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Committee on Herbal Medicinal Products (HMPC)

List of references supporting the assessment of *Plantago ovata* Forssk., semen

Final

The Agency acknowledges that copies of the underlying works used to produce this monograph were provided for research only with exclusion of any commercial purpose.

Alemán AM, Quirce S, Bombin C, Sastre J. Asthma related to inhalation of Plantago ovata. *Medicina Clinica* 2001, 116:20-22

Bajorek SA, Morello CM. Effects of Dietary Fiber and Low Glycemic Index Diet on Glucose Control in Subjects with Type 2 Diabetes Mellitus. *Ann Pharmacother* 2010, 44:1786-1792

Bardy JD, Malo JL, Sehuin P, Ghezzo H, Desjardins J, Dolovich J et al. Occupational asthma and IgE sensitization in a pharmaceutical company processing psyllium. *Am Rev Respir Dis* 1987, 135(5):1033-1038

Bernedo N, Garcia M, Gastaminza G, Fernández E, Bartolomé B, Algorta J et al. Allergy to the Laxative Compound (*Plantago ovata* seed) Among Health Care Professionals. *J Investig Allergol Clin Immunol* 2008, 13(3):181-189

Bijkerk CJ, de Wit NJ, Muris JW, Whorwell PJ, Knottnerus JA, Hoes AW. Soluble or insoluble fibre in irritable bowel syndrome in primary care? Randomised placebo controlled trial. *BMJ* 2009, 339:b3154

Bishop C. Nonprescription drugs: guide to the pregnant patient. Part 4. *Can Pharm J* 1978, 111:385-388.

Blaschek W, Ebel S, Hackenthal E, Holzgrabe U, Keller K, Reichling J, editors. HagerROM 2003, Hagers Handbuch der Drogen und Arzneistoffe, Version 3.0, CD-ROM. Springer, Berlin, 2003

Bliss DZ, Savik K, Jung HJ, Whitebird R, Lowry A. Symptoms Associated With Dietary Fiber Supplementation Over Time in Individuals With Fecal Incontinence. *Nursing Res* 2011, 60 (3S):58-67

Chouinard LE. The Role of Psyllium Fibre Supplementation in Treating Irritable Bowel Syndrome. *Can J Dietetic Pract Res* 2011, 72 (1):e107-e114

Commission E Monographs. Plantaginis ovatae semen, Bundesanzeiger Nr. 22a vom 01.02.1990, correction Bundesanzeiger Nr. 74 vom 19.04.1991 [German]



Federal Register. The Daily Journal of the United States Government. Rule. Laxative Drug Products for Over-the-Counter Human Use; Psyllium Ingredients in Granular Forms. A Rule by the Food and Drug Administration on 03/29/2007. Available at: <https://www.federalregister.gov/articles/2007/03/29/E7-5740/laxative-drug-products-for-over-the-counter-human-use-psyllium-ingredients-in-granular-dosage-forms>. Accessed: 23/11/2011

Fianu S et al. Comparison between bulk laxative and irritant laxatives in obstetrical and gynaecological departments. *Opusc Med* 1975, 20:167-171

Ganji V, Kuo J. Serum lipid responses to psyllium fiber: differences between pre- and post-menopausal, hypercholesterolemic women. *Nutrition J* 2008, 7:22

Gelissen IC et al. Effect of *Plantago ovata* (psyllium) husk and seeds on sterol metabolism: studies in normal and ileostomy subjects. *Am J Clin Nutr* 1994, 59:395-400

Greenhalf JO et al. Laxative in the treatment of constipation in pregnant and breast-feeding mothers. *The Practitioner* 1973, 210:259-263

Hamouz W. Die Behandlung der akuten und chronischen Diarröhö mit Agiocur®. *Med Klin* 1984, 79:32-33

Heckers H et al. Fecal composition and colonic function due to dietary variables. Results of a long-term study in healthy young men consuming 10 different diets. Practical Gastroenterology - Special Issue on the Symposium on Intestinal Motility (Lisbon) 1984:24-39

Karhunen LJ, Juvonen KR, Flander SM, Liukkonen KH, Lähteenmäki L, Siloaho M et al. A Psyllium Fiber-Enriched meal Strongly Attenuates Postprandial Gastrointestinal Peptide Release in healthy Young Adults. *J Nutr* 2010, 140:737-744

Khalili B, Bardana EJ Jr, Yunginger JW. Psyllium-associated anaphylaxis and death: a case report and review of the literature. *Ann Allergy Asthma Immunol* 2003, 91:579-584

Kooperation Phytopharma, editor. Kinderdosierungen von Phytopharma. 3rd ed. Krahe Druck, Unkel 2002

Kritchevsky D, Tepper SA, Klurfeld DM. Influence of psyllium preparations on plasma and liver lipids of cholesterol-fed rats. *Artery* 1995, 21:303-311

Leng-Peschlow E. Interference of dietary fibres with gastrointestinal enzymes in vitro. *Digestion* 1989, 44:200-210

Leng-Peschlow E. *Plantago ovata* seeds as dietary fibre supplement: physiological and metabolic effects in rats. *Br J Nutr* 1991, 66:331-349

Ligny G. Therapie des Colon irritabile. *Therapeutikon* 1988, 7:449-453

López JC, Villanueva R, Martínez-Hernández D, Albaladejo R, Regidor E, Calle ME. *Plantago ovata* consumption and colorectal mortality in Spain, 1995-2000. *J Epidemiol* 2009, 19(4):206-211

Machado L, Zetterstrom O, Fagerberg E. Occupational allergy in nurses to a bulk laxative. *Allergy* 1979, 34 (1):51-55

Madaus. Post-evaluation of the studies with Agiocur® from the publication by Sölter and Lorenz (Today's therapeutic Trends 1 (1983), 45-59) with reference to the effective *Plantago ovata* dosage in comparison to dosages published in monographs. Cologne 25 July 2005

Mahapatra SC, Bijlani RL, Nayar U. Effect of cellulose and ispaghula on intestinal function of hamsters maintained on diets of varying fibre content. *Indian Journal of Medical Research* 1988, 88:175-180

Malo JL, Cartier A, L'Archeveque J, Ghezzo H, Lagier F, Trudeau C et al. Prevalence of occupational asthma and immunologic sensitization to psyllium among health personnel in chronic care hospitals. *Am Rev Respir Dis* 1990, 142 (6 Pt 1):1359-1366

Marks GB, Salome CM, Woolcock AJ. Asthma and allergy associated with occupational exposure to ispaghula and senna products in a pharmaceutical work force. *Am Rev Respir Dis* 1991, 144(5):1065-1069

McClung HJ, Boyne L, Heitlinger L. Constipation and dietary fiber intake in children. *Pediatrics* 1995, 96: 999-1001

McConnochie K, Edwards JH, Fified R. Ispaghula sensitization in workers manufacturing a bulk laxative. *Clin Exp Allergy* 1990, 20(2):199-202

Petticrew M, Watt I, Brand M. What's the 'best buy' for treatment constipation? Results of a systematic review of the efficacy and comparative efficacy of laxatives in elderly. *Br J Gen Pract* 1999, 49:387-393

Rubira N, Valero A, Amat P, Elices A, Lluch M, Malet A et al. Occupational asthma and anaphylaxis due to seeds of *Plantago ovata*. *Alergología e Inmunología Clínica* 2000, 15: 96-99

Sartore G, Reitano R, Barison A, Magnanini P, Cosma C, Burlina S et al. The effects of psyllium on lipoproteins in type II diabetic patients. *Eur J Nutr* 2009; 63:1269-1271

Segawa K, Kataoka T, Fukuo Y. Cholesterol-lowering effects of psyllium seed associated with urea metabolism. *Biol & pharm bull* 1998, 21:184-187

Sharma PK, Koul AK. Mucilage in seeds of *Plantago ovata* and its wild allies. *J Ethnopharmacol* 1986, 17: 289-295

Shoenwetter W. Anaphylaxis in nurses caused by inhaled psyllium seed. *J Allergy Clin Immunol* 1985, 75:209

Singh B. Psyllium as therapeutic and drug delivery agent. *Int J Pharm* 2007, 334:1-14

Sölter H, Lorenz D Summary of clinical results with Prodiem® Plain. A bowel-regulating agent. *Today's therapeutic Trends* 1983, 1: 45-59

Solà R, Godàs G, Ribalta J, Vallvé JC, Girona J, Anguera A et al. Effects of soluble fiber (*Plantago ovata*) husk on plasma lipids, lipoproteins, and apolipoproteins in men with ischemic heart disease. *Am J Clin Nutr* 2007, 85:1157-1163

Spiller G, editor. CRC Handbook of Dietary Fibre in Human Nutrition. Boca Raton (FL): CRC Press, Inc., 1986, 218

Tan KY, Seow-Choen F. Fiber and colorectal diseases: Separating fact from fiction. *World J Gastroenterol* 2007, 13(31):4161-4167

Tramonte SM, Brand MB, Mulrow CD, Amato MG, O'Keefe ME, Ramirez G. The treatment of chronic constipation in adults. *J Gen Intern Med* 1997, 12:15 -24

Wichtl M. Indische Flohsamen – Plantaginis ovatae semen. In: Hartke K, Hartke H, Mutschler E, Rücker G, Wichtl M, editors. Kommentar zum Europäischen Arzneibuch. Stuttgart: Wissenschaftliche Verlagsgesellschaft, 1999 (12.Lfg): F 12

Williams CL, Dwyer J, Agostoni C, Hillemeier C, Kimm SYS, Kwiterovich PO Jr et al. A summary of conference recommendations on dietary fiber in childhood. Conference on Dietary Fiber in Childhood, New York (New York, USA), May 24, 1994. *Pediatrics* 1995, 96:1023-1028

Williams CL, Bollela M. Is a high-fiber diet safe for children? *Pediatric* 1995, 96:1014-1019