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List of references supporting the assessment of *Saccharomyces cerevisiae* CBS 5926

Final

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

Adam J, Barret A, Barret-Bellet C. Essais cliniques contrôlés en double insu de l'ultra-levure lyophilisée. Etude multicentrique par 25 médecins de 388 cas. *Gaz Med Fr* 1977, 84:2072-2078 [in French]

Akhondi-Meybodi M, Rahimian M, Salmanroghani H, Amirbeigy M, Baghbanian M, Ghelmani SY. Study of the effect of probiotic *Saccharomyces boulardii* on the treatment of irritable bowel syndrome. *J Biol Today's World* 2014, 3(7):152-156

Akil I, Yilmaz O, Kurutepe S, Degerli K, Kavukcu S. Influence of oral intake of *Saccharomyces boulardii* on *Escherichia coli* in enteric flora. *Pediatr Nephrol* 2006, 21:807-810

Amorissani Folquet M, Saizonou R, Guedehoussou T, Vandenplas Y. *Saccharomyces boulardii* in acute gastroenteritis in children. *Webmed Central Paediatrics* 2011, 2(11):WMC001627

Asmat S, Shaukat F, Asmat R, Bkhat H, Asmat T. Clinical efficacy comparison of *Saccharomyces boulardii* and lactic acid as probiotics in acute pediatric diarrhea. *JCPSP* 2018, 28(3):214-217

Bafutto M, de Almeida JR, Leite NV, Costa M, de Oliveira EC, Resende-Filho J. Treatment of diarrhea-predominant irritable bowel syndrome with mesalazine and/or *Saccharomyces boulardii*. *Arq Gastroenterol* 2013, 50(4):304-309

Barc MC, Charrin-Sarnel C, Rochet V, Bourlioux F, Sandré C, Boureau H, et al. Molecular analysis of the digestive microbiota in a gnotobiotic mouse model during antibiotic treatment: influence of *Saccharomyces boulardii*. *Anaerobe* 2008, 14(4):229-233

Bartlett JG. Antibiotic-associated diarrhea. *N Engl J Med* 2002, 346:334-339

Bassetti S, Frei R, Zimmerli W. Fungemia with *Saccharomyces cerevisiae* after treatment with *Saccharomyces boulardii*. *Am J Med* 1998, 105(1):71-72

Bedi MK, Shenefelt PD. Herbal therapy in dermatology. *Arch Dermatol* 2002, 138:232-242

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Benhamou PH, Berlier P, Danjou G, Plique O, Jessueld D, DuPont C. La diarrhée aux antibiotiques chez l'enfant: une étude informatisée en double aveugle chez des patients ambulatoires comparant un agent protecteur et un agent probiotique. *Méd Chir Dig* 1999, 28:163-168 [in French]

Besirbellioglu BA, Ulcay A, Can M, Erdem H, Tanyuksel M, Avci IY, et al. *Saccharomyces boulardii* and infection due to *Gardia lamblia*. *Scand J Infect Dis* 2006, 38:479-481

Billoo AG, Memon MA, Khaskhelli SA, Murtaza G, Iqbal K, Saeed Shekhani M, et al. Role of a probiotic (*Saccharomyces boulardii*) in management and prevention of diarrhoea. *World J Gastroenterol* 2006, 28(12):4557-4560

Bin Z, Ya-Zheng X, Zhao-Hui D, Bo C, Li-Rong J, Vandenplas Y. The efficacy of *Saccharomyces boulardii* CNCM I-745 in addition to standard *Helicobacter pylori* eradication treatment in children. *Pediatr Gastroenterol Hepatol Nutr* 2015, 18(1):17-22

Biocodex. Compositions and methods for preventing infections. Patent WO 2015189337 A1. 17.12.2015; Biocodex homepage. Available at: <https://www.biocodex.com/en/therapeutic-areas-products/>

Blackwell B, Marley E. Interactions of yeast extracts and their constituents with monoamine in man and rat. *Brit J Pharmacol* 1966; 26:142-161

Blaschek W, Hilgenfeldt U, Holzgrabe U, Reichling J, Ruth P, Schulz. HagerROM. Hagers Enzyklopädie der Arzneistoffe und Stoffe. Springer Verlag, Berlin Heidelberg 2013 [in German]

Blehaut H, Massot J, Elmer GW, Levy RH. Disposition kinetics of *Saccharomyces boulardii* in man and rat. *Biopharm Drug Dispos* 1989, 10:353-364

Bleichner G, Bléhault H, Mentec H, Moysé D. *Saccharomyces boulardii* prevents diarrhea in critically ill tube-fed patients. A multicenter, randomized, double-blind placebo-controlled trial. *Intensive Care Med* 1997, 23:517-523

Bravo MV, Bunout D, Leiva L, de la Maza MP, Barrera G, de la Maza J et al. Effect of probiotic *Saccharomyces boulardii* on prevention of antibiotic-associated diarrhea in adult outpatients with amoxicillin treatment. *Rev Méd Chile* 2008, 136:981-988 [in Spanish]

Burande MA. Comparison of efficacy of *Saccharomyces boulardii* strain in the treatment of acute diarrhea in children: a prospective, single-blind, randomized controlled clinical trial. *J Pharmacol Pharmacother* 2013, 4(3):205-208

Buts JP, Bernasconi P, van Craynest MP, Maldague P, de Meyer R. Response of human and rat small intestinal mucosa to oral administration of *Saccharomyces boulardii*. *Pediatr Res* 1986, 20:192-196

Buts JP, Bernasconi P, Vaerman J-P, Dive C. Stimulation of secretory IgA and secretory component of immunoglobulins in small intestine of rats treated with *Saccharomyces boulardii*. *Digest Dis Sci* 1990, 35(2):251-256

Buts JP, Corthier G, Delmee M. *Saccharomyces boulardii* for *Clostridium difficile*-associated enteropathies in infants. *J Pediatr Gastroenterol Nutr* 1993, 16:419-425

Buts JP. Twenty-five years of research on *Saccharomyces boulardii* trophic effects: Updates and perspectives. *Digest Dis Sci* 2009, 54(1):15-18

Byron JK, Clemons KV, Mc Cusker JH, Davis RW, Stevens DA. Pathogenicity of *Saccharomyces cerevisiae* in complement factor five-deficient mice. *Infect Immun* 1995, 63:478-485

- Can M, Beşirbellioğlu BA, Avci IY, Beker CM, Pahsa A. Prophylactic *Saccharomyces boulardii* in the prevention of antibiotic-associated diarrhea: a prospective study. *Med Sci Monit* 2006, 12(4):PI19-22
- Canani RB, Cirillo P, Terrin G, Cesarano L, Spagnuolo MI, De Vincenzo A *et al.* Probiotics for treatment of acute diarrhoea in children: randomized clinical trial of five different preparations. *BMJ* 2007, 335:340-342
- Casem RAO. *Saccharomyces boulardii* in the prevention of antibiotic associated diarrhea in children: a randomized controlled trial. *Pediatr Infect Dis Soc Philipp J* 2013, 13(2):70-76
- Cassone M, Serra P, Mondello F, Girolamo A, Scafetti S, Pistella E *et al.* Outbreak of *Saccharomyces cerevisiae* subtype *boulardii* fungemia in patients neighboring those treated with a probiotic preparation of the organism. *J Clin Microbiol* 2003, 41(11):5340-5343
- Cetina-Sauri G, Sierra Basto G. Evaluación terapéutica de *S. boulardii* en niños con diarrea aguda. *Comp Inv Lat Am Mex* 1989, 9:108-112 [in Spanish]
- Cetina-Sauri G, Sierra Basto G. Antidiarrhöische Therapie bei Kindern-Therapeutische Prüfung von *Saccharomyces boulardii* an Kindern mit acuter Diarrhö. *Der Kinderarzt* 1991, 22(12):2059-2061 [in German]
- Cetina-Sauri G, Sierra Basto G. Evaluation of *Saccharomyces* for the treatment of acute diarrhea in pediatric patients. *Ann Pediatr* 1994, 41(6):397-400
- CFR – Code of Federal regulations Title 21 (FDA), 21CFR172.896. Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=172.896>
- Chapoy P. Traitement des diarrhées aiguës infantiles. *Ann Pédiatr* 1985, 32:561-563 [in French]
- Chapoy P. Behandlung akuter Diarrhöe bei Kleinkindern. *Therapiewoche* 1986, 40:3-6 [in German]
- Chen J, Wan C-M, Gong S-T, Fang F, Sun M, Qian Y *et al.* Chinese clinical practice guidelines for acute infectious diarrhea in children. *World J Pediatr* 2018, 14:429-436
- CHMP (Committee for Medicinal Products for Human use). Guideline on the evaluation of medicinal products for the treatment of irritable bowel syndrome. CPMP/EWP/785/97 Rev. 1 from 25.09.2014
- Choi CW, Jo SY, Park HJ, Chang SK, Byeon JS, Myung SJ. A randomized, double-blind, placebo-controlled, multicenter trial of *Saccharomyces boulardii* in irritable bowel syndrome. Effect of quality of life. *J Clin Gastroenterol* 2011, 45:679-683
- Chosewood LC, Wilson DE. (editors) Biosafety in Microbiological Laboratories. U.S. Department of Health and Human Services HHS Publication No. (CDC) 21-1112, revised December 2009. Available at: <http://www.cdc.gov/biosafety/publications/bmbl5/index.htm>
- Chouraqui JP, Dietsch J, Musial C, Blehaut H. Controlled treatment trial with *Saccharomyces boulardii* (SB) in the irritable-bowel-syndrome of infancy (IBSI) [abstract]. *Gastroenterology* 1995, 4(108):584
- Chu Y, Zhu H, Zhou Y, LV L, Huo J. Intervention study on *Saccharomyces boulardii* with proton pump inhibitor (PPI)-based triple therapy for *Helicobacter pylori* related peptic ulcer. *African J Pharm Pharmacol* 2012, 6:2900-2904
- Cindoruk M, Erkan G, Karkan T, Dursun A, Unal S. Efficacy and safety of *Saccharomyces boulardii* in the 14-day triple anti-*Helicobacter pylori* therapy: a prospective randomized placebo-controlled double-blind study. *Helicobacter* 2007, 12:309-316

Clemons KV, McCusker JH, Davis RQ, Stevens DA. Comparative pathogenesis of clinical and nonclinical isolates of *Saccharomyces cerevisiae*. *J Infect Dis* 1994, 169:859-867

CMDh: *Saccharomyces boulardii*: CMDh scientific conclusions and grounds for variation, amendments to the product information and timetable for implementation – PSUSA/00009284/201702, last updated: 01 December 2017

Cohen SH, Gerding DN, Johnson S, Kelly CP, Loo VG, McDonald LC *et al*. Clinical practice guidelines for *Clostridium difficile* infection in adults: 2010 update by the society for healthcare epidemiology of America (SHEA) and the infectious diseases society of America (IDSA). *Infect Control Hosp Epidemiol* 2010, 31:431-455

Corrêa NB, Penna FJ, Lima FM, Nicoli JR, Filho LA. Treatment of acute diarrhea with *Saccharomyces boulardii* in infants. *J Pediatr Gastroenterol Nutr* 2011, 53(5):497-501

Costalos C, Skouteri V, Gounaris A, Sevastiadou S, Triandafilidou A, Ekonomidou C *et al*. Enteral feeding of premature infants with *Saccharomyces boulardii*. *Early Human Development* 2003, 74:89-96

Cottrell J, Koenig K, Perfekt R, Hofmann R. Comparison of two forms of loperamide-simeticone and a probiotic yeast (*Saccharomyces boulardii*) in the treatment of acute diarrhoea in adults: a randomized non-inferiority clinical trial. *Drugs R D* 2015, 15:363-373, doi 10.1007/s40268-015-0111-y

Cremonini F, DiCaro S, Covino M, Armuzzi A, Gabrielli M, Santarelli L *et al*. Effect of different probiotic preparations on anti-*Helicobacter pylori* therapy-related side effect: a parallel group, triple blind, placebo-controlled study. *Am J Gastroenterol* 2002a, 97(11):2744-2749

Cremonini F, Di Caro S, Nista EC, Bartolozzi F, Capelli G, Gasbarrini G *et al*. Meta-analysis: the effect of probiotic administration on antibiotic-associated diarrhea. *Aliment Pharmacol Ther* 2002b, 16:1461-1467

Czerucka D, Rampal P. Diversity of *Saccharomyces boulardii* CNCM I-745 mechanisms of action against intestinal infections. *World J Gastroenterol* 2019, 25(18):2188-2203, doi 10.3748/wjg.v25.i18.2188

Dalgic N, Sancar M, Bayraktar B, Pullu M, Hasim O. Probiotic, zinc and lactose-free formula in children with rotavirus diarrhea: Are they effective? *Pediatr Int* 2011, 53:677-682

Das S, Gupta PK, Das RR. Efficacy and safety of *Saccharomyces boulardii* in acute rotavirus diarrhea: double blind randomized controlled trial from a developing country. *Journal of Tropical Pediatrics* 2016, 62:464-470, doi 10.1093/tropej/fmw032

De Boer WA, Thys JC, Borody TJ, Graham DY, O'Morain C, Tytgat GNJ. Proposal for use of a standard side effect scoring system in studies exploring *Helicobacter pylori* treatment regimens. *Eur J Gastroenterol Hepatol* 1996, 8:641-643

Dendukuri N, Costa V, McGregor M, Brophy M. Probiotic therapy for the prevention and treatment of *Clostridium difficile*-associated diarrhea: a systematic review. *CMAJ* 2005, 173(2):167-170

Didari T, Solki S, Mozaffari S, Nikfar S, Abdollah M. A systematic review of the safety of probiotics. *Expert Opin. Drug Saf.* 2014, 13(2):227-239

Dinleyici EC, Eren M, Yargic ZA, Dogan N, Vandenplas Y. Clinical efficacy of *Saccharomyces boulardii* and metronidazole compared to metronidazole alone in children with acute bloody diarrhea caused by amebiasis: a prospective, randomized, open label study. *Am J Trop Med Hyg* 2009, 80(6):953-955

- Dinleyici EC, Eren M, Dogan N, Reyhanioglu S, Yargic ZA, Vandenplas Y. Clinical efficacy of *Saccharomyces boulardii* or metronidazole in symptomatic children with *Blastocystis hominis* infection. *Parasitol Res* 2011, 108:541-545
- Dinleyici EC, Eren M, Ozen M, Yargic ZA, Vandenplas Y. Effectiveness and safety of *Saccharomyces boulardii* for acute infectious diarrhea. *Expert Opin Biol Ther* 2012, 12(4):395-410
- Duman DG, Bor S, Özütemiz Ö, Sahin T, Oguz D, Isitan F *et al.* Efficacy and safety of *Saccharomyces boulardii* in prevention of antibiotic-associated diarrhea due to *Helicobacter pylori* eradication. *Eur J Gastroenterol Hepatol* 2005, 17:1357-1361
- D'Souza AL, Rajkumar C, Cooke J, Bulpitt CJ. Probiotics in prevention of antibiotic-associated diarrhoea: meta-analysis. *BMJ* 2002, 324:1361-1364
- DuPont H. Therapy for and prevention of traveler's diarrhea. *Clin Infect Dis* 2007, 45:S78-84
- Edwards-Ingram L, Gitsham P, Burton N, Warhurst G, Clarke I, Hoyle D *et al.* Genotypic and physiological characterization of *Saccharomyces boulardii* the probiotic strain of *Saccharomyces cerevisiae*. *App Environ Microbiol* 2007, 73(8):2458-2467
- Edwards-Ingram LC, Gent ME, Hoyle DC, Hayes A, Stateva LI, Oliver SG. Comparative genomic hybridization provides new insights into the molecular taxonomy of the *Saccharomyces sensu stricto* complex. *Genome Res* 2004, 14(6):1043-1051
- EFSA: Scientific Opinion on the substantiation of health claims related to non-characterised bacteria and yeasts pursuant to Article 13(1) of Regulation (EC) No 1924/2006. *EFSA Journal* 2010, 8(2):1470
- EFSA: Scientific opinion on the substantiation of health claims related to *Saccharomyces cerevisiae* var. *boulardii* CNCM I-1079 and defense against pathogenic gastro-intestinal microorganisms (ID 913, further assessment) pursuant to article 13(1) of regulation (EC) no 1924/2006. *EFSA Journal* 2012a, 10(6):2717
- EFSA: Scientific opinion on the substantiation of a health claim related to *Saccharomyces cerevisiae* var. *boulardii* CNCM I-3799 and reducing gastrointestinal discomfort pursuant to article 13(5) of regulation (EC) no 1924/2006. *EFSA Journal* 2012b, 10(7):2801
- Ehrhardt S, Guo N, Hinz R, Schoppen S, May J, Reiser M *et al.* *Saccharomyces boulardii* to prevent antibiotic-associated diarrhea: a randomized, double-masked, placebo-controlled trial. *Open Forum Infectious diseases* 2016, 3(1), doi 10.1093/ofid/ofw011
- Elmer GW, Moyer KA, Vega R, Surawicz CM, Collier AC, Hooton TM *et al.* Evaluation of *Saccharomyces boulardii* for patients with HIV-related chronic diarrhea and in healthy volunteers receiving antifungals. *Microecol Ther* 1995, 25:23-31
- Elmer GW, Martin SW, Horner KL, McFarland LV, Levy RH. Survival of *Saccharomyces boulardii* in the rat gastrointestinal tract and effects of dietary fiber. *Microb Ecology health Dis* 1999a, 37:315-317
- Elmer GW, McFarland LV, Surawicz M, Danko L, Greenberg RN. Behaviour of *Saccharomyces boulardii* in recurrent *Clostridium difficile* disease patients. *Aliment Pharmacol Ther* 1999b, 13:1663-1668
- Enache-Angoulvant A, Hennequin C. Invasive *Saccharomyces* infection: a comprehensive review. *Clin Infect Dis* 2005, 41:1559-1568
- Erdeve O, Tiras U, Dallar Y. The probiotic effect of *Saccharomyces boulardii* in a pediatric age group. *J Trop Pediatr* 2004, 50:234-236

- Erdeve O, Tiras U, Dallar Y, Savas S. *Saccharomyces boulardii* and antibiotic-associated diarrhoea in children. *Aliment Pharmacol Ther* 2005, 21:583-590
- Erdoğan Ö, Tanyeri B, Torun E, Gönüllü E, Arslan H, Erenberk U, et al. The comparison of the efficacy of two different probiotics in rotavirus gastroenteritis in children. *J Trop Med* 2012, ID:787240
- Eren M, Dinleyici EC, Vandenplas Y. Clinical efficacy comparison of *Saccharomyces boulardii* and yogurt fluid in acute non-bloody diarrhea in children: a randomized, controlled, open label study. *Am J Trop Med Hyg* 2010, 82(3):488-491
- Eriksson OE, Winka K. Supraordinal taxa of Ascomycota. *Myconet* 1997, 1:1-16
- Feizizadeh S, Salehi-Abargouei A, Akbari V. Efficacy and safety of *Saccharomyces boulardii* for acute diarrhea. *Pediatrics* 2014, 134(1):e176-e191
- Feng J, Wang F, Qiu X, Mc Farland LV, Chen P, Zhou R et al. Efficacy and safety of probiotic-supplemented triple therapy for eradication of *Helicobacter pylori* in children: a systematic review and network analysis. *Eur J Clin Pharmacol* 2017, 73:1109-1208, doi 10.1007/s00228-017-2291-6
- Fischbach W, Malfertheiner P, Hoffmann JC, Bolten W, Bornschein J, Götze O et al. S3-Leitlinie „*Helicobacter pylori* und gastroduodenale Ulkuskrankheit“. *Z Gastroenterol* 2009, 47:68-102 [in German]
- Flatley EA, Wilde AM, Nailor MD. *Saccharomyces boulardii* for the prevention of hospital *Clostridium difficile* infection. *Gastrointestinal Liver Dis* 2015, 24(1):21-24, doi 10.15403/jgld.2014.1121.fly
- Florez I, Veroniki A, Khalifah R, Yepes-Nunez J, Sierra J, Vernooij R et al. Comparative effectiveness and safety of interventions for acute diarrhea and gastroenteritis in children: a systematic review and network meta-analysis. *PLoS ONE* 2018, 13(12):e0207701
- Gao C, Xie R, Ma T, Wu S. Therapeutic effect of *Saccharomyces boulardii* combined with standard triple therapy for *Helicobacter pylori* eradication. *Chin J Gastroenterol* 2012, 17:555-557 [in Chinese, only abstract in English]
- Gaon D, Garcia H, Winter L, Rodriguez N, Quintas R, Gonzales SN et al. Effect of *Lactobacillus* strains and *Saccharomyces boulardii* on persistent diarrhea in children. *Medicina (Buenos Aires)* 2003, 63:293-298
- Garcia Vilela E, De Lourdes De Abreu Ferrari M, Oswaldo Da Gama Torres H, Guerra Pinto A, Carneiro Aguirre C, Paiva Martins F et al. Influence of *Saccharomyces boulardii* on the intestinal permeability of patients with Crohn's disease in remission. *Scan J Gastroenterol* 2008, 43:842-848
- Girard-Pipau F, Pompei A, Schneider S. Intestinal microflora, short chain and cellular fatty acids, influence of a probiotic *Saccharomyces*. *Microb Ecology Health Dis* 2002, 14:220-227
- Gorbach SL. Probiotics and gastrointestinal health. *Am J Gastroenterol* 2000, 95:S2-S4
- Graff S, Chaumeil J-C, Boy P, Lai-Kuen R, Charrueau Cl. Influence of pH conditions on the viability of *Saccharomyces boulardii* yeast. *J Gen Appl Microbiol* 2008, 54:221-227
- Grandy G, Medina M, Soria R, Terán CG, Araya M. Probiotics in the treatment of acute rotavirus diarrhoea. A randomized, double-blind, controlled trial using two different probiotic preparations in Bolivian children. *BMC Infect Dis* 2010, 10:253
- Guarino A, Ashkenazi S, Gendrel D, Lo Vecchio A, Shamir R, Szajewska H. European Society for Pediatric Gastroenterology, Hepatology, and Nutrition / European Society for pediatric Infectious

Diseases Evidence-based guidelines for the management of acute gastroenteritis in children in Europe: update 2014. *JPGN* 2014, 59(1):132-152

Guarino A, Guandalini S, Lo Vecchio A. Probiotics for prevention and treatment of diarrhea. *J Clin Gastroenterol* 2015, 49:S37-S45

Guo Q, Goldenberg JZ, Humphrey C, El Dib R, Johnston BC. Probiotics for the prevention of pediatric antibiotic-associated diarrhea. *Cochrane Database of Systematic Reviews* 2019, 4(4):CD00482, doi 10.1002/14651858.CD004827.pub5

Hafeez A, Tariq P, Ali S, Kundi ZU, Khan A, Hussan M. The efficacy of *Saccharomyces boulardii* in the treatment of acute watery diarrhea in children: a multicentre randomized controlled trial. *J Coll Physicians Surg Pak* 2002, 12:432-434 [cited in Szajewski *et al.* 2007, publication not available]

Hempel S, Newberry SJ, Maher AR, Wang Z, Miles JN, Shanman R *et al.* Probiotics for the prevention and treatment of antibiotic-associated diarrhea. A systematic review and meta-analysis. *JAMA* 2012, 307(18):1959-1969

Hennequin C, Kaufmann-Lacroix C, Jobert A, Viard JP, Ricour C, Jaquemin JL *et al.* Possible role of catheters in *Saccharomyces boulardii* fungemia. *Eur J Microbiol Infect Dis* 2000, 19:16-20

Hill DR, Ericsson CD, Pearson RD, Keystone JS, Freedman DO, Kozarsky PE *et al.* The practice of travel medicine: guidelines by the Infectious Diseases Society of America. *Clin Infect Dis* 2006, 43:1499-1539

Höchter W, Chase D, Hagenhoff G. *Saccharomyces boulardii* bei akuter Erwachsenenendiarrhoe. *MMW* 1990, 132:188-192 [in German]

Htwe K, Yee KS, Tin M, Vandenplas Y. Effect of *Saccharomyces boulardii* in the treatment of acute watery diarrhea in Myanmar children: a randomized controlled study. *Am J Trop Med Hyg* 2008, 78(2):214-216

Hurduc V, Plesca D, Dragomir D, Sajin M, Vandenplas Y. A randomized, open trial evaluating the effect of *Saccharomyces boulardii* on the eradication rate of *Helicobacter pylori* infection in children. *Acta Paediatr* 2009, 98(1):127-131

Im E, Pothoulakis C. Recent advances in *Saccharomyces boulardii* research. *Gastroenterol Clin Biol* 2010, 34 (Suppl 1):62-70

Izquierdo-Pulido M, Font-Fábregas J, Vidal-Carou C. Influence of *Saccharomyces cerevisiae* var. *uvarum* on histamine and tyramine formation during beer fermentation. *Food Chem* 1995, 54:51-54

Jahn HU, Ullrich R, Schneider T, Liehr RM, Schieferdecker HL, Holst H *et al.* Immunological and trophical effects of *Saccharomyces boulardii* on the small intestine in healthy human volunteers. *Digestion* 1996, 57:95-104

Ji D, Zou S, Yuan L. *Saccharomyces boulardii* in treatment of acute children diarrhea: a randomized placebo-controlled trial. *Journal of Pediatric Pharmacy* 2009, 15(1):13-15 [in Chinese, only abstract in English]

Jindal M, Goyal Y, Iata S, Sharma RK. Preventive role of probiotics in antibiotic associated diarrhoea in children. *Indian Journal of Public Health Research & Development* 2017, 8(3):66-69

Johnston BC, Supina AL, Ospina M, Vohra S. Probiotics for the prevention of pediatric antibiotic-associated diarrhea (review). *Cochrane Database of Systematic Reviews* 2007, 2:CD004827

- Johnston BC, Goldenberg JZ, Vandvik PO, Sun X, Guyatt GH. Probiotics for the prevention of pediatric antibiotic-associated diarrhea. *Cochrane Database of Systematic Reviews* 2011, 11:CD004827, doi 10.1002/14651858.CD004827.pub3
- Kabbani TA, Pallav K, Dowd SE, Villafuerte-Galvez J, Vanga RR, Castillo NE *et al.* Prospective randomized controlled study on the effects of *Saccharomyces boulardii* CNCM I-745 and amoxicillin-clavulanate or the combination on the gut microbiota of healthy volunteers. *Gut Microbes* 2017, 8(1):17-32
- Kabir MA, Ishaque SM, Ali MS, Mahmuduzzaman M, Hasan M. Role of *Saccharomyces boulardii* in diarrhea predominant irritable bowel syndrome. *Mymensingh Med J* 2011, 20(3):397-401
- Karen M, Yuksel O, Akyürek N, Ofluoğlu E, Cağlar K, Sahin TT *et al.* Probiotic agent *Saccharomyces boulardii* reduces the incidence of lung injury in acute necrotizing pancreatitis induced rats. *J Surg Res* 2010, 160(1):139-144
- Kelesidis T, Pothoulakis C. Efficacy and safety of the probiotic *Saccharomyces boulardii* for the prevention and therapy of gastrointestinal disorders. *Ther Adv Gastroenterol* 2012, 5(2):111-125
- Khan A, Javed T, Chishti AL. Clinical efficacy of use of probiotic “*Saccharomyces boulardii*” in children with acute watery diarrhea. *Pakistan Paed J* 2012, 36(3):122-127
- Kim JH, Lee DH, Jeong SC, Chung KS, Lee JS. Characterizations of antihypertensive angiotensin I-converting enzymes inhibitor from *Saccharomyces cerevisiae*. *J Microbiol Biotechnol* 2004, 14(6):1318-1323
- Klein SM, Elmer GW, McFarland LV, Surawicz CM, Levy RH. Recovery and elimination of the biotherapeutic agent, *Saccharomyces boulardii*, in healthy human volunteers. *Pharm Res* 1993, 10(11):1615-1619
- Kollaritsch HH, Kreamsner P, Wiedermann G, Scheiner O. Prevention of traveller’s diarrhea: comparison of different non-antibiotic preparations. *Travel Med Internat* 1989, 7:9-18
- Kollaritsch H, Holst H, Grobara P, Wiedermann G. Prophylaxe der Reisediarrhöe mit *Saccharomyces boulardii*. Ergebnisse einer plazebokontrollierten Doppelblindstudie. *Fortschr Med* 1993, 11:152-156 [in German]
- Kommission E. Aufbereitungsmonographie Faex medicinalis (Medizinische Hefe). *BAnz*, Nr. 85, 05 May 1988 [in German]
- Kommission E. Aufbereitungsmonographie Trockenhefe aus *Saccharomyces cerevisiae* HANSEN CBS 5926 (Synonym: *Saccharomyces cerevisiae*, *BAnz*, Nr. 71, 15 April 1994 [in German]
- Korpela R, Niittynen L. Probiotics and irritable bowel syndrome. *Microb Ecol Health Dis* 2012, 23:18573
- Kotowska M, Albrecht P, Szajewska H. *Saccharomyces boulardii* in the prevention of antibiotic-associated diarrhoea in children: a randomized double-blind placebo-controlled trial. *Aliment Pharmacol Ther* 2005, 21:583-590
- Kujath P, Sipp H. Neuartige Therapiemöglichkeit der Akne vulgaris. *Wehrmed Mschr* 1978, 12:374-376 [in German]
- Kurtzman CP, Fell JW. Yeast Systematics and Phylogeny – Implications of Molecular Identification Methods for Studies in Ecology. *The Yeast Handbook Carlos Augusto Rosa, Gabor Peter, Springer-Verlag, Berlin Heidelberg* 2006

- Kurugöl Z, Koturoglu G. Effects of *Saccharomyces boulardii* in children with acute diarrhoea. *Acta Paediatr* 2005, 94:44-47
- Kyriakos N, Papamichael K, Roussos A, Theodoropoulos I, Karakoidas C, Smyrnidis A *et al.* A lyophilized form of *Saccharomyces boulardii* enhances the *Helicobacter pylori* eradication rates of omeprazole-triple therapy in patients with peptic ulcer disease or functional dyspepsia. *Hospital Chronicles* 2013, 8(3):127-133
- Lacarrière C, Rieckhof B. Behandlung akuter Diarrhöe in der Praxis. *Therapiewoche* 1986, 36:2551-2556 [in German]
- Laux G, Ulrich S. Tranylcypromin. *PPT* 2006, 13 (4):130-41 [in German]
- Lee J, Choi SP, Park JH, Shin JW, Joo YH. The effect of *Saccharomyces boulardii* as an adjuvant to the 14-day triple therapy for eradication of *Helicobacter pylori* [abstract]. *J Gastroenterol Hepatol* 2011, 26(5):257
- Le Luyer B, Makhoul G, Duhamel JF. Étude multicentrique, contrôlée en double insu d'une formule adaptée enrichie en *Saccharomyces boulardii* dans le traitement des diarrhées aiguës du nourrisson. *Arch Pédiatr* 2010, 17:459-465 [in French]
- Lentze MJ. Physiologie des Verdauungstraktes im Kindesalter. In: von Schweinitz D, Ure B (eds.) *Kinderchirurgie*. Springer-Verlag, Berlin Heidelberg 2013
- Lewis SJ, Potts LF, Barry RE. The lack of therapeutic effect of *Saccharomyces boulardii* in the prevention of antibiotic-related diarrhea in elderly patients. *J Infect* 1998, 36:171-174
- Lherm T, Monet C, Nougère B, Soulier M, Larbi D, Le Gall C *et al.* Seven cases of fungemia with *Saccharomyces boulardii* in critically ill patients. *Intensive Care Med* 2002, 28(6):797-801
- Li BZ, Threapleton DE, Wang J-Y, Xu JM, Yuan JQ, Zhang C *et al.* Comparative effectiveness and tolerance of treatments for *Helicobacter pylori*: systematic review and network meta-analysis. *BMJ* 2015, 351:h4052
- Lukaszewicz M (2012) *Saccharomyces cerevisiae* var. *boulardii* – Probiotic Yeast. In: Rigobelo EC (ed.), *Probiotics*. Chapter 16. InTech 2012
- Machado Caetano JA, Paramés MT, Babo MJ, Santos A, Bandeira Ferreira, Freitas AA *et al.* Immunopharmacological effects of *Saccharomyces boulardii* in healthy human volunteers. *Int J Immunopharmac* 1986, 8(3):245-259
- Maejima K, Shimoda K, Morita C, Fujiwara T, Kitamura T. Colonization and pathogenicity of *Saccharomyces cerevisiae*, MC 16, in mice and cynomolgus monkeys after oral and intravenous administration. *Jpn J Med Sci Biol* 1980, 33(5):271-276
- Malgoire JY, Bertout S, Renaud F, Bastide JM, Mallié M. Typing of *Saccharomyces cerevisiae* clinical strains by using microsatellite sequence polymorphism. *J Clin Microbiol* 2005, 43(3):1133-1137
- Mandrella C. Erfolgreicher Behandlungsversuch der Akne mit einem neuartigen Hefepräparat. *Die Heilkunst* 1973, 2:48-50 [in German]
- Mansour-Ghanaei F, Dehbashi N, Yazdanparast K, Shafaghi A. Efficacy of *Saccharomyces boulardii* in acute amoebiasis. *World J Gastroenterol* 2003, 9:1832-1833
- Marshall BJ, Warren JR. Unidentified curved bacilli in the stomach of patients with gastritis and peptic ulceration. *Lancet* 1984, 16:1311-1314

Martin SW, Heatherington AC, Elmer GW. Pharmacokinetics of Biotherapeutic Agents. In: Elmer GW, McFarland LV, Surawicz CM (eds.) *Biotherapeutic Agents and Infectious Diseases*. Chapter 3. Humana Press Inc Totowa NJ 1999:47-84

Maupas JL, Champemont P, Delforge M. Treatment of irritable bowel syndrome. Double-blind trial of *Saccharomyces boulardii*. *Med Chirur Dig* 1983, 12(1):77-79

Mayr P, Hotz J, Brandau J, Körner J. Erfolgreiche Durchfallbehandlung mit *Saccharomyces boulardii*. *Der Kassenarzt* 1996, 43:52-60 [in German]

McCullough MJ, Clemons KV, Cusker JH, Stevens DA. Species identification and virulence attributes of *Saccharomyces boulardii* (nom. inval.). *J Clin Microbiol* 1998, 36:2613-2617

McFarland LV, Surawicz CM, Greenberg RN, Fekety R, Elmer GW, Moyer KA *et al.* A randomized placebo-controlled trial of *Saccharomyces boulardii* in combination with standard antibiotics for *Clostridium difficile* disease. *JAMA* 1994, 271:1913-1918

McFarland LV, Surawicz CM, Greenberg RN, Elmer GW, Moyer KA, Melcher SA *et al.* Prevention of β -lactam associated diarrhea by *Saccharomyces boulardii* compared with placebo. *Am J Gastroenterol* 1995, 90(3):439-448

McFarland LV. *Saccharomyces boulardii* is not *Saccharomyces cerevisiae*. *Clin Infect Dis* 1996, 22:200-201

McFarland LV. Meta-analysis of probiotics for the prevention of antibiotic associated diarrhea and the treatment of *Clostridium difficile* disease. *Am J Gastroenterol* 2006, 101:812-822

McFarland LV. Meta-analysis of probiotics for the prevention of traveler's diarrhea. *Travel Med Infect Dis* 2007, 5:97-105

McFarland LV, Dublin S. Meta-analysis of probiotics for the treatment of irritable bowel syndrome. *World J Gastroenterol* 2008, 14(17):2650-2661

McFarland LV. Systematic review and meta-analysis of *Saccharomyces boulardii* in adult patients. *World J Gastroenterol* 2010, 16(18):2202-2222

Micklefield G. *Saccharomyces boulardii* bei Antibiotika-assoziiierter Diarrhoe. *MMW Fortschr Med Originalien* 2014, 156(Suppl. 1):18-22 [in German]

Mitterdorfer G, Mayer HK, Kneifel W, Viernstein H. Clustering of *Saccharomyces boulardii* strains within the species *S. cerevisiae* using molecular typing techniques. *J Appl Microbiol* 2002a, 93(4):521-530

Mitterdorfer G, Mayer HK, Kneifel W, Viernstein H. Protein fingerprinting of *Saccharomyces* isolates with therapeutic relevance using one- and two-dimensional electrophoresis. *Proteomics* 2002b, 2(11):1532-1538

Monteiro E, Fernandes JP, Vieira MR, Correia JP, Caetano JM, Ribeiro T *et al.* Ensaio clinico duplamente cego da ultra-levure na profilaxia das perturbações gastro-intestinais e muco-cutâneas da antibioticoterapia. *Acta Med Port* 1981, 3:143-145 [in Portuguese]

Moré M, Swidsinski A. *Saccharomyces boulardii* CNCM I-745 supports regeneration of the intestinal microbiota after diarrheic dysbiosis – a review. *Clin Exp Gastroenterol* 2015, 8:237-255

Moré M, Vandenplas Y. *Saccharomyces boulardii* CNCM I-745 Improves Intestinal Enzyme Function: A Trophic Effects Review. *Clin Med Insights Gastroenterol* 2018, 11:1-14

- Moslehi-Jenabian S, Pedersen LL, Jespersen L. Beneficial effects of probiotic and food borne yeasts on human health. *Nutrients* 2010, 2:449-473
- Ozkan TB, Sahin E, Erdemir G, Budak F. Effect of *Saccharomyces boulardii* in children with acute gastroenteritis and its relationship to the immune response. *J Int Med Res* 2007, 35:201-212
- Padayachee M, Visser J, Viljoen E, Musekiwa A, Blaauw R. Efficacy and safety of *Saccharomyces boulardii* in the treatment of acute gastroenteritis in the paediatric population: a systematic review. *South African Journal of Clinical Nutrition* 2019, 32(3):58-69, doi 10.1080/16070658.2018.1449378
- Pan J, Hu J, Qi X, Tu Z. A meta analysis of the efficacy of *Saccharomyces boulardii* in children with acute diarrhea. *Afr J Pharm Pharmacol* 2012, 6(21):1508-1514
- Pecquet S, Guillaumin D, Tancrede C, Andremont A. Kinetics of *Saccharomyces cerevisiae* elimination from the intestines of human volunteers and effect of this yeast on resistance to microbial colonization in gnotobiotic mice. *Appl Environ Microbiol* 1991, 57(10):3049-3051
- Perapoch J, Planes AM, Querol A, López V, Martínez-Bendayán I, Tormo R *et al.* Fungemia with *Saccharomyces cerevisiae* in two newborns, only one of whom had been treated with ultra-levura. *Eur J Clin Microbiol Infect Dis* 2000, 19(6):468-470
- Piarroux R, Millon L, Bardonnnet K, Vagner O, Koenig H. Are live *Saccharomyces* yeast harmful to patients? *Lancet* 1999, 353:1851-1852
- Pineton de Chambrun G, Neut C, Chau A, Cazaubiel M, Pelerin F, Justen P *et al.* A randomized clinical trial of *Saccharomyces cerevisiae* versus placebo in the irritable bowel syndrome. *Digest Liv Dis* 2015, 47:119-124
- Pozzoni P, Riva A, Bellatorre AG, Amigoni M, Redaelli E, Ronchetti A *et al.* *Saccharomyces boulardii* for the prevention of antibiotic-associated diarrhea in adult hospitalized patients: a single-center, randomized, double-blind, placebo-controlled trial. *Am J Gastroenterol* 2012, 107:922-931
- Reuter J, Merfort I, Schempp CM. Botanicals in dermatology. An evidence-based review. *Am J Clin Dermatol* 2010, 11(4):247-267
- Riaz M, Alam S, Malik A, Ali SM. Efficacy and safety of *Saccharomyces boulardii* in acute childhood diarrhea: a double blind randomized controlled trial. *Indian J Pediatr* 2012, 79(4):478-482
- Riquelme AJ, Calvo MA, Guzmán AM, Depix MS, García P, Pérez C *et al.* *Saccharomyces cerevisiae* fungemia after *Saccharomyces boulardii* treatment in immunocompromised patients. *J Clin Gastroenterol* 2003, 36(1):41-43
- Roy U, Jessani LG, Rudramurthy SM, Gopalakrishnan R, Dutta S, Chakravarty C *et al.* Seven cases of *Saccharomyces* fungaemia related to use of probiotics. *Mycoses* 2017, 60:375-380, in press, doi 10.1111/myc.12604
- Saint-Marc T, Blehaut H, Musial C, Touraine JL. Diarrhées en relation avec le sida. *Sem Hôp Paris* 1995, 71(23-24):735-741 [in French]
- Sankoff D. Reconstructing the history of yeast genomes. *PLoS Genet* 2009, 5:e1000483
- Savaş-Erdeve S, Gökay S, Dallar Y. Efficacy and safety of *Saccharomyces boulardii* in amebiasis-associated diarrhea in children. *Turk J Pediatr* 2009, 51(3):220-224
- Scevola D, Perversi L, Cavanna C, Candiani C, Uberti F, Castiglioni B *et al.* Acid tolerance and fecal recovery following oral administration of *Saccharomyces cerevisiae*. *J Chemoth* 2003, 15(2):143-147

Schlotterer M, Bernasconi P, Lebreton F, Wassermann D. Intérêt de *Saccharomyces boulardii* dans la tolérance digestive de la nutrition entérale à débit continu chez le brûlé. *Nutr Clin Metabol* 1987, 1:31-34 [in French]

Schneider SM, Girard-Pipau F, Filippi J, Hébuterne X, Moyses D, Hinojosa GC *et al.* Effects of *Saccharomyces boulardii* on fecal short chain fatty acids and microflora in patients on long-term total enteral nutrition. *World J Gastroenterol* 2005, 11:6165-6169

Shaikh F, Bhand SA, Kumar P, Nizamani MA. Acute diarrhea; role of *Saccharomyces boulardii* in the treatment. *Professional Med J* 2015, 22(3):281-284

Shan LS, Hou P, Wang ZJ, Liu FR, Chen N, Shu LH *et al.* Prevention and treatment of diarrhea with *Saccharomyces boulardii* in children with acute lower respiratory tract infections. *Beneficial Microbes* 2013, 4(4):329-334

Shen Y, Liu W, Jiang L, Shao C, Xu C. Effects of *Saccharomyces boulardii* in children with acute diarrhea. *J Clin Pediatr* 2008, 26(6):528-531 [in Chinese, only abstract in English]

Song J, Park DI, Park JH, Kim HJ, Cho YK, Sohn CI *et al.* The effect of probiotics and mucoprotective agents on PPI-based triple therapy for eradication of *Helicobacter pylori*. *Helicobacter* 2010, 15:206-213

Summary of Product Characteristics (SmPC), various products

Stickl H. Das Immunverhalten des Menschen nach Einnahme von Hefe. *Natura-med* 1987, 3:156-157 [in German]

Stüttgen M. Aknetherapie mit *Saccharomyces boulardii*. *Akt Dermatol* 1991, 17:206-209 [in German]

Suardi E, Crippa F, d'Arminio Montforte A. Probiotics in the prevention of antibiotic-associated diarrhea in adults. *Int J Probiotics Prebiotics* 2013, 8(1):41-44

Sudha MR. Safety assessment studies of probiotic *Saccharomyces boulardii* strain Unique 28 in Sprague-Dawley rats. *Benef Microbes* 2011, 2(3):221-227

Surawicz CM, Elmer GW, Speelman P, McFarland L, Chinn J, van Belle G. Prevention of antibiotic-associated diarrhea by *Saccharomyces boulardii*: a prospective study. *Gastroenterology* 1989a, 96:981-988

Surawicz CM, McFarland LV, Elmer G, Chinn J. Treatment of recurrent *Clostridium difficile* colitis with vancomycin and *Saccharomyces boulardii*. *Am J Gastroenterol* 1989b, 84(19):1285-1287

Surawicz CM, McFarland L, Greenberg RN, Rubin M, Fekety R, Mulligan RN *et al.* The search for a better treatment for recurrent *Clostridium difficile* disease: use of high-dose vancomycin combined with *Saccharomyces boulardii*. *Clin Infect Dis* 2000, 31:1012-1017

Swidsinski A, Loening-Baucke V, Verstralen H, Osowska S, Doerffel Y. Biostructure of fecal microbiota in healthy subjects and patients with chronic idiopathic diarrhea. *Gastroenterology* 2008, 135(2):568-579

Swidsinski A, Loening-Baucke V, Schulz S, Manowsky J, Verstraelen H, Swidsinski S. Functional anatomy of the colonic bioreactor: Impact of antibiotics and *Saccharomyces boulardii* on bacterial composition in human fecal cylinders. *Systematic and Applied Microbiology* 2016, 39:67-75, doi 10.1016/j.syapm.2015.11.002

Szajewska H, Mrukowicz J. Meta-analysis: non-pathogenic yeast *Saccharomyces boulardii* in the prevention of anti-biotic-associated diarrhea. *Aliment Pharmacol Ther* 2005, 22:365-372

- Szajewska H, Ruszczynski M, Radzikowski A. Probiotics in the prevention of antibiotic-associated diarrhea in children: a meta-analysis of randomized controlled trials. *J Pediatr* 2006, 149:367-372
- Szajewska H, Skórka A, Dylag M. Meta-analysis: *Saccharomyces boulardii* for treating acute diarrhoea in children. *Aliment Pharmacol Ther* 2007, 25:257-264
- Szajewska H, Skórka A. *Saccharomyces boulardii* for treating acute gastroenteritis in children: updated meta-analysis of randomized controlled trials. *Aliment Pharmacol Ther* 2009, 30:955-963
- Szajewska H, Horvath A, Piwowarczyk A. Meta-analysis: the effects of *Saccharomyces boulardii* supplementation on *Helicobacter pylori* eradication rates and side-effects during treatment. *Aliment Pharmacol Ther* 2010, 32:1069-1079
- Szajewska H, Guarino A, Hojsak I, Indrio F, Kolacek S, Shamir R *et al.* Use of probiotics for management of acute gastroenteritis: a position paper by the ESPGHAN Working Group for Probiotics and Prebiotics. *JPGN* 2014, 58(4):531-539
- Szajewska H, Horvath A, Kolodziej M. Systematic review with meta-analysis: *Saccharomyces boulardii* supplementation and eradication of *Helicobacter pylori* infection. *Aliment Pharmacol Ther* 2015a, 41:1237-1245
- Szajewska H, Kolodziej M. Systematic review with meta-analysis: *Saccharomyces boulardii* in the prevention of antibiotic-associated diarrhea. *Aliment Pharmacol Ther* 2015b, 42:793-801
- Tempé JD, Steidel AL, Blehaut, Hasselmann M, Lutun P, Maurier F. Prévention par *Saccharomyces boulardii* des diarrhées de l'alimentation entérale à débit continu. *Sem Hop Paris* 1983, 59(18):1409-1412 [in French]
- Terciolo C, Dapoigny M, Andre F. Beneficial effects of *Saccharomyces boulardii* CNCM I-745 on clinical disorders associated with intestinal barrier disruption. *Clin Exper Gastroenterol* 2019, 12:67-82
- Tung JM, Dolovich LR, Lee CH. Prevention of *Clostridium difficile* infection with *Saccharomyces boulardii*: a systematic review. *Can J Gastroenterol* 2009, 23(12):817-821
- Turck D, Bernet J-P, Marx J, Kempf H, Giard P, Walbaum O *et al.* Incidence and risk factors of oral antibiotic-associated diarrhea in an outpatient pediatric population. *J Pediatr Gastroenterol Nutr* 2003, 37:22-26
- Urganci N, Polat T, Uysalol M, Çetinkaya F. Evaluation on the efficacy of *Saccharomyces boulardii* in children with acute diarrhoea. *Arch Gastroenterohepatol* 2001, 20(3-4):81-83
- Vandenplas Y, Badriul H, Thapa B, Elizabeth K, Bhav S. A multi-centre DBRPC-trial in developing countries with *S. boulardii* in acute gastroenteritis. *J Pediatr Gastroenterol Nutr* 2007, 44(6):e86
- Vandenplas Y, Brunser O, Szajewska H. *Saccharomyces boulardii* in childhood. *Eur J Pediatr* 2008, 168(3):253-265
- Vaughan-Martini A, Martini A. Three newly delimited species of *Saccharomyces sensu strictu*. *Antonie van Leeuwenhoek* 1987, 53:77-87
- Vaughan-Martini A. Reflections on the Classification of yeast for different end-users in biotechnology, ecology, and medicine. *Int Microbiol* 2003, 6:175-182
- Venugopalan V, Shriner KA, Wong-Beringer A. Regulatory oversight and safety of probiotic use. *Emerg Infect Dis* 2010, 16:1661-1665

Villarruel G, Rubio DM, Lopez F, Cintioni J, Gurevech R, Romero G *et al.* *Saccharomyces boulardii* in acute childhood diarrhoea: a randomized, placebo-controlled study. *Acta Paediatr* 2007, 96(4):538-541

Weber G, Adamczyk A, Freytag S. Behandlung der Akne mit einem Hefepräparat. *Fortschr Med* 1989, 10:563-566 [in German]

Xie C, Li J, Wang K Li Q, Chen D. Probiotics for the prevention of antibiotic-associated diarrhea in older patients: a systematic review. *Travel Med Infect Dis* 2015, 13(2):128-134, doi 10.1016/j.tmaid.2015.03.001

Zhao HM, OU-Yang HJ, Duan BP, Xu B, Chen ZY, Tang J *et al.* Clinical effect of triple therapy combined with *Saccharomyces boulardii* in the treatment of *Helicobacter pylori* infection in children. *Chin J Contemp Pediatr* 2014, 16(3):230-233 [in Chinese, only abstract in English]

Zojaji H, Ghobakhlou M, Rajabalinia H, Ataei E, Sherafat SJ, Moghimi-Dehkordi B. The efficacy and safety of adding the probiotic *Saccharomyces boulardii* to standard triple therapy for eradication of *H. pylori*: a randomized controlled trial. *Gastroenterol Hepatol* 2013, 6(1):S99-S104

References assessed but not cited in the assessment report

FAO/WHO Expert Consultation Group. Probiotics in Food: Health and nutritional properties and guidelines for evaluation. Nutrition Paper 85, ISSN 0254-4725; Rome 2006; Available at: <https://www.fao.org/3/a0512e/a0512e.pdf>

LPT. Mutagenicity study of *Saccharomyces cerevisiae* HANSEN CBS 5926 in the *Salmonella typhimurium* reverse mutation assay (*in vitro*). 2014. Report No. 30428/1