# **35624®** Strain: Clinical Evidence in Irritable Bowel Syndrome (IBS)

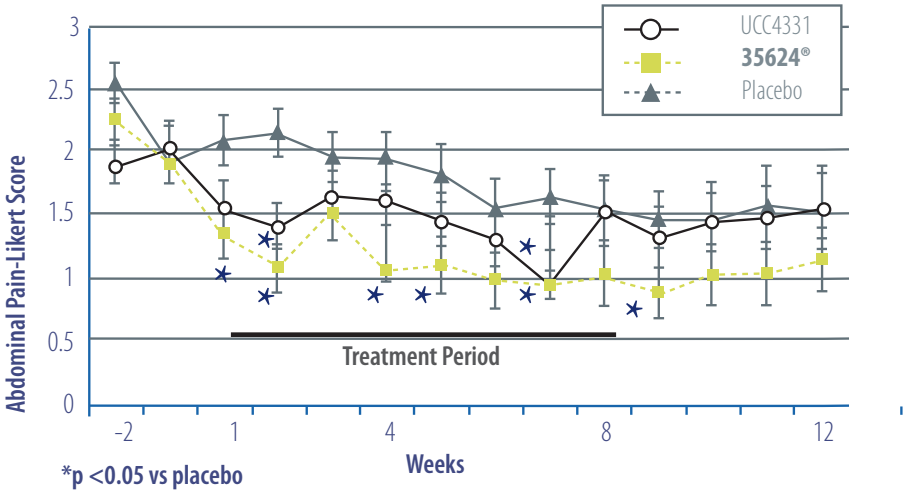
## O'Mahony *et al.* (2005) *Gastroenterology.*

**Objective:** To compare the response of symptoms in IBS with ingestion of probiotic preparations containing a *Lactobacillus* or *Bifidobacterium* strain.

**Method:** This study was a randomised, double-blind, placebo-controlled, study. 77 subjects with IBS were randomised to receive either *Lactobacillus salivarius* UCC4331 or the **35624®** *(Bifidobacterium infantis*[†]*)* strain each in a dose of $1x10^{10}$ CFU[§] in a malted milk drink, or the malted milk drink alone as placebo for 8 weeks. The cardinal symptoms of IBS were recorded on a daily basis and assessed each week. Quality of life assessment and stool microbiologic studies were performed at the beginning and at the end of the treatment phase.

## Results:

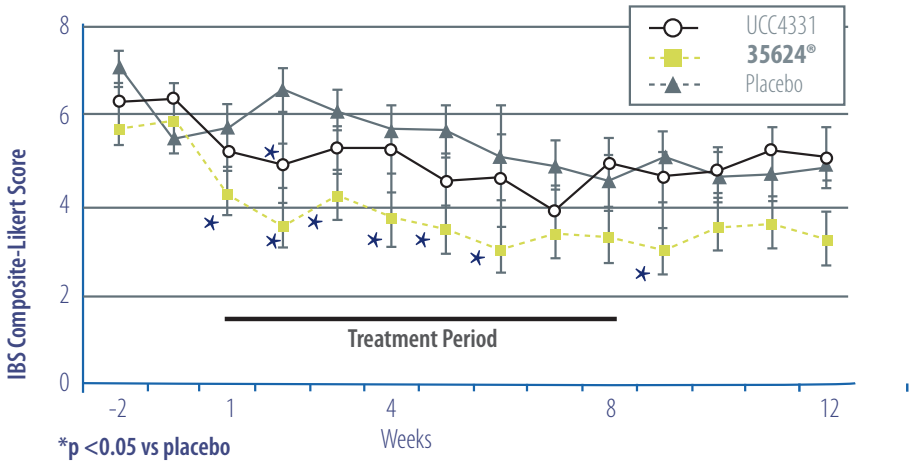
Only the **35624®** strain improved IBS abdominal pain / discomfort compared to placebo.




Adapted from: O'Mahony *et al.* (2005)

Only the **35624®** strain improved the IBS composite score [‡] compared to placebo.

[‡] Sum of abdominal pain/ discomfort, bloating/ distension, and bowel movement difficulty scores.




Adapted from: O'Mahony *et al.* (2005)

**Conclusion:** The **35624®** strain alleviates symptoms in IBS and manages each of the cardinal symptoms of IBS.

[†] The **35624®** strain has been reclassified from *Bifidobacterium longum* subsp. *infantis* to *Bifidobacterium longum* subsp. *longum*.

[§] CFU= Colony Forming Units.

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# Efficacy of *Bifidobacterium infantis*† 35624® in Women with IBS

**Whorwell *et al.* (2006) *American Journal of Gastroenterology.***

**Study Objective:** To evaluate the efficacy of the **35624®** culture at various doses, for female IBS patients in a primary care setting.

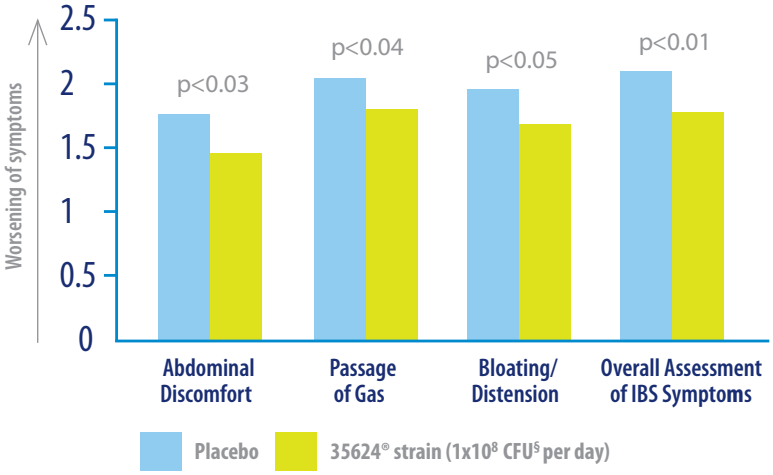
**Method:** This study was a randomised, double-blind, placebo-controlled, multi-centre (20 centres) study. After a 2 week baseline assessment period, 362 IBS patients, with any bowel habit subtype, were randomised to receive either placebo or **35624®** strain at a dose of $1x10^6$ or $1x10^8$ CFU§ daily for 4 weeks. IBS symptoms were monitored daily and scored on 6-point Likert scale with the primary outcome variable being abdominal pain or discomfort. A composite IBS symptom score, the subject's global assessment of IBS symptom relief and measures of quality of life (using the IBS-QOL# instrument), were also recorded.

## Results:

Statistically significant improvement associated with the **35624®** strain (compared to the placebo) for:

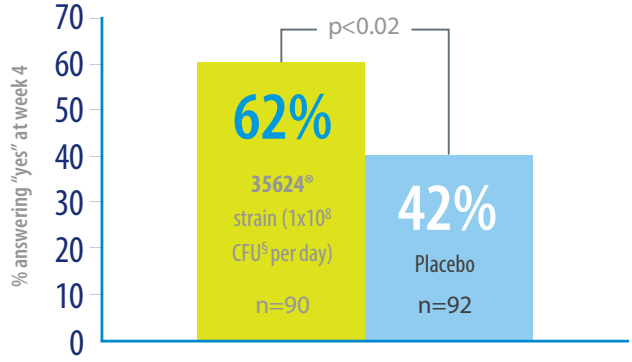
- ✓ Abdominal pain/discomfort
- ✓ Passage of gas
- ✓ Bloating/distension

**Mean Scores for Efficacy Variables at Week 4**




Significant (20%) increase in global IBS symptom relief for patients taking the **35624®** strain, compared to those on placebo.

**Comparison of E ffects of Placebo and 35624® Strain on Subjects' Global Assessment of IBS Symptoms**




**Conclusion:** The **35624®** strain at a dosage of $1x10^8$ CFU§ is effective within 4 weeks in reducing the symptoms of IBS, irrespective of bowel habit subtype.


**REFERENCES**

1. O'Mahony, L., McCarthy, J., Kelly, P., Hurley, G., Luo, F., Chen, K., O'Sullivan, G., Kiely, B., Collins, J., Shanahan, F. & Quigley, E. (2005). *Gastroenterology* **128**, 541-551.
2. Whorwell, P., Altringer, L., Morel, J., Bond, Y., Charbonneau, D., O'Mahony, L., Kiely, B., Shanahan, F. & Quigley, E. (2006). *American Journal of Gastroenterology*, **101**, 1581-1590.


§ CFU= Colony Forming Units

# QOL= Quality of Life

† The **35624®** strain has been reclassified from *Bifidobacterium longum* subsp. *infantis* to *Bifidobacterium longum* subsp. *longum*.