

# BENIZER

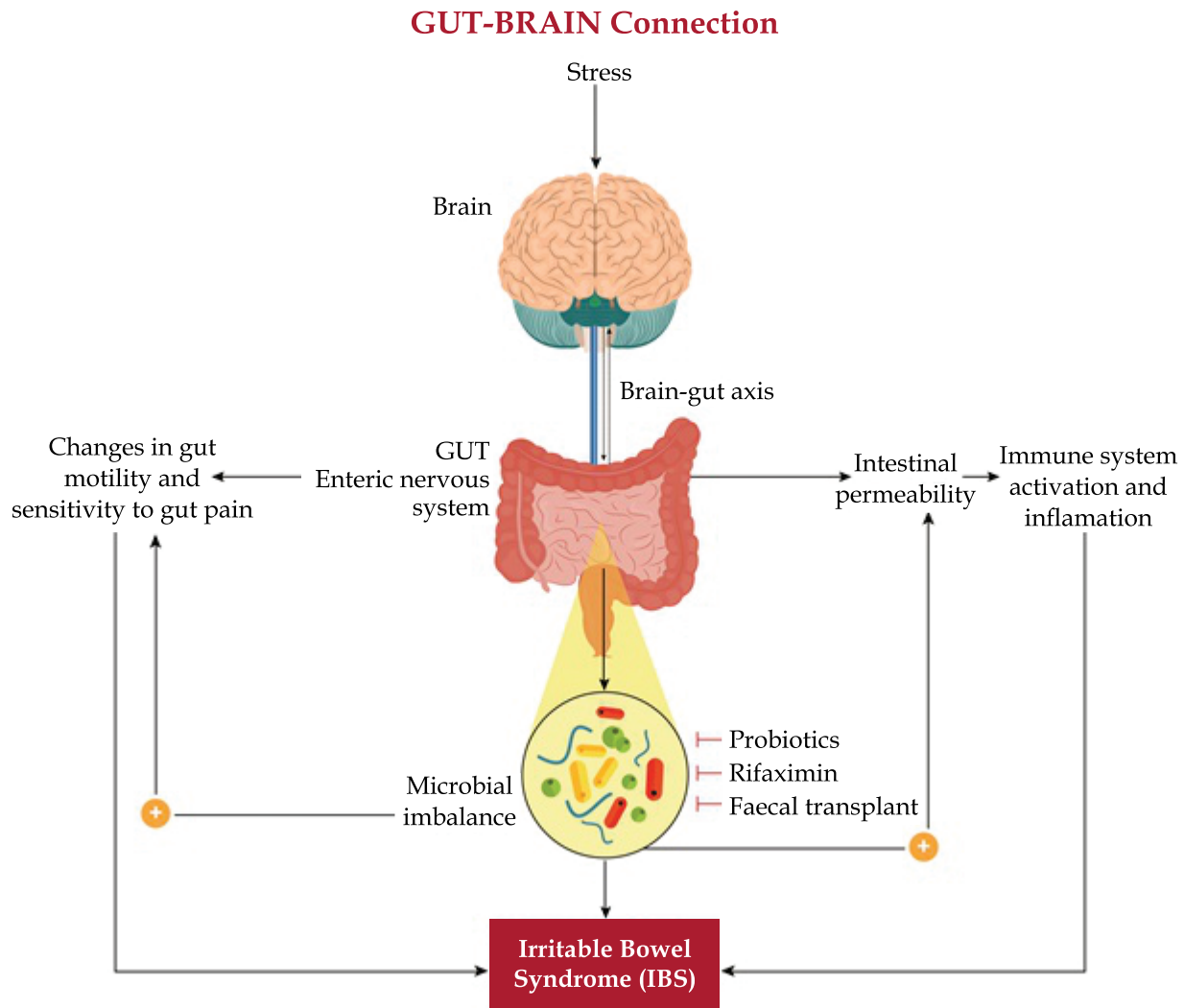
Chlordiazepoxide 5 mg and Sustained Release Mebeverine 135 mg Capsules

# BENIZEP

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Mebeverine 135 mg Capsules

## INTRODUCTION:

- Irritable bowel syndrome is a functional GI disorder characterized by abdominal pain and altered bowel habits in the absence of specific organic pathology.
- Irritable bowel syndrome (IBS) affects 10%–15% of the population worldwide. Among patients about 40% of people have mild IBS, 35% moderate IBS, and 25% severe IBS. Many people don't recognize IBS symptoms.
- **A significant proportion** { 35% to 40% are male &  
60% to 65% are female
- Living with IBS can be anxiety



- The gut-brain axis links emotional and cognitive centres within the brain to peripheral functioning of the gastrointestinal tract, which is controlled by the enteric nervous system. Scientists are looking into the factors that influence this two-way system, including stress, which may be connected to changes in gut motility, an increased sensitivity to pain, and immune system activation and inflammation, all symptoms that characterize irritable bowel syndrome.

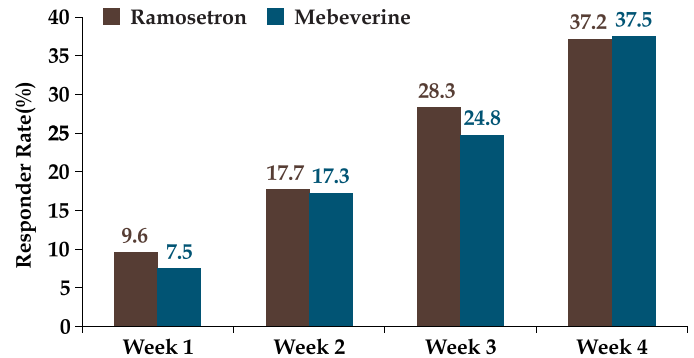
# CLINICAL EVIDENCE

## STUDY-1:

**Efficacy of ramosetron in the treatment of male patients with irritable bowel syndrome with diarrhea: a multicenter, randomized clinical trial, compared with Mebeverine.<sup>1</sup>**

### Study design and observation:

- A multicenter, randomized, open-label study on 343 male patient with IBS-D who were randomized to either a 4-week treatment of ramosetron 5 µg once daily or a 4-week treatment of mebeverine 135 mg three times daily were analyzed by the intent-to-treat analysis.
- The primary end point : Patients with adequate relief of IBS symptoms at the last week of treatment.
- The secondary end point : Changes in each symptom score and the safety profiles.
- The responder rates for global IBS symptoms, abdominal pain/discomfort and abnormal bowel habits in the ramosetron and mebeverine groups significantly increased during the treatment period.



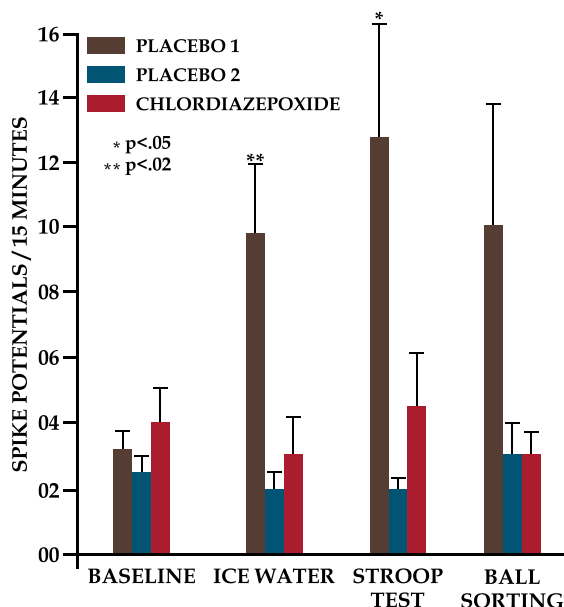
The weekly responder rate of 'patient-reported assessment of relief of global IBS symptoms'. The responder rates significantly increased during the study in both treatment.

## STUDY-2:

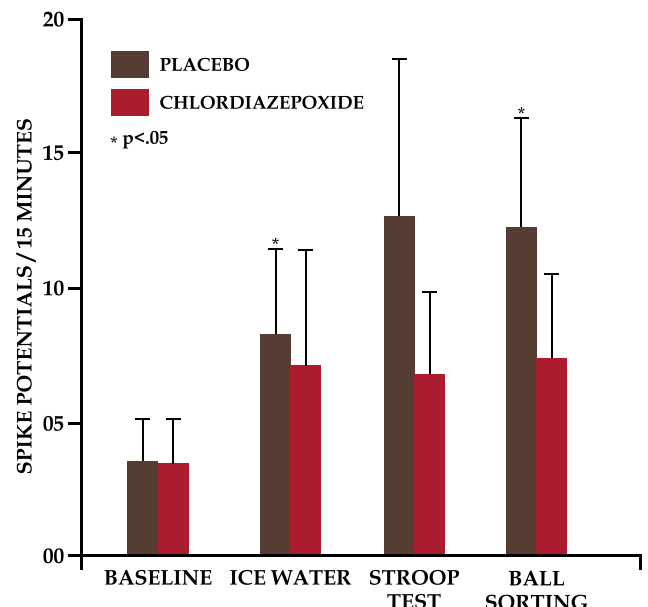
**Increased Colonic Motility During Exposure to a Stressful Situation.<sup>2</sup>**

### Study design and observation:

- In the first study the six healthy subjects received a placebo tablet 30 min prior to the study in a single-blind manner; the second and third studies irritable colon syndrome (ICS) patient received either chlordiazepoxide (10 mg) or placebo in a double-blind crossover manner
- Healthy subjects and patients with the irritable colon syndrome (ICS) were exposed to three standardized stressful conditions: (i) ice-water immersion, (2) Stroop stimulus differentiation test, and (3) ball sorting.



Effect of acute stress on colonic spike activity in healthy subjects. The response to the acute stresses of ice water, Stroop test, and ball sorting are compared to the baseline. The effects of Pre-treatment with placebo (first study) and placebo and Chlordiazepoxide (repeat studies) are shown.



Effect of acute stress on colonic spike activity in patients with the irritable colon syndrome. The response to acute stress is compared to baseline for placebo and Chlordiazepoxide Pre-treatment.

# BENIZEP

Chlordiazepoxide 5 mg and Sustained Release  
Mebeverine 135 mg Capsules

## DESCRIPTION:

- **BENIZEP** is hard gelatin capsule consisting of Chlordiazepoxide 5mg and sustained release Mebeverine Hydrochloride 135 mg.
- Benizep is synthetic anti cholinergic agent combination with psycholeptic agent.

## INDICATION:

- **BENIZEP** is indicated for the treatment of irritable bowel syndrome (IBS).
- This medicine is used to relieve abdominal pain, spasm, flatulence, and other symptoms of irritable bowel syndrome (IBS), and also the excessive tension and anxiety associated with IBS.

## MECHANISM OF ACTION:

**Chlordiazepoxide** binds to stereospecific benzodiazepine (BZD) binding site on GABA (A) receptor complexes at several sites within the CNS, including the limbic system and reticular formation. This will increase the concentration of inhibitory neurotransmitter GABA & chloride ions in the CNA and decrease firing rate of neurons. This turn alter normal excitatory function of the body.

**BENIZEP**

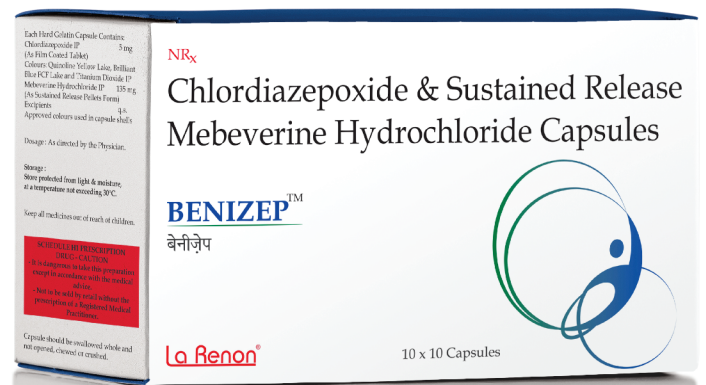
**Mebeverine** is an antispasmodic medicine which direct relaxant effect on smooth muscle. This will inhibit gastrointestinal propulsive motility and gastric acid secretion

## DOSAGE:

- As directed by the physician.

### Reference:

1. *Neurogastroenterol Motil* (2011) 23, 1098–e540.
2. *Digestive Diseases and Sciences*, Vol. 30, No. 1 (January 1985), pp. 40-44



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