MD_PERELIGYN_ · GUIDE

OTILONIUM BROMIDE (SPASMOMEN 40 MG): A COLON ANTISPASMODIC FOR IRRITABLE BOWEL SYNDROME

Otilonium bromide (Spasmomen **40 mg**) relieves colon spasm and is barely absorbed into the blood. In three irritable bowel syndrome trials, **77.2%** of people on the drug versus **65.8%** on placebo improved on the global pain assessment at week 15. In plain words: how it works, what the trials showed, how it is taken and who should see a doctor first.

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01 · KEY POINTS

Fewer pain episodes. In the OBIS trial of 356 people with irritable bowel syndrome, the weekly frequency score of pain episodes fell more than on placebo over 15 weeks: −0.90 versus −0.65 (Clavé P Aliment Pharmacol Ther 2011. PMID 21679214).

About 3 in 4 improved. In a pooled analysis of 3 trials, **77.2%** of 415 people on the drug versus **65.8%** of 424 on placebo improved on the patients' global pain assessment at week 15 (Clavé P, Tack J Ther Adv Gastroenterol 2017. PMID 28246548).

Less bloating and longer without relapse. Bloating eased more than on placebo, and after treatment stopped **10%** versus **27%** dropped out because symptoms came back (PMID 21679214).

Works in the gut. About **3%** of the dose is absorbed into the blood; the drug stays in the muscle of the colon and rectum (Spasmomen SmPC, section 5.2).

OTILONIUM BROMIDE (SPASMOMEN 40 MG)

HOW MUCH

1 tablet of **40 mg** 2–3 times a day, preferably before meals

WHAT IT DOES

relieves spasm of the colon and rectum; about **3%** is absorbed into the blood

WHAT STUDIES SHOWED

3 trials, 415 versus 424 people: **77.2%** versus **65.8%** on placebo improved on the global pain assessment at week 15

OTILONIUM BROMIDE IN THE OBIS TRIAL

HOW MUCH

40 mg 3 times a day for 15 weeks, then 10 weeks of follow-up

WHAT IT DOES

fewer pain episodes, less bloating

WHAT STUDIES SHOWED

179 versus 177 people: pain frequency –0.90 versus –0.65; after stopping, **10%** versus **27%** dropped out due to relapse

02 · HOW IT WORKS

In irritable bowel syndrome the colon muscle contracts too strongly, which causes spasms, pain and bloating.

Otilonium bromide acts on the smooth muscle of the colon and rectum. According to the SmPC, it reduces calcium entry into muscle cells, most likely through L-type and T-type calcium channels in the muscle cells and the sensory nerves of the gut. Contractions become weaker and pain from the gut quieter. It also interacts with the tachykinin receptors NK1 and NK2 (Spasmomen SmPC, section 5.1).

It works at doses that do not affect gastric secretion and do not cause typical atropine-like effects (Spasmomen SmPC, section 5.1).

About **3%** of the dose reaches the blood. The drug probably reaches the muscle directly through the gut wall and builds up in the muscle of the colon and rectum, then leaves with the stool mostly unchanged. Taking it shortly before a meal, the SmPC says, helps it work where and when symptoms are expected to be strongest (Spasmomen SmPC, section 5.2).

03 · WHAT THE STUDIES SHOWED

OBIS, CLAVÉ 2011, DOUBLE-BLIND, 15 WEEKS + 10 WEEKS OF FOLLOW-UP (PMID 21679214)

WHO TOOK PART

356 people with irritable bowel syndrome (179 and 177), mean age 46, **71%** women

COMPARISON

otilonium bromide **40 mg** 3 times a day versus placebo

RESULT

pain episode frequency −0.90 versus −0.65; bloating −1.2 versus −0.9; after stopping, **10%** versus **27%** dropped out due to relapse

POOLED ANALYSIS OF 3 TRIALS, CLAVÉ AND TACK 2017, 15 WEEKS (PMID 28246548)

WHO TOOK PART

883 people (442 and 441), of whom 415 and 424 in the efficacy analysis

COMPARISON

otilonium bromide **40 mg** 3 times a day versus placebo

RESULT

77.2% versus **65.8%** improved on the global pain assessment at week 15; **71.8%** versus **62.4%** at week 10

04 · THE OBIS TRIAL

356 adults with irritable bowel syndrome took otilonium bromide **40 mg** 3 times a day (179 people) or placebo (177) for 15 weeks. They were then followed for another 10 weeks without treatment (Clavé P Aliment Pharmacol Ther 2011. PMID 21679214).

- The weekly frequency of pain episodes fell more: −0.90 versus −0.65. This was the main goal of the trial.
- Bloating eased more: −1.2 versus −0.9.
- Patients rated the overall benefit of treatment higher: 1.3 versus 1.0.
- After treatment stopped, **10%** of those on the drug versus **27%** on placebo dropped out because symptoms came back, and the time without relapse was longer.

Safety and quality of life were comparable in the two groups.

05 · THE POOLED ANALYSIS OF THREE TRIALS

The authors pooled 3 trials with the same design, OBIS among them. Everyone first took placebo for 2 weeks, then otilonium bromide **40 mg** 3 times a day or placebo for 15 weeks. In total 883 people, **70%** women, mean age 46 (Clavé P, Tack J Ther Adv Gastroenterol 2017. PMID 28246548).

- On the global pain assessment (strength and frequency together), **77.2%** of 415 people on the drug versus **65.8%** of 424 on placebo improved at week 15. Put simply, about 3 in 4 versus 2 in 3.
- The difference from placebo became significant by week 10 and was largest by week 15.
- Bloating also eased more on the drug.
- Stool frequency and consistency did not change significantly: the drug works on spasm and pain, not on the stool.

The course was completed equally often: **16.1%** dropped out in both groups.

06 · INDICATIONS

According to the Spasmomen SmPC (section 4.1), the drug is used in adults aged 18 and over for:

— **irritable bowel syndrome**;

— **painful spasms of the lower intestine**, above all the colon.

07 · HOW IT IS USED

- **Dose:** 1 tablet of **40 mg** 2–3 times a day, depending on how strong the symptoms are. The maximum recommended dose is **40 mg** 3 times a day.
- **How to take it:** swallow the tablet whole with a glass of water, preferably before meals.
- **How long:** the length of the course is set by a doctor. The Belgian SmPC gives a usual course of 4 weeks, after which the doctor decides whether to continue. In the trials the drug was given for 15 weeks.
- Antispasmodics are not taken continuously without a doctor's advice (Spasmomen SmPC, sections 4.2 and 4.4).

08 · SAFETY

- Uncommon: dry mouth, nausea, vomiting, upper abdominal pain, headache, dizziness, itching, skin redness, tiredness. Rarely allergy: hives, angioedema (Spasmomen SmPC, section 4.8).
- The drug has no or negligible effect on driving (section 4.7).

09 · IMPORTANT

See a doctor first, not reach for an antispasmodic, if there are red flags — they call for tests:

— symptoms first appeared after age 50;

— blood in the stool;

— unexplained weight loss;

— pain that wakes you at night;

— anaemia.

Discuss the drug with a doctor in these cases too:

— bowel obstruction (a contraindication in the Belgian SmPC) or allergy to the drug;

— glaucoma, an enlarged prostate, narrowing of the stomach outlet (pyloric stenosis);

— you take many medicines;

— hereditary lactose or galactose intolerance: the tablet contains lactose;

— pregnancy or breastfeeding: there are no clinical data, the drug is used only when absolutely necessary;

— age under 18: the drug is not recommended.

10 · SUMMARY

Otilonium bromide relieves colon spasm and barely reaches the blood. In irritable bowel syndrome, across 3 trials `77.2%` of 415 people on the drug versus `65.8%` of 424 on placebo improved on the global pain assessment, and in OBIS there were fewer pain episodes, less bloating and fewer relapses after stopping. `40 mg` 2–3 times a day before meals, and the decision made with a doctor, especially with red flags.

11 · SOURCES

Studies cited in the text, by PubMed ID

Clavé P Aliment Pharmacol Ther 2011 · PMID 21679214

Clavé P, Tack J Ther Adv Gastroenterol 2017 · PMID 28246548

Article and plain-language version:

universum.earth/en/blog/otilonium-bromide-spasmomen-irritable-bowel-syndrome

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