ASACOL® COMBINED Abbreviated Prescribing Information. Presentations: Tablets: Coated, red-brown, oblong gastro-resistant tablets containing 400mg or 800mg mesalazine. Suppository: Light grey-brown, torpedo-shaped suppositories containing 500mg mesalazine. Enema: Brownish suspension containing mesalazine 2g in 50mL or 4g in 100mL. **Indications:** Tablets: Induction and maintenance of remission of mild to moderate ulcerative colitis (UC), maintenance of remission of Crohn's ileo-colitis in adults and children (age 6-18 years). Suppository: Induction of remission of mild to moderate proctitis and proctosigmoiditis and maintenance of remission of mild to moderate proctitis in adults. Enema: Induction and maintenance of remission of proctitis, proctosigmoiditis and left-sided colitis in adults. **Pharmacokinetics:** Asacol® gastro-resistant tablets release mesalazine at a pH above 7 e.g. within the terminal ileum and the colon. Asacol® tablets have been designed to be poorly absorbed in the digestive tract. The majority of the administered dose remains in the gut lumen and mucosal tissue. Mesalazine is metabolised both by the intestinal mucosa and the liver to the inactive metabolite N-acetyl mesalazine. The elimination of mesalazine is essentially urinary and faecal in the form of mesalazine and its N-acetyl metabolite. **Dosage and administration:** Tablets: The tablets must be swallowed whole and not chewed, crushed or broken. *Adults*: *Induction of remission of UC*: 2.4g once daily or in divided doses up to 4.8g mesalazine daily in divided doses. *Maintenance of remission of UC*: 1.6g – 2.4g mesalazine a day taken once daily or in divided doses. *Maintenance or remission of Crohn's ileo-colitis*: 2.4g mesalazine daily in divided doses. *Children 6 years of age and older*: *Induction of remission*: To be determined individually, starting with 30-50 mg/kg/day in divided doses. Maximum dose: 75 mg/kg/day in divided doses. The total dose should not exceed 4.0 g/day. *Maintenance of remission*: To be determined individually, starting with 15-30 mg/kg/day in divided doses. The total dose should not exceed 2.0 g/day. It is generally recommended that half the adult dose may be given to children up to a body weight of 40 kg; and the normal adult dose to those above 40 kg. Suppository: *Induction of remission*: 1 suppository (500mg mesalazine) 3 times daily after defecation. *Maintenance of remission*: 1 suppository (500mg mesalazine) twice daily after defecation. Enema: *Induction and maintenance of remission*: One enema (2g or 4g mesalazine) administered at night after defecation daily. **Contraindications:** Patients with known hypersensitivity to salicylates or mesalazine, severe liver or renal impairment (GFR < 30 mL/min/1.73 m²). **Precautions:** Blood tests (differential blood count; liver function parameters such as ALT or AST; serum creatinine) and urinary status (dip sticks) should be determined prior to and during treatment, at the discretion of the treating physician. As a guideline, follow-up tests are recommended 14 days after commencement of treatment and then every 4 weeks for the following 12 weeks. If the findings are normal, follow-up tests should be carried out every three months. If additional symptoms occur, these tests should be performed immediately. Asacol® is not recommended for use in patients with renal impairment. Patients with galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Caution should be exercised in patients with: raised serum creatinine, proteinuria, liver impairment, gastric or duodenal ulcers, previous myo- or pericarditis of allergic background regardless of its origin, pulmonary disease, in particular asthma in the elderly. In case of previous mesalazine-induced cardiac hypersensitivity Asacol® must not be reintroduced. Treatment must be stopped immediately and patients must seek immediate medical attention in case of acute symptoms of intolerance such as cramps, abdominal pain, fever, severe headache or rash or if blood dyscrasia is suspected. In patients with a history of sensitivity to sulphasalazine, therapy should be initiated only under close medical supervision. There is only limited documentation for an effect in children (age 6-18 years). **Pregnancy and lactation:** There are no adequate data on the use of Asacol® in pregnant women. However, data on a limited number of exposed pregnancies indicate no adverse effect of mesalazine on pregnancy or on the health of the fetus/newborn child. N-acetyl-5-aminosalicylic acid and to a lesser degree mesalazine are excreted in breast milk. The clinical significance of this has not been determined. Asacol® should only be used during pregnancy or breast-feeding if the potential benefit outweighs the possible risk. **Interactions:** Mesalazine can increase the myelosupressive effects of azathioprine, or 6-mercaptopurine or thioguanine. Haematological parameters, especially the leucocyte, thrombocyte, and lymphocyte cell counts should be monitored regularly (weekly), especially at initiation of such combination therapy. If white blood cells are stable after 1 month, testing every 4 weeks for the following 12 weeks followed by 3 monthly monitoring intervals appears to be justified. There is weak evidence that mesalazine might decrease the anticoagulant effect of warfarin. **Adverse reactions:** *Common**: Dyspepsia and rash. *Uncommon**: Eosinophilia, paresthesia, urticaria, pruritus, pyrexia and chest pain. *Rare*: Headache, dizziness, myocarditis, pericarditis, photosensitivity, abdominal pain, diarrhoea, flatulence, nausea and vomiting. *Very rare*: Altered blood counts (aplastic anaemia, agranulocytosis, pancytopenia, neutropenia, leukopenia, thrombocytopenia), hypersensitivity reactions such as allergic exanthema, drug fever, lupus erythematosus syndrome, pancolitis, peripheral neuropathy, allergic and fibrotic lung reactions (including dyspnoea, cough, bronchospasm, alveolitis, pulmonary eosinophilia, lung infiltration, pneumonitis), interstitial pneumonia*, eosinophilic pneumonia*, lung disorder*, acute pancreatitis, changes in liver function parameters (increase in transaminases and cholestasis parameters), hepatitis, cholestatic hepatitis, alopecia, myalgia, arthralgia, impairment of renal function including acute and chronic interstitial nephritis and renal insufficiency, nephrotic syndrome*, renal failure which may be reversible on early withdrawal* and oligospermia (reversible). **Licence holder and supplier:** Tillotts Pharma AG, Switzerland.
* Only for Asacol® Tablets formulation.

This abbreviated prescribing information is based on the Products' Company Core Data Sheets (last update October 2017). Trade name, formulations, pack sizes, indications and dosages may vary from country to country. Before prescribing, please consult your local Summary of Product Characteristics. Detailed prescribing information is available from all suppliers of Asacol® and Tillotts Pharma AG, Switzerland (www.tillotts.com). **The trademark Asacol is registered in over 55 countries as Asacol® and as Octasa™, Fivasa™, Lixacol™, Asacolon™ in the United Kingdom, France, Spain and Ireland, respectively. The rights to Asacol, including the rights to the trademark, are owned by Tillotts Pharma AG in various countries except for the following: Switzerland, USA, United Kingdom, Canada, Italy, Belgium, the Netherlands and Luxembourg.**

(1) Sandborn et al., Gastroenterology 2010;138:1286–1296. (v 1.0) p.1. The Asacol™ reference in this study relates to Allergan's Asacol™, to which Tillotts Pharma's Asacol™ 400mg is functionally equivalent. Allergan and its affiliates market their mesalazine products under the trademark Asacol™ in the USA, Canada and the United Kingdom. Tillotts Pharma markets its mesalazine products under the trademark Asacol™ in over 55 countries throughout continental Europe and the rest of the world. Allergan and Tillotts Pharma are not related companies.
(2) Timeus S. And Marchi P. Poster P492, 12th European Crohn's Colitis Organization (ECCO) Congress, Barcelona, Spain, Feb 15.18, 2017.

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- ✓ Very low drug interactions[3]
- ✓ No interaction with Clopidogrel based on FDA label 2012[4]
- ✓ Class B in pregnancy[1]

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References:
1. Drug Facts and Comparisons. St. Louis, MO: Wolters Kluwer Health, Inc; 2011. p 1975.
2. Am J Gastroenterol 2001; 96: 3089-3098.
3. Drug Safety 2006; 29: 769-784.
4. Lansoprazole: highlight of prescribing information. FDA label 2012; Reference ID: 3193013.

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- Positive effects in Inflammatory Bowel Disease (IBD), especially in moderately active Crohn's disease
- Positive effects in Diverticulitis
- Treatment of acute and chronic intestinal infections caused by susceptible Gram-positive, Gram-negative, Aerobic and Anaerobic bacteria
- Treatment of Summer diarrhea, Traveler's diarrhea and Enterocolitis

References

1. Drug Fact and Comparisons 2016.
2. Natalya Lorio, et al. Profile of Rifaximin and its potential in the treatment of irritable bowel syndrome. Clin Exp Gastroenterol. 2015 ; 8:159-167.
3. Roberto Lorenzetti, et al. Rationale for the use of rifaximin in inflammatory bowel diseases based on clinical trial results. Clin. Invest. (2013) 3(12), 1187–1193.

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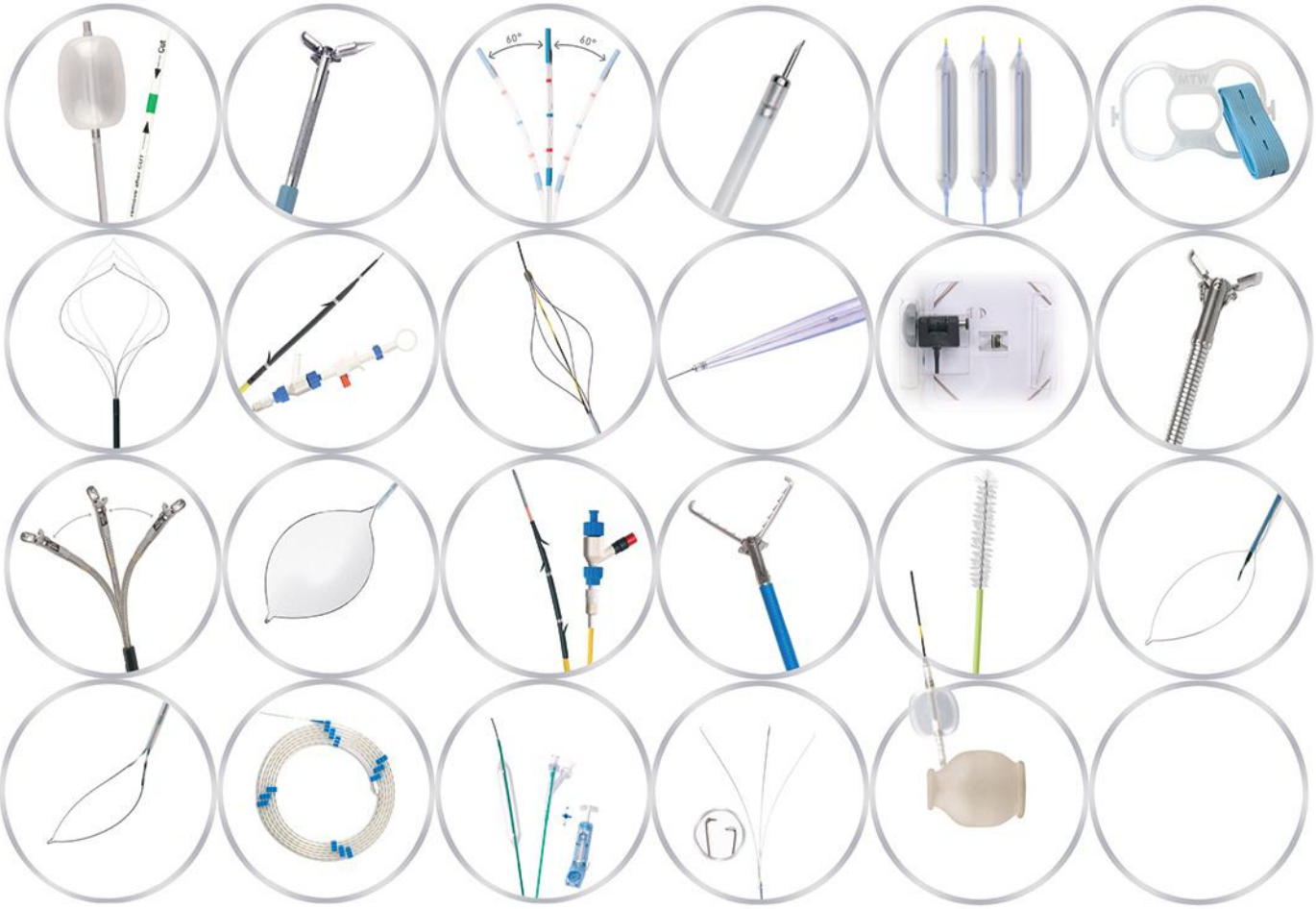

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G-Pe-MA-Oct-182227

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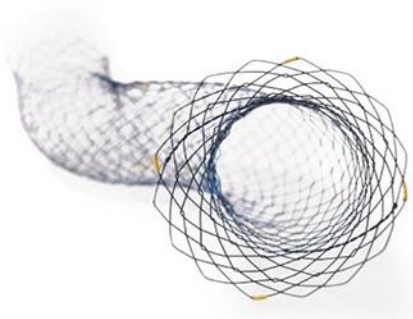

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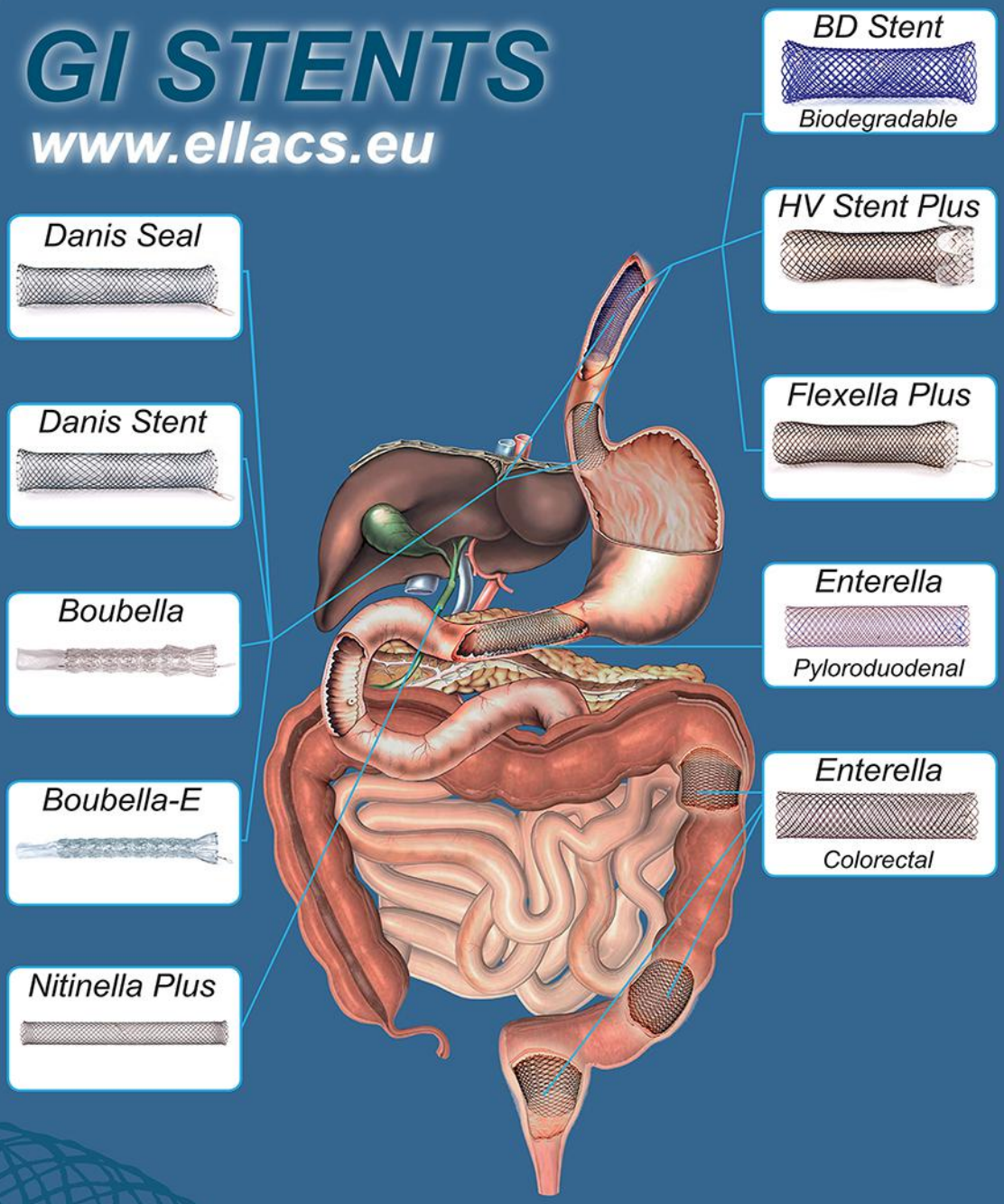

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