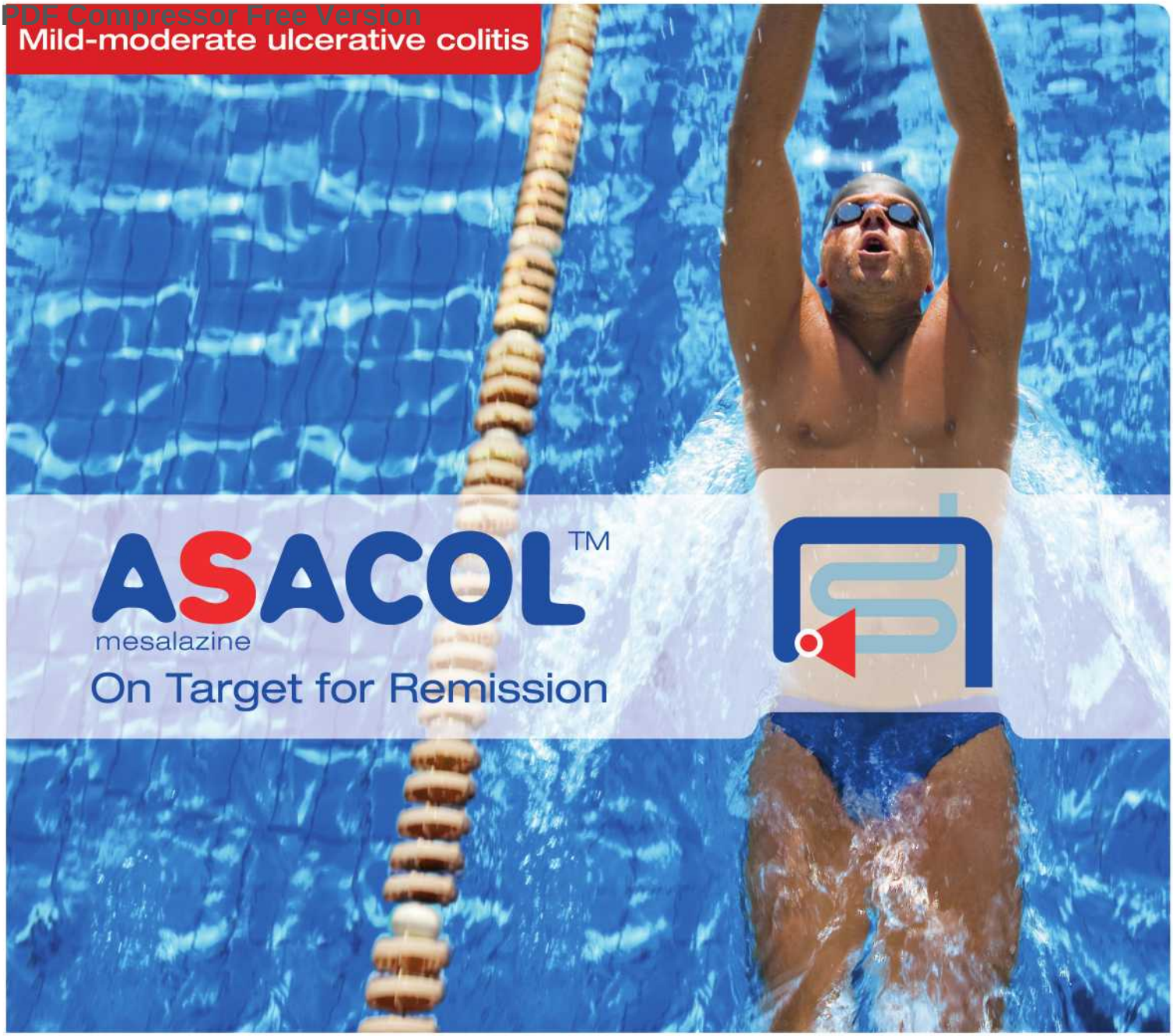
Mild-moderate ulcerative colitis



9 OUT OF 10 ASACOL™ patients maintain clinical remission at 6 months (1)

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- ✓ **Highest number of FDA approved indications** [1]
- ✓ **High efficacy and rapid acid-related symptoms relief** [2]
- ✓ **Rapid onset of action** [2]
- ✓ **As safe as placebo** [3]
- ✓ **Very low drug interactions** [3]
- ✓ **No interaction with Clopidogrel based on FDA label 2012** [4]
- ✓ **Class B in pregnancy** [1]

IR-0717-LNZ-2603-AD

1. Drug Facts and Comparisons. St. Louis, MO: Wolters Kluwer Health, Inc; 2011. p 1975.
2. Richter Joel E, Kahrilas Peter J, Sontag Stephen J, et al. Comparing Lansoprazole and Omeprazole in Onset of Heartburn Relief: Am J Gastroenterol 2001; 96: 3089-3098.
3. Blume H, Donath F, Warnke A, et al. Pharmacokinetic drug interaction profiles of proton pump inhibitors. Drug Safety 2006; 29: 769-784.
4. Lansoprazole: highlight of prescribing information. FDA label 2012; Reference ID: 3193013.

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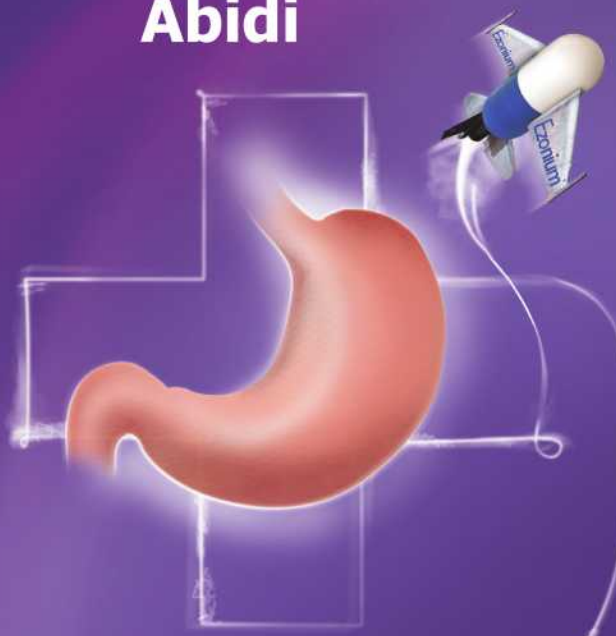

The power to heal

IR-1116-EZN-2100-AD

- **Fast and long-lasting acid control** [1]
- **The best choice in GERD and EE management** [1,2]
- **Proven efficacy in resistant patients with GERD and EE** [2]

References:

1. *Am J Gastroenterol 2003; 98: 2616-2620.*
2. *Clin Drug Invest 2009; 29* (12): 803-810.

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- Esomeprazole is effective in patients with persistent **GERD**[2]
- Esomeprazole – **effective and well tolerated** in reducing the recurrence of PU[3]

ACTOVERCO
Together for a healthy future

KRKA

1. Miner P J. et al. Am. J. Gastroenterol. 2003; 98 (12): 2616–20.
2. Jones R. et al. Int. J. Clin. Pract. 2008; 62, 12: 1844–50.
3. Sugano K et al. Gut 2013; 0: 1–8.

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G.Pe.MS.Sep.12/499

Abbreviated Prescribing Information

Presentations: Prolonged release 500 mg Tablets, prolonged release 1g Sachets, prolonged release 2g Sachets, 1g Suppositories, and 1g/100 ml Enema. **Uses: Tablets & Sachets:** Chronic Inflammatory Bowel Disease (Ulcerative Colitis & Crohn's Disease). **Suppositories:** Chronic Inflammatory Bowel Disease located to the Rectum (Ulcerative Proctitis). **Enema:** Ulcerative Proctosigmoiditis. **Contraindications:** Hypersensitivity to mesalazine, any of the excipients, or salicylates. Severe liver or renal impairment. **Dosage: Tablets: Ulcerative Colitis: Treatment of Active Disease: Adults:** 2g mesalazine per day, divided into two single doses. In case of insufficient response, the dose can be increased to 4g daily. Relapse Prophylaxis: In general, 1.5g mesalazine, divided into 2-3 single doses. **Crohn's Disease: Treatment of Active Disease: Adults:** Up to 4g mesalazine per day, divided into 2-3 single doses. **Sachets 1g & 2g: Ulcerative Colitis: Treatment of Active Disease: Adults:** Individual Dosage, up to 4g mesalazine daily divided into 2-4 doses. **Maintenance Treatment: Adults:** Individual Dosage. Recommended dosage, 2 g mesalazine once daily. **Crohn's Disease: Treatment of Active Disease: Adults:** Individual dosage, up to 4g mesalazine daily in divided dose. **Maintenance Treatment: Adults:** Individual dosage, up to 4g mesalazine daily in divided dose. **Tablets & Sachets: Ulcerative Colitis & Crohn's Disease: Treatment of Active Disease: Children:** Children 6 years of age and older: 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 g/day (maximum adult dose). **Maintenance Treatment: Children:** Children 6 years of age and older: To be determined individually, starting with 15-30 mg/kg/day in divided doses. The total dose should not exceed 2 g/day (recommended adult dose). **Enema:** 1 enema at bed time. **Suppositories:** One suppository 1-2 times/day. **Special Warnings and Precautions:** Caution is recommended when treating patients allergic to sulphasalazine (risk of allergy to salicylates). Caution is recommended in patients with impaired liver function. The drug is not recommended for use in patients with renal impairment. Mesalazine-induced cardiac hypersensitivity reactions (myo- and pericarditis) have been reported rarely. Serious blood dyscrasias have been reported very rarely with mesalazine. Adverse Reactions: **Tablets:** Occasional adverse reactions seen in clinical trials are diarrhea, nausea, abdominal pain, headache, vomiting, and rash. Hypersensitivity reactions and drug fever may occasionally occur. **Sachets 1g:** The most frequent adverse reactions seen in clinical trials are diarrhea, nausea, abdominal pain, headache, vomiting, and rash. **Sachets 2g:** Nervous System: Occasional: headache, nausea, dizziness. **Enema:** Occasionally, reactions of the central nervous system such as headache and vertigo as well as gastro-intestinal impairments (diarrhea, abdominal pain, nausea, vomiting) and rash (allergic exanthema, urticaria) have been observed. **Suppositories:** Pentasa suppositories are generally well tolerated, in 1-3% of patients diarrhea, nausea abdominal pain, headache, vomiting and rash, e.g. urticaria and eczema have been observed.

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IR-071-SFR-3496-AD

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*Sofosbuvir; highlights of prescribing information. FDA label 2015. Reference ID: 3719423

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