AUREA PHARMA

Obesimed® Forte - Lyon M, Wood S, Pelletier X, Donazzolo Y, Gahler R, Bellisle F. Effects of a 3-month supplementation with a novel soluble highly viscous polysaccharide on anthropometry and blood lipids in nondieting overweight or obese adults. J Hum Nutr Diet. 2011 Aug; 24(4):351-9.

Authors (year published)	Study design	Total patients	Intervention	Reported outcomes/results	Adverse events	Appraisal	Level
	Randomized, double-		5-15 g	Beneficial although	No	D2 A1 P1 R1 T1 O1	I
Lyon MR et al 2011	blind, controlled clinical trial	59	PolyGlycopleX for 15 weeks	modest effects appeared after several weeks of daily PolyGlycopleX®		F1 S1 C1	

CASP Questions for making sense of evidence

1. Did the study ask a clearly focused question?	2. Was this a RCT, and was it appropriately so?	3. Were participants appropriately allocated to intervention and control groups?	4. Were participant, staff, and study personnel blinded to participants' study group?	5. Were all participants who entered the trial accounted for at its conclusion?	6. Were the participants in all groups followed up and data collected in the same way?	7. Did the study have enough participants to minimize the play of chance?	8. How are the results presented, and what is the main result?	9. How precise are these results?	10. Were all important outcomes considered so that the results can be applied?
Yes	Yes. Appropriate for this study	Yes. Participants randomly assigned to PGX® 5 g for 15 weeks	Yes	Yes. 30 overweight or obese adults	Safety and efficacy data obtained on all patients	Yes-power analysis performed.	Mean decreases in body weight approximately 2% of initial weight and hip circumference	Statistical tests appropriately used can have confidence in results.	Efficacy and safety both considered.

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Synopsis - Lyon M, Wood S, Pelletier X, Donazzolo Y, Gahler R, Bellisle F. Effects of a 3-month supplementation with a novel soluble highly viscous polysaccharide on anthropometry and blood lipids in nondieting overweight or obese

Aim: to investigate the effects of the daily intake of a novel high viscosity polysaccharide over 3 months in nondieting obese or overweight men and women. Study design: randomized, double-blind, controlled clinical trial.

adults. J Hum Nutr Diet. 2011 Aug; 24(4):351-9.

Subjects: 30 overweight or obese adults (15 women and 15 men, aged 18-50 years) with a body mass index (BMI) in the range 27–35 kg/m2. The experimental fibre PolyGlycopleX® (Inovobiologic Inc., Calgary, Canada) was manufactured from three natural fibers (konjac, sodium alginate and xanthan gum). Participants ingested 5-15 g per day of either PolyGlycopleX® (n = 29) or inulin (n = 30, control group) for 15 weeks. Changes in anthropometry (weight, waist and hip circumferences), blood lipids and glucose tolerance were studied from the beginning to the end of administration.

Results: differences appeared between PolyGlycopleX® and inulin supplementation in female participants only. Mean (SD) decreases in body weight [1,6 (3,2) kg; approximately 2% of initial weight] and hip circumference [2,8 (3,6) cm] occurred in women of the PolyGlycopleX® group but not in controls (Time × Group interactions, $p \le 0,002$). Total, high-density lipoprotein and low-density lipoprotein-cholesterol were lower at the end of supplementation in the women of the PolyGlycopleX® group compared to controls ($p \le 0,021$).

No effect appeared in waist circumference and triacylglycerol. No difference was noted in the number or severity of the adverse effects reported in both groups. Adverse effects were mild and agreed with commonly reported reactions to intake of dietary fibre