bhw silicol® gel

Colloidal Silicic Acid for Gastrointestinal Disorders



To Treat

- Heartburn
- Reflux
- Vomiting

And IBS symptoms

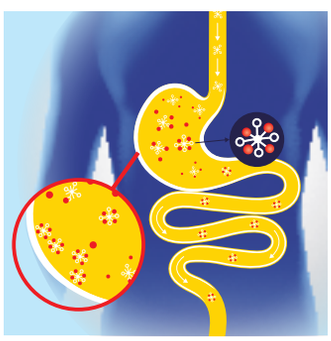
- Nausea
- Flatulence
- Abdominal pain
- Bowel discomfort
- Diarrhoea

bhw silicol® gel is an enteroadsorbent gel to treat gastrointestinal disorders such as reflux, heartburn and vomiting and also the IBS symptoms; nausea, flatulence, abdominal pain, bowel discomfort and diarrhoea. The oral gel contains silicic acid in a colloidal (highly dispersed) and hydrated form. Gastrointestinal disorders are often caused by irritants, pathogens and other harmful and toxic substances. bhw silicol® gel works to remove these, and as a result alleviate the associated symptoms.

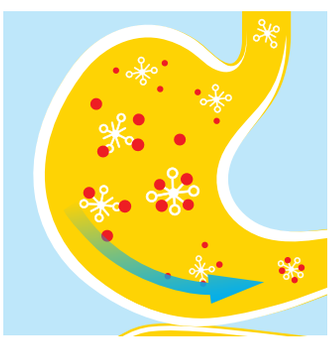
Mode of Action



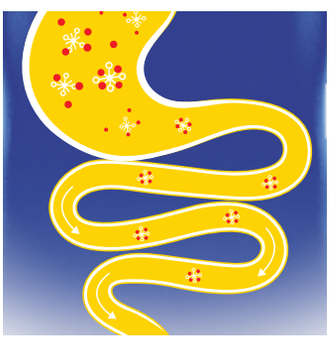
bhw silicol® gel forms a protective and soothing layer over the lining of the stomach and intestines.



bhw silicol® gel acts "like a magnet" attracting irritants, toxins & pathogens & binds them to the gel.



During this process the bhw silicol® gel particles also adsorb excess acidity & gases.



When the stomach empties naturally the bound molecules are passed through the body.

In-vitro Studies

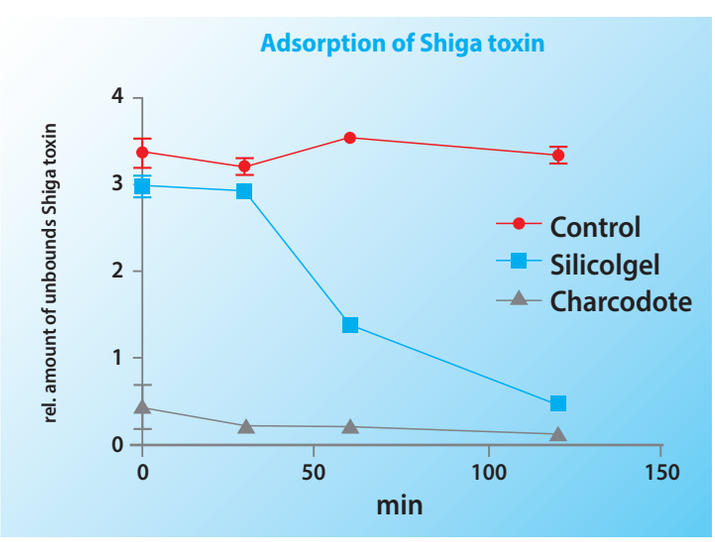
Evaluating the adsorption of toxins by bhw silicol® gel, *Biotesys, 2020*

Method:

- Shiga toxin 2B was the bacterial toxin used to test adsorption
- Test groups: bhw silicol® gel, negative control, and activated charcoal (Charcodote) (positive control)
- Incubation times: 0, 30, 60 and 120 mins
- Suspended in buffer (PBS), sedimented by centrifugation (2 mins, 7500 x g) and analysed with an ELISA kit specific to Shiga toxin

Results:

- Shiga toxin is immediately bound to the charcodote
- The toxin is then adsorbed by bhw silicol® gel at a steadier rate
- After 120 mins, 80% of Shiga toxin is adsorbed by bhw silicol® gel



Testing the anti-inflammatory effect of bhw silicol® gel, *Biotesys, 2019*

Method:

- LPS treated blood samples
- Test groups: silicolgel, LPS only (negative control), and Prednisolone (positive control)
- Analysed by measurement of levels of TNF-α excretion (a major cytokine)

Results:

- The test product showed an anti-inflammatory effect in the majority of volunteer samples, indicated by the reduced release of TNF-α compared to the control
- The difference between inflamed control samples and bhw silicol® gel at a dilution of 1/100 (1%) was significant

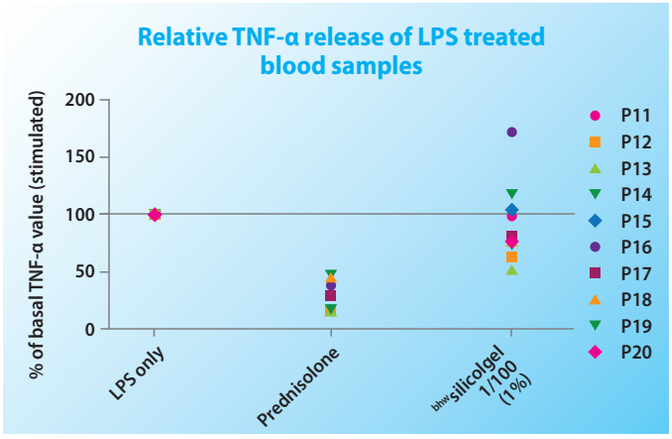


Figure: TNF-α release relative to the control treated with LPS only (basal). All other samples were treated with LPS + Prednisolon or LPS + test product diluted 1/100, 1/500 or 1/1000. Reduced percentages of TNF-α indicate reduced inflammation. Volunteer samples are coded with P followed by a number.

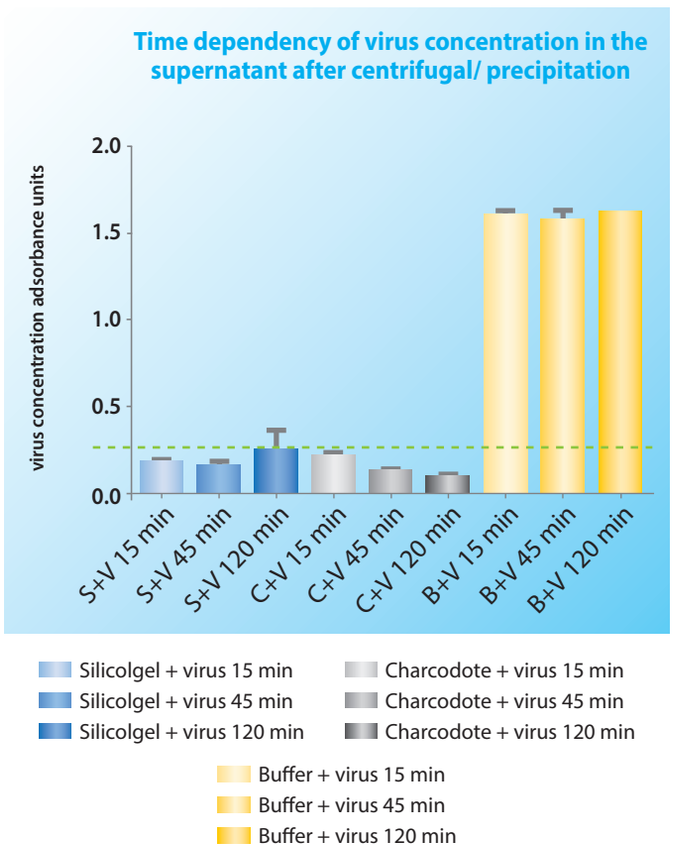
Evaluation of the adsorption of Rota-virus particles to bhw silicolgel and another adsorbent, *Biotesys, 2022*

Method:

- Virus was held in suspension
- Test groups: bhw silicol® gel, buffer control (negative), Charcodote (positive control)
- Shaken in water bath at 37 degrees for 15 min, 45 min and 2 h
- Separated from suspended virus by centrifugation
- Analysed by ELISA procedure
- Second phase: two different concentrations of bhw silicol® gel and Charcodote were tested to evaluate dose response

Results:

- bhw silicol® gel and Charcodote adsorbents both significantly reduce virus particles in a suspension by adsorbing/binding the virus particles to their molecular matrix
- Viruses adsorbed/bound to the molecular matrix of bhw silicol® gel would be prevented from affecting the intestinal cells of the gut wall and thus effectively reduce the severity of viral induced gasto-intestinal disease
- Dose response relationship with higher concentration exists for both bhw silicol® gel and Charcodote adsorbing more virus (1 in 50 dilution of bhw silicol® gel still reduces the virus concentration significantly versus buffer control)



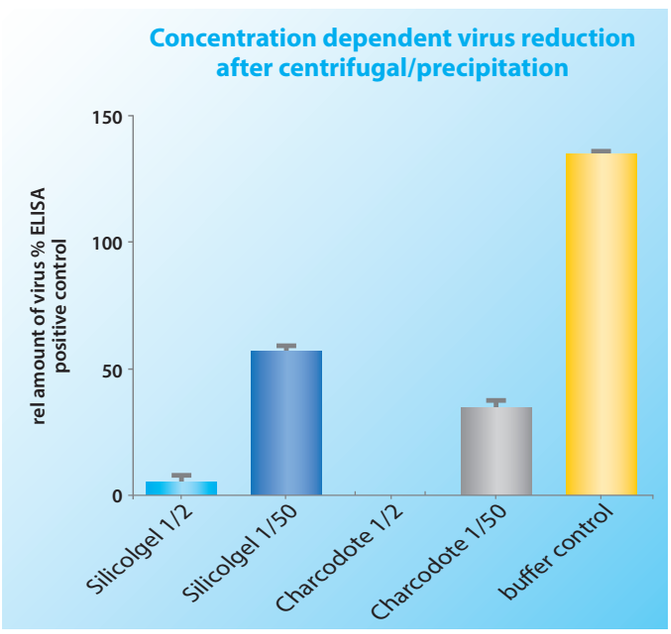


Figure: Relative virus concentration in the supernatants after centrifugation. The dotted line represents the limit of detection for the virus. Adsorption of the colour reaction of the ELISA is relative to the amount of virus. Mean + SEM n = 2.

- - - - - - - - - This dashed line is the limit of detection of the ELISA analysis. bhw silicol® gel + Virus and Charcodote + Virus were all below the limit of detection of the ELISA analysis, i.e. minimal. The Buffer control shows no reduction in Virus.

BioTeSys

Clinical Reports

Efficacy of the enteroadsorbent bhwsilicol®gel in adults with irritable bowel syndrome subtypes IBS-D or IBS-M, *Gastroenterology Research & Practice, Crawford, Taylor, Young & Hatton, 2023*

Method:

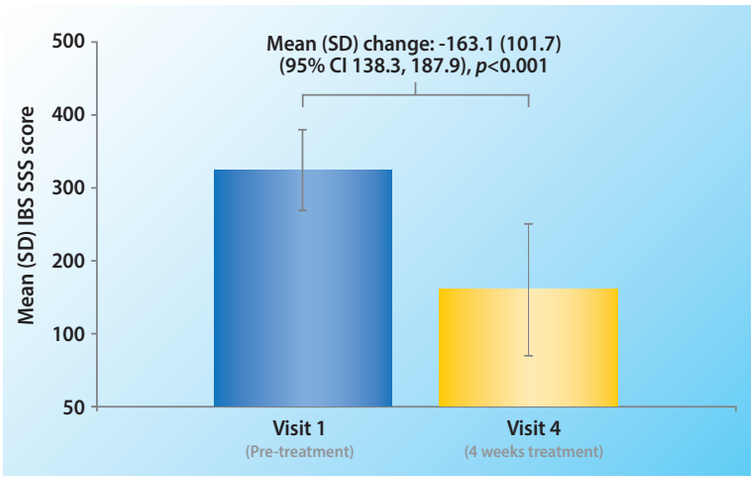
In line with recommended dosage, participants suffering Severe or Moderate IBS according to the IBS SSS scores (Francis et al) underwent 4 weeks of treatment with bhwsilicol®gel and had assessments to monitor their progress after 1 week (Visit2; telephone), 2 weeks (Visit 3; telephone) and 4 weeks (Visit 4; in-clinic).

- Primary endpoint – proportion of participants with overall reduction in IBS-SSS > 50, representing clinically meaningful improvement
- Key secondary endpoints:
  - reduction in 4 key IBS symptoms (diarrhoea, bloating, abdominal pain/cramping and flatulence)
  - improvement in quality of life.

Results:

Mean IBS SSS scores of Visit 1 vs Visit 4

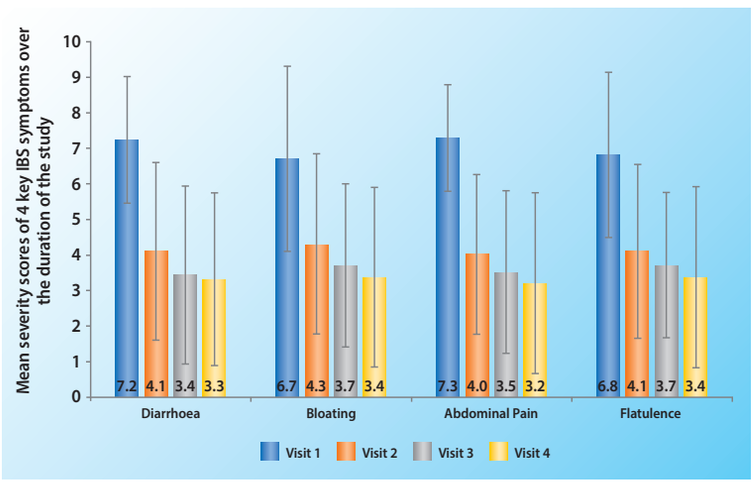
- After 4 weeks of treatment, 83.6% of participants achieved the primary endpoint of a reduction in IBS SSS >50, representing a clinically meaningful improvement in IBS.
- After 4 weeks treatment Mean IBS SSS score reduced from 323 to 160 a reduction of -163 representing a change from Severe to Mild IBS on the Francis scale.



Reduction of key IBS symptoms over the duration of the study

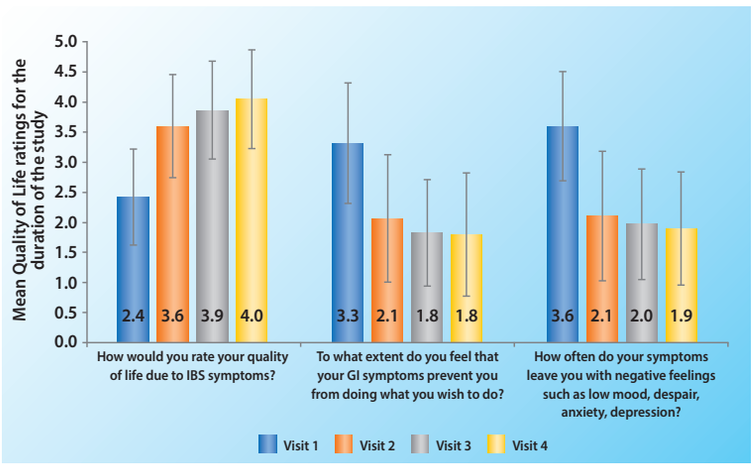
Scores were based on a scale of 0 to 10, where 0 "doesn't bother me at all" and 10 is "as bad as I can imagine" and represent symptom severity over the previous 7 days.

- Significant improvements in symptom ratings were seen after 4 weeks of treatment for all 4 IBS symptoms,
- Symptom improvements were seen throughout the duration of the treatment and were noted for all symptoms from as early as after just one week of treatment.



Improvement in Quality of Life (QoL) scores over the duration of the study

- Significant improvement was seen in all QoL ratings after 4 weeks of treatment,
- Progressive improvement in QoL were noted throughout the course of the study



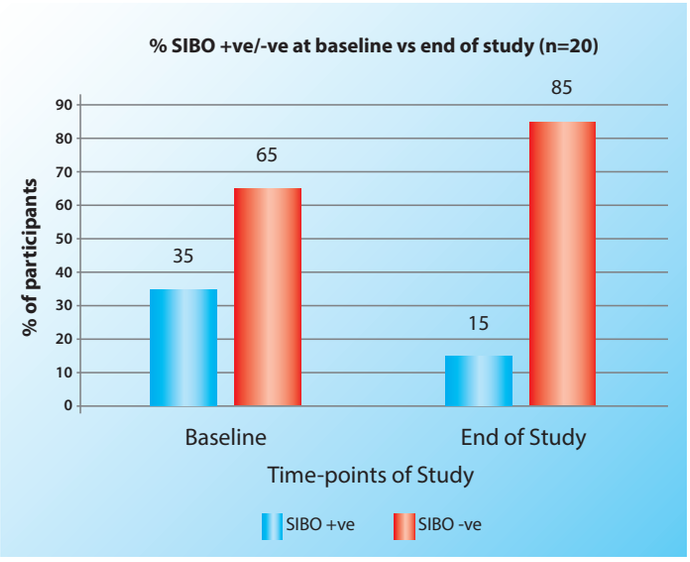
Testing the effectiveness of bhwsilicol®gel in Small Intestinal Bacterial Overgrowth (SIBO) – A Pilot Study, *The Functional Gut Clinic, 2018*

Method:

- 20 participants completed the study
- bhwsilicol®gel taken 3 times daily for 10 days
- Hydrogen Methane breath test (HMBT) at day 0 and retested at day 10
- To assess abdominal and bowel symptoms, the validated IBS-Symptom Severity Score (IBS-SSS) questionnaire was used

Findings:

- 60% of participants had elimination of heartburn, regurgitation or both
- 75% reduction in IBS scores
- 57% of participants who were SIBO positive were SIBO negative by day 10



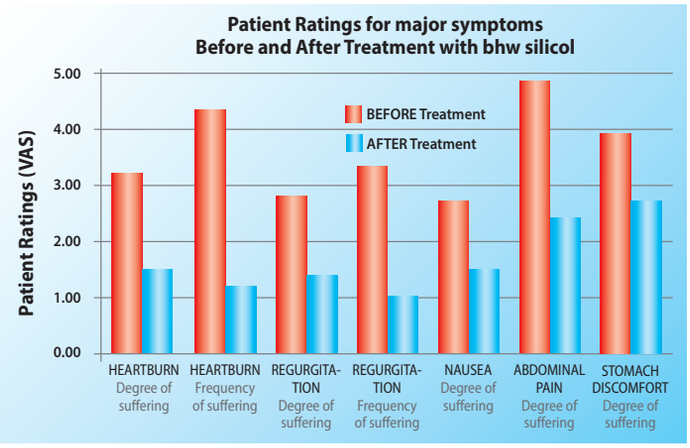
Double-blind, placebo controlled, multi cross-over trial on sufferers of IBS, *Erling Thom, 1996*

Method:

30 patients were treated with either bhwsilicol®gel or placebo during a 6-week period, with 1 week of treatment in each period due to the MCO nature of the study.

Results:

It can be seen that bhwsilicol®gel had a significant effect on improving patients' experience of IBS symptoms. There were significant reductions on the Patients' Rating (VAS) for all IBS symptoms from Before Treatment to After Treatment.



Literature

The principal intended action of bhwsilicol®gel can be summarized as elimination of harmful / noxious or irritant substances from the gastrointestinal tract in order to alleviate gastrointestinal symptoms such as heartburn, reflux / acid regurgitation, vomiting, nausea, flatulence, abdominal pain, bowel discomfort and diarrhoea.

The key articles from literature are:

1. Wagner, S. Colloidal silicon dioxide for ulcerative colitis and Crohn's disease. A therapeutic alternative to traditional treatment. Forschung Klinik Praxis, 6186–6198 (1982).
2. Gobet, J. & Kováts, E. s. Specific surface area of hydrated silicon dioxide measured by chemisorption (Adsorption Science & Technology, 1984).
3. Francis H. Harlow & John P. Shannon. Chromatographic Silica Gel: Surface Area Determined by Adsorption.
4. Evonik Industries. Technical Information 1281: AEROSIL® and AEROPERL® - Colloidal Silicon Dioxide for Pharmaceuticals.
5. Kugelmeier, R. Vergleichende Untersuchungen Über die Adsorption von Makromolekülen und Bakterien an Poröse Kieselsäuren. Rheinische Friedrich-Wilhelms-Universität, 1980.

Bayerische Heilmittel Wissenschaften GmbH

For further information about bhwsilicol®gel, please contact us on:
Email: info@bhw-silicol.com Tel: +49 89 54558161