

# EFFECTS OF A NUTRACEUTICAL ON THE SYMPTOMS OF FIBROMYALGIA

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**Introduction:** Current medications for the treatment of fibromyalgia (FM) are symptomatic and often poorly tolerated or rejected by patients, leaving us with few tools for therapeutic management. For this reason, nutritional supplements are increasingly being used without medical supervision and often in combination with medication with which they interact, so we must devote part of our research to these therapies. In this context, we studied FibroFixPlus® (composition attached), a food supplement targeted at central and peripheral alterations in FM.

Contents of one sachet:

INGREDIENTS	QUANTITY	%NRV
Collagen – bioactive peptides	4000 mg	*
Chondroitin sulphate	1200 mg	*
γ-aminobutírico acid (GABA)	400 mg	*
Curcuminoids (Curcuma longa L. extract)	303 mg	*
Vitamin C	80 mg	100
Saffron extract (Crocus sativus L.)	30 mg	*
Manganese	1 mg	50
Copper	1 mg	100
Folic acid	200 µg	100

\* NRV: Nutrient Reference Values.

**Objective:** To observe the efficacy on FM symptoms after taking FibroFixPlus® for 8 weeks and its safety.

**Material and methods:** Prospective observational pilot study, 30 patients with FM.

**Inclusion criteria:** Women ≥ 18 years of age with ACR 1990/2010 criteria for FM with initial VAS pain and fatigue ≥4. Period of ≥4 weeks without concomitant treatments, except paracetamol ≤2 g/day and/or tramadol ≤100 mg/8h.

**Exclusion criteria:** Unstable psychiatric disorder other than major depressive disorder. Pain due to an objectifiable secondary cause. Active chronic autoimmune and inflammatory diseases. Use of medications that may interfere with pain assessment, except paracetamol ≤2 g/day and/or tramadol ≤100 mg/8h. Therapeutic rehabilitation. Intention to apply for or current process of applying for disability. Concomitant natural therapies. Hypersensitivity to active ingredients or excipients. Pregnancy or breastfeeding. Having participated in clinical trials in the previous 3 months.

**Results:** All symptoms studied decreased during the study. Only two clinical episodes were related to the product, gastrointestinal discomfort and nocturnal urination, which did not prevent continuation of the study. Therapeutic compliance was over 96%, and most patients continue to use the product after the study.

ITT population					
	Mean	SD	Friedman (P)	Wilcoxon signed rank test (P)	
sFIQ	baseline	64,79	14,33		4 weeks - baseline 0,001*
	4 weeks	55,41	16,70	0,001*	8 weeks - 4 weeks 0,719
	8 weeks	55,57	16,64		8 weeks - baseline 0,002*
Fatigue VAS	baseline	8,10	1,37		4 weeks - baseline 0,177
	4 weeks	7,43	1,79	0,005*	8 weeks - 4 weeks 0,153
	8 weeks	7,10	1,73		8 weeks - baseline 0,005*
Pain VAS	baseline	7,75	1,15		4 weeks - baseline 0,0010*
	4 weeks	6,62	1,79	0,001*	8 weeks - 4 weeks 0,593
	8 weeks	6,55	1,65		8 weeks - baseline 0,001*
Symptoms Severity Score, SSS	baseline	8,43	1,524		4 weeks - baseline 0,001*
	4 weeks	6,80	2,024	0,001*	8 weeks - 4 weeks 0,197
	8 weeks	6,53	1,995		8 weeks - baseline 0,001*
Widespread Pain index	baseline	10,30	2,12		4 weeks - baseline 0,001*
	4 weeks	6,40	2,343	0,001*	8 weeks - 4 weeks 0,169
	8 weeks	5,70	2,307		8 weeks - baseline 0,001*
PSQI	baseline	13,67	3,517		4 weeks - baseline -
	4 weeks	12,33	3,942	0,192	8 weeks - 4 weeks -
	8 weeks	12,10	4,205		8 weeks - baseline -
FHAQ	baseline	1,94	0,484		4 weeks - baseline 0,190
	4 weeks	2,03	0,447	0,040*	8 weeks - 4 weeks 0,018*
	8 weeks	2,13	0,430		8 weeks - baseline 0,009*

(\*) Statistically significant p < 0,05

## MEANING OF THE SCALES:

- **Fibromyalgia Impact Questionnaire (s-FIQ):** FM patients usually have s-FIQ scores averaging around 50 points, although in severe cases the scores are above 70.
- **VAS = EVA:** Visual analogue scale for pain and fatigue.
- **Symptom Severity Index (SSI):** fatigue, non-restorative sleep, cognitive manifestations and somatic symptoms.
- **Wide-ranging Pain Index (WPI):** counts the number of painful areas in which the patient has experienced pain during the last week.
- **Pittsburgh Sleep Quality Index (PSQI):** a score of 0 points indicates no difficulties, and a score of 21 indicates severe difficulties in all areas studied.

ITT population					
	Mean	SD	Wilcoxon signed rank test (P)		
SF-36 Physical function	baseline	38,83	18,74		
	8 weeks	46,83	19,804		8 weeks - baseline 0,012*
SF-36 Role Physical	baseline	37,92	24,671		
	8 weeks	44,79	22,269		8 weeks - baseline 0,089
SF-36 Bodily Pain	baseline	19,90	17,091		
	8 weeks	32,13	15,516		8 weeks - baseline 0,001*
SF-36 General Health	baseline	31,55	14,601		
	8 weeks	36,67	16,470		8 weeks - baseline 0,023*
SF-36 Vitality	baseline	21,67	18,035		
	8 weeks	29,38	23,046		8 weeks - baseline 0,066
SF-36 Social Functioning	baseline	42,92	23,370		
	8 weeks	57,08	21,446		8 weeks - baseline 0,002*
SF-36 Role Emotional	baseline	63,33	29,895		
	8 weeks	72,22	28,730		8 weeks - baseline 0,049*
SF-36 Mental health	baseline	51,83	25,444		
	8 weeks	58,17	24,014		8 weeks - baseline 0,066
SF-36 Change in health status	baseline	3,63	1,066		
	8 weeks	3,17	1,177		8 weeks - baseline 0,024*
ICG - MG	baseline	3,23	1,278		
	8 weeks	2,87	1,074		8 weeks - 4 weeks 0,128
HAD - Anxiety	baseline	10,5	4,939		
	8 weeks	9,87	4,577		8 weeks - baseline 0,087
HAD - Depression	baseline	10,03	4,131		
	8 weeks	9,17	4,496		8 weeks - baseline 0,058

- **Functional Health Assessment Questionnaire (FHAQ):** specifically measures the patient's functional capacity.
- **SF-36 questionnaire:** questionnaire that provides a profile of the person's state of health. The higher the score, the better the state of health.
- **Clinical Global Impression - Severity of Illness (CGI-S):** provides a simple assessment of the severity of the condition and its improvement over time following treatment.
- **HADS questionnaire:** the higher the score, the greater the anxiety and depression.

## Conclusion:

**FibroFixPlus® can be a supplement that facilitates the control of the more general central and peripheral symptoms of fibromyalgia.**

# FibroFix<sup>®</sup>Plus



It is a **food supplement** that helps improve the **symptoms of generalised pain** conditions, such as:

- Fibromyalgia
- Chronic pelvic pain
- Totalgia
- Central sensitisation due to whiplash
- Complex Regional Pain Syndrome (CRPS) or Reflex Sympathetic Dystrophy (RSD) or Südeck's syndrome
- Ankylosing spondylitis



Gluten-free



Salt-free



Lactose-free

## DOSAGE:

The recommended dose is one sachet per day, preferably during dinner.

Pour the contents of the sachet into a 200 ml glass of water and stir with a spoon until completely dissolved.

For rapid dissolution, pour the contents slowly into the glass while stirring with a spoon.

Minimum treatment: 6 months.



PLEASANT TASTE



**PACKAGE CONTENTS:** One package of FibroFixPlus<sup>®</sup> contains 30 sachets of granules.

## FibroFix<sup>®</sup>Plus

The unique combination of components is capable of improving the symptoms of these pathologies, enabling patients to regain their quality of life.



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