plymouth said: "The 'Treating with Acute Diarrhoea in Healthy Adults' Algorithm is an important step forward in improving the management of acute diarrhoea as it provides clear guidance for UK GPs that remains consistent with the [WGO practice] guidance. People who suffer from acute diarrhoea should be recommended adequate fluid intake, diet as tolerated and loperamide as required, so that they can get on with their lives."

The IMODIUM® range of products contains loperamide and is available in pharmacies as IMODIUM® Capsules, IMODIUM® Instants, IMODIUM® Instant Melts and IMODIUM® Plus Caplets (containing loperamide and simeticone). IMODIUM® has a rapid onset of action and can stop diarrhoea in one hour. Two large studies have demonstrated the excellent efficacy and safety profile of IMODIUM® Plus in the treatment of acute diarrhoea associated with gas-related abdominal discomfort including bloating, cramping or flatulence.^{5,6} The IMODIUM® range is suitable for adults and children over 12 years of age.

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Notes to Editors

About Acute Diarrhoea

Worldwide, diarrhoeal diseases claimed an estimated 1.4 to 2.5 million lives in 2000. Both the incidence and the risk of mortality from diarrhoeal diseases are greatest among children younger than 1 year of age.⁴ In industrialised countries, relatively few patients die from diarrhoea, but it continues to be an important cause of morbidity and incurs substantial healthcare costs. In the UK, survey results suggest more than 20 million UK adults have suffered from diarrhoea in the last 6 months.³

Acute diarrhoea can have an impact on everyday life and workplace absenteeism. In a recent survey, 76% of sufferers admitted avoiding work or other social meeting places when experiencing a bout of acute diarrhoea.¹

About the 'Treating with Acute Diarrhoea in Healthy Adults' Algorithm

In August 2009, a group of experts* from primary and secondary care met to review the current guidelines with the aim of providing clear guidance for GPs on the management of acute diarrhoea in healthy adults. The result was a consensus recommending that in healthy adults not at risk of dehydration, acute diarrhoea should be self-managed through adequate fluid intake, diet as tolerated and appropriate use of loperamide.⁷ An algorithm providing guidance on treating acute diarrhoea in primary care was also agreed and will be published in the November issue of *GP*.

*The meeting was sponsored by McNeil Products Ltd and attended by Dr Stephen Lewis, Consultant Gastroenterologist, Derriford Hospital, Plymouth, Dr Jamie Dalrymple, Chair of the Primary Care Society for Gastroenterology and Honorary Senior Lecturer, Schools of Medicine, Health Policy and Practice, University of East Anglia, Catherine Stansfield, Inflammatory Bowel Disease Specialist Nurse, Chair of the Royal College of Nursing IBD special interest group for nurses and an honorary lecturer at Manchester University. Veronica Hall, Nurse Consultant in Gastroenterology for Royal Bolton Hospitals NHS Foundation Trust and Noel Wickes, Pharmacist, Central Scotland.

About the New Research

The diarrhoea sufferer's and GP survey, sponsored by McNeil Products Ltd, was undertaken in the UK during August 2009 and October 2008 respectively. The research, which involved the participation of 1,002 diarrhoea sufferers and 100 GPs, was unveiled at a satellite symposium entitled "Acute Diarrhoea – Turning Guidelines into Practice" to be held at the third RCGP Annual National Primary Care Conference, in Glasgow on 5th November 2009.

References

1. Diarrhoea Sufferer's Survey by TNS Healthcare, August 2009
2. GP Survey by TNS Healthcare, October 2008
3. TNS Survey September 08
4. World Gastroenterology Organisation practice guideline: Acute diarrhoea, March 2008.
http://www.worldgastroenterology.org/assets/downloads/en/pdf/guidelines/01_acute_diarrhea.pdf
5. Kaplan M.A. et al (1999), Loperamide-Simethicone vs Loperamide Alone and Placebo in the Treatment of Acute Diarrhoea with Gas-related abdominal Discomfort, Arch Fam Med, 8, p. 243-48
6. DuPont H. L. et al (1990), A Randomised Comparison of Nonprescription Loperamide and Attapulgite in the Symptomatic Treatment of Acute Diarrhoea, Amer Jour Med, 88 (S6A), p. 20S – 23S
7. Turning Guidelines into Practice Advisory Board Findings McNeil Products Ltd: Data on File. August 2009

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to McNeil Products Limited on 00 44 (0) 1344 864042.

Product Information

IMODIUM® Plus Caplet Product Information

Presentation: White, capsule-shaped tablet containing loperamide hydrochloride 2mg and simeticone equivalent to 125mg polydimethylsiloxane. **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:** *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. Hypersensitivity to any component of the product. Not to be used in acute dysentery, acute ulcerative colitis, pseudomembranous colitis associated with broad spectrum antibiotics, bacterial enterocolitis caused by invasive organisms. Should not be used when inhibition of peristalsis is to be avoided. Therapy must be discontinued if constipation, subileus and/or abdominal distension develop. **Precautions:** In patients with severe diarrhoea, attention should be paid to appropriate fluid and electrolyte replacement. If symptoms persist for more than 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. **Pregnancy and lactation:** Not recommended. **Side Effects:** Nausea, taste perversion, skin rashes, pruritis, urticaria, angioedema, allergic reactions and in some cases severe hypersensitivity reactions including anaphylactic shock and anaphylactoid reactions, abdominal pain, constipation, flatulence, vomiting, dyspepsia, abdominal distension, ileus and megacolon including toxic megacolon, urinary retention, dizziness, drowsiness. **RRP (ex-VAT):** 6 tablets, £3.65. **Legal Category:** GSL. **PL Holder:** McNeil Products Ltd, Foundation Park, Roxborough Way, Maidenhead, Berkshire, SL6 3UG. **PL Number:** 15513/0343. **Date of Preparation:** January 2009.

IMODIUM® Capsules Product Information

Presentation: Capsules containing loperamide hydrochloride 2mg. **Indications:** Symptomatic treatment of acute diarrhoea. For the symptomatic treatment of acute episodes of diarrhoea associated with Irritable Bowel Syndrome in adults following initial diagnosis by a doctor. **Dosage and Administration:** 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 8 capsules (P); 6 capsules (GSL). Symptomatic treatment of acute episodes of diarrhoea associated with Irritable Bowel Syndrome in adults: **P:** 2 capsules to be taken initially. The usual dose is between 2 and 4 capsules per day in divided doses, depending upon severity. If required, this dose can be adjusted according to results, up to a maximum of 8 capsules daily. **GSL:** 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:** Not to be used in children under 12 years of age. Hypersensitivity to loperamide hydrochloride or any component of the product. Conditions when inhibition of peristalsis is to be avoided, in particular when ileus or constipation are present or when abdominal distension develops or in patients with acute ulcerative colitis, pseudomembranous colitis associated with broad spectrum antibiotics or bacterial enterocolitis caused by invasive organisms. Not to be used alone in acute dysentery, characterised by blood in stools and elevated body temperatures. **Precautions:** The priority in acute diarrhoea is the prevention or reversal of fluid and electrolyte depletion, particularly important in young children and in frail and elderly patients with acute diarrhoea. Use of Imodium does not preclude the administration of appropriate fluid and electrolyte replacement therapy. Imodium should not be used for prolonged periods until the underlying cause of the diarrhoea has been investigated. Severe hepatic dysfunction. Patients with AIDS should stop therapy with Imodium if abdominal distension develops. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine because it contains lactose. If symptoms persist for more than 24 hours, consult a doctor. If Imodium is being used to control episodes of diarrhoea associated with Irritable Bowel Syndrome, a doctor should be notified of any changes in the pattern of symptoms and if there is a need for continuous treatment of more than 2 weeks. **Pregnancy and lactation:** Not recommended. **Side Effects:** Very rarely rash, urticaria, pruritis, isolated occurrences of angioedema and bullous eruptions including Stevens-Johnson syndrome, erythema multiforme and toxic epidermal necrolysis, isolated occurrences of allergic reactions and hypersensitivity reactions including anaphylactic shock and anaphylactoid reactions, abdominal pain, ileus, abdominal distension, nausea, constipation, vomiting, megacolon including toxic megacolon, flatulence, dyspepsia, isolated reports of urinary retention, drowsiness, dizziness. **RRP (ex-VAT):** 6 capsules, £3.01, 8 capsules, £

3.79, 12 capsules, £ 5.30, 18 capsules, £ 6.64. **Legal Category:** 6 capsules, GSL: 8, 12 & 18 capsules, P. **PL Holder:** Janssen-Cilag Limited, Saunderton, High Wycombe, Buckinghamshire, HP14 4HJ. **PL Number:** 00242/0028. **Date of Preparation:** July 2008.

IMODIUM® Instant Melts (P) & Instants (GSL) Product Information

Presentation: White to off-white, circular, orodispersible tablet containing loperamide hydrochloride 2mg. **Indications:** Symptomatic treatment of acute diarrhoea; acute episodes of diarrhoea associated with Irritable Bowel Syndrome diagnosed by a doctor. **Dosage and Administration:** Acute Diarrhoea: *Adults and children over 12 years old:* 2 tablets initially followed by 1 tablet after every loose stool. The usual dose is 3-4 tablets per day. Maximum daily dose should not exceed 8 tablets (P) or 6 tablets (GSL). Symptomatic treatment of acute episodes of diarrhoea associated with Irritable Bowel Syndrome in adults: *Adults aged 18 years and over:* **P:** 2 tablets initially. Usual dose is 2-4 tablets per day in divided doses, depending upon severity. This dose can be adjusted according to response, up to a maximum of 8 tablets daily. **GSL:** Two tablets to be taken initially, followed by 1 tablet after every loose stool, or as previously advised by your doctor. Maximum daily dose 6 tablets. **Contraindications:** Children under 12 years of age. Hypersensitivity to loperamide or any excipient. Conditions when inhibition of peristalsis is to be avoided: ileus, constipation, abdominal distension, acute ulcerative colitis, pseudomembranous colitis associated with broad spectrum antibiotics or bacterial enterocolitis caused by invasive organisms. Not to be used alone in acute dysentery, characterised by blood in stools and elevated body temperatures. **Precautions:** The priority in acute diarrhoea is the prevention or reversal of fluid and electrolyte depletion, particularly important in young children and in frail and elderly patients with acute diarrhoea. Use of IMODIUM® Instant Melts or Instants does not preclude appropriate fluid and electrolyte replacement therapy. IMODIUM® Instant Melts or Instants should not be used for prolonged periods until the underlying cause of the diarrhoea has been investigated. Severe hepatic dysfunction. Patients with AIDS should stop therapy with IMODIUM® Instant Melts or Instants if abdominal distension develops. If symptoms persist for more than 24 hours, consult a doctor. If IMODIUM® Instant Melts are being used to control episodes of diarrhoea associated with Irritable Bowel Syndrome, a doctor should be notified of any changes in the pattern of symptoms or if there is a need for continuous treatment of more than 2 weeks. **Pregnancy and lactation:** Not recommended. **Side Effects:** Very rarely rash, urticaria, pruritis, isolated occurrences of angioedema and bullous eruptions including Stevens-Johnson syndrome, erythema multiforme and toxic epidermal necrolysis, isolated occurrences of allergic reactions, hypersensitivity reactions including anaphylactic shock and anaphylactoid reactions, abdominal pain, ileus, abdominal distension, nausea, constipation, vomiting, megacolon including toxic megacolon, flatulence, dyspepsia, isolated reports of urinary retention, drowsiness, loss of consciousness, depressed level of consciousness, dizziness. **RRP (ex-VAT):** IMODIUM® Instant Melts 12 tablets, £5.48; IMODIUM® Instants 6 tablets £2.74. **Legal Category:** P, GSL. **PL Holder:** McNeil Products Ltd., Roxborough Way, Maidenhead, Berkshire, SL6 3UG. **PL No.:** IMODIUM® Instant Melts 15513/00346; IMODIUM® Instants 15513/0345. **Date of Prep:** Oct 2009.