Focus on Spasmomen®

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Introduction

Irritable bowel syndrome (IBS) is the disorder most encountered by gastroenterologists.[1] In the absence of a reliable disease biomarker, several symptom-based criteria have been proposed to standardise the diagnosis of IBS.[2] The most widely used among them are the ROME IV criteria.[2]

IBS is a multifactorial disorder, with the following among the proposed mechanisms contributing to symptomatology: gastrointestinal dysmotility, inflammation, visceral hypersensitivity, and altered intestinal microbiota.[1] Diet and stress exposure (including early life events) have been proposed as contributing factors.[1] Lastly, genetic predisposition and environmental interactions have been implicated in the pathogenesis of IBS.[1]

Substantial advances have been made in understanding the complex pathophysiology of IBS, resulting in its re-classification as a disorder of gut-brain interaction, rather than as a functional gastrointestinal disorder.[3]

Treatment of IBS is diverse, geared towards the predominant symptom, and includes lifestyle and dietary modifications and medical therapy if these modifications do not provide adequate symptom improvement.[4,5]

Indication

Spasmomen® 40 mg film-coated tablets each contain 40 mg otilonium bromide and are indicated for the symptomatic treatment of established IBS associated with painful, spastic states of distal parts of the intestinal tract (colon and rectum), abdominal pain, distension and motility disorders in patients older than 18 years.[6]

Mechanism of action

Otilonium bromide is an antispasmodic agent belonging to the family of quaternary ammonium derivatives.[7] A combination of calcium (Ca^{2+}) channel blocker and antimuscarinic properties on the intestinal smooth muscle cells and muscarinic receptors of the colonic epithelium, respectively, accounts for most of the therapeutic effects of otilonium bromide in IBS.[6,8]

Dosing and administration

The recommended daily dose for adults 18 years and older is 80 to 120 mg (1 tablet twice to three times daily) and may be adjusted according to the clinical response to treatment.[6] However, safety and efficacy have not been established beyond 25 weeks of treatment.[6]

Tablets should be swallowed whole, with a glass of water, preferably 20 minutes before meals.[6]

Clinical efficacy

The efficacy of otilonium bromide in patients with IBS has been documented in several clinical trials:[8]

- Battaglia et al.[9] conducted a double-blind, placebo-controlled, randomised, 15-week study in patients (n = 325) with IBS. The reduction in abdominal pain episodes was significantly higher in patients receiving otilonium bromide (55.3 %) than in those taking placebo (39.9%), as was the reduction in the severity of abdominal distension (42.0% versus 30.2%; $p < 0.05$).[9]
- Glende et al.[10] conducted a double-blind, placebo-controlled, parallel-group study in 378 IBS patients treated for 15 weeks with 40 mg otilonium bromide or placebo three times daily. The rate of response to treatment within two to four months (primary endpoint) was significantly higher in the otilonium bromide group than in the placebo group (36.9% *vs.* 22.5%; $p = 0.007$).[10]
- Baldi et al.[11] showed that otilonium bromide in a dose of 40 mg three times daily significantly reduced pain and bloating and significantly increased the pain threshold throughout treatment when compared with placebo.

- Chang et al.[12] showed that otilonium bromide showed similar efficacy compared with mebeverine in reducing abdominal pain, flatulence, and abdominal bloating.

Safety and tolerability

Otilonium bromide is poorly absorbed orally and acts mainly at the local level, characteristics that support its good tolerability and safety profile.[8] It is without systemic anticholinergic adverse effects, but caution is needed when used in patients with glaucoma, prostatic hypertrophy and pyloric stenosis.[6,8] In clinical trials, otilonium bromide was shown to have adverse event rates similar to placebo.[6] No drug interactions have been reported to date.[8]

In summary

Otilonium bromide (Spasmomen®) reduces abdominal pain and discomfort in patients with IBS.[8] It shows a localised activity as it is poorly absorbed orally, factors that support its good tolerability and safety profile.[7,8] Therapeutic benefits are maximal after 15 weeks of treatment.[7]

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