

## What is Fibromyalgia?

- ❑ Fibromyalgia (FM) is an increasingly recognized chronic pain illness.
- ❑ It is characterized by widespread musculoskeletal pain and stiffness, soft tissue tenderness, general fatigue and sleep disturbances.
- ❑ The most common sites of pain include the neck, back, shoulders, pelvic girdle and hands, but any body part can be involved. Fibromyalgia patients experience a range of symptoms of varying intensities that wax and wane over time.

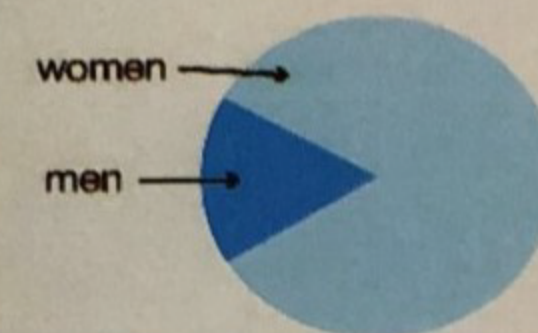


## Who is affected?

- Approximately 3-6% of the population has FM. In a country with a population of 23 million, approximately 0.7 – 1.4 million people will be affected.
- Although a higher percentage of women are affected (75-80%), it may strike men and children of all ages and races.
- Fibromyalgia may have a serious impact on patients' family, friends, and employers, as well as society at large.

### Epidemiological data

Majority of FM patients are women

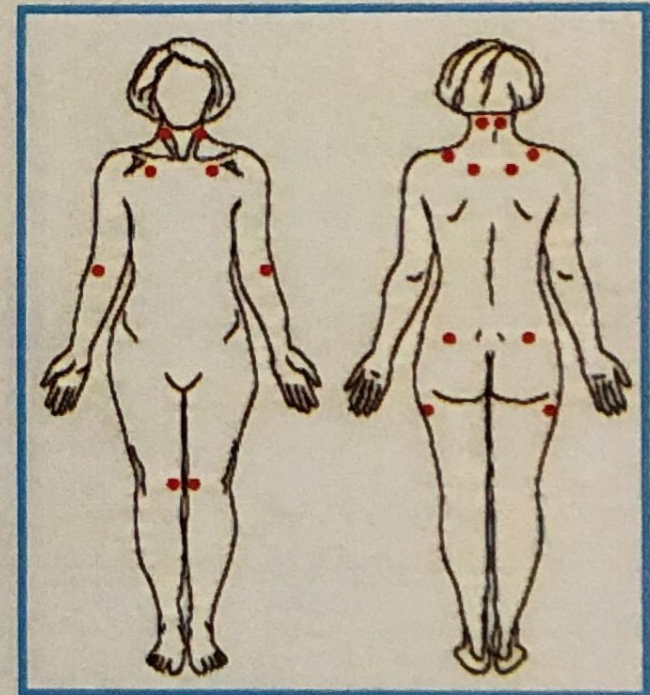


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## How is it diagnosed?

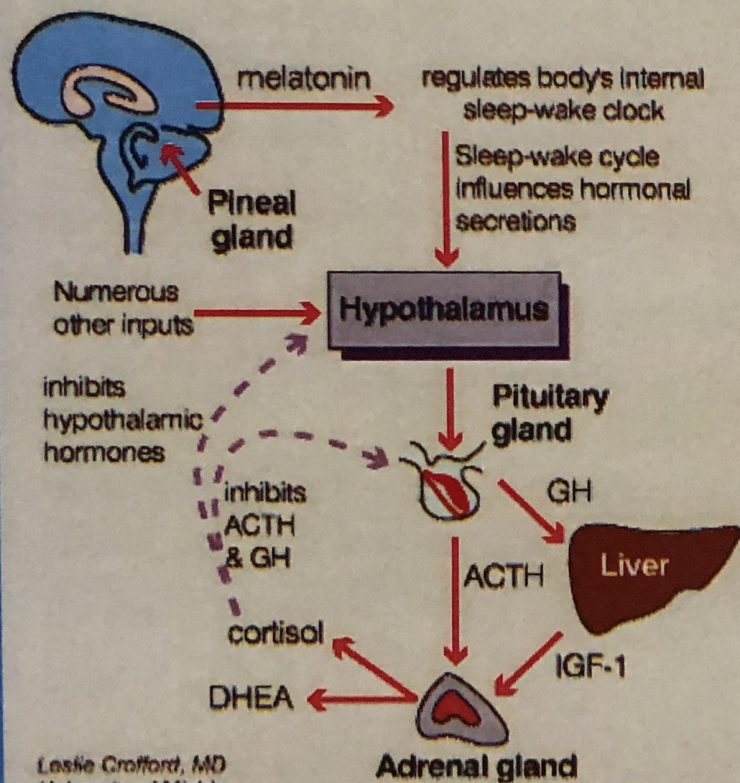
- Currently there are no laboratory tests available for diagnosing Fibromyalgia.
- It takes five years for a FM patient to get an accurate diagnosis. To receive a diagnosis of FM, the patient must meet the following diagnostic criteria according to ACR:
  - Widespread pain in all four quadrants of the body for a minimum duration of three months
  - Tenderness or pain in at least eleven of the eighteen specified tender points when pressure is applied (see figure)





# What causes FM?

Improper hormone secretion rhythm in FM patients causes sleep disturbances



Leslie Crofford, MD  
University of Michigan

- The underlying cause of FM remains unknown
- The FM patient experiences pain amplification due to abnormal sensory processing in the central nervous system
- Studies show an imbalance of 3 key hormones: cortisol, DHEA and melatonin.



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# Fibromya®

## Ingredients

Daisy Leaves B.E.E.®, Grape Leaves B.E.E.®, Olive Pit fractions B.E.E.®, Pineapple Fruit and Stem B.E.E.® Almond powder, Orange juice powder

## Indications

Fibromyalgia, Chronic Fatigue Syndrome, muscle stiffness of a different origin.

## Dosage and administration

Take 1-2 tablets when needed; best taken at 10 am each morning. Chew for better assimilation and absorption.



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# Composition

Active compounds are obtained in the innovative technology **BioEnhanced Extraction**, known as **B.E.E.**<sup>®</sup>, that offers fast relief, exceptional efficiency and full safety.

Fibromya provides a unique complex of active herbal compounds.



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# Composition and action (1)

## 1 tablet provides:

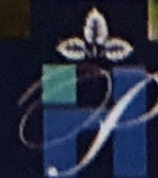
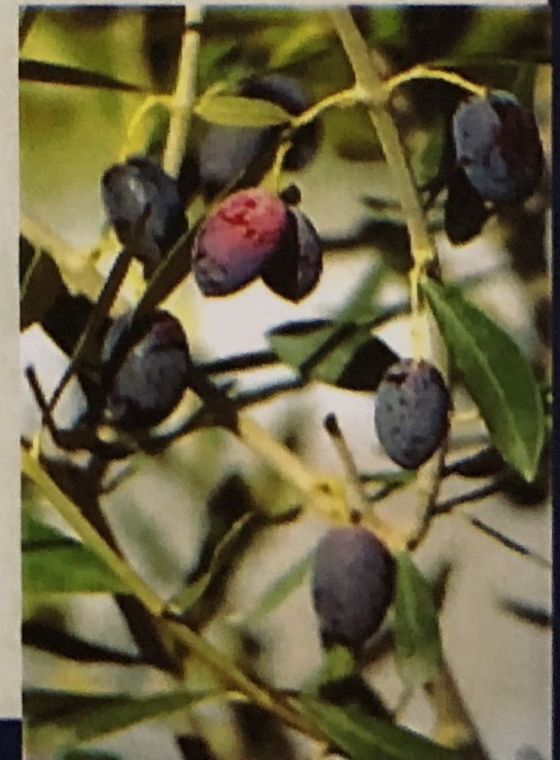
75 mg BioEnhanced Extract from *Olea europaea* (olive pit fraction)

60mg BioEnhanced Extract from *Bromelia annanas* (pineapple fruit and stem)

75 mg BioEnhanced Extract from *Bellis perennis* (daisy leaves)

75 mg BioEnhanced Extract from *Vitis vinifera* (grape leaves)

Almond powder and orange juice powder



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# Composition and action(2)



## **Daisy Leaves (*Bellis perennis*) BioEnhanced Extract**

Provides bioflavonoid complexes, volatile oils and tannins

- Relieves muscle and joint pain as well as body tenderness
- Has calming properties that help improve sleep quality
- Combats different pains including migraine, neuralgic pain, gastric pain, etc.
- Helps with GI disturbances, gall bladder dysfunction, urinary tract problems, heart palpitations, water retention and night sweating



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# Composition and action(3)



**Grape Leaves** (*Vitis vinifera*)  
BioEnhanced Extract



**Olive** (*Olea europaea*)  
BioEnhanced Extract



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## Composition and action(3)



**Grape Leaves** (*Vitis vinifera*)  
BioEnhanced Extract



**Olive** (*Olea europaea*)  
BioEnhanced Extract



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# Composition and action(3a)

## **Grape leaves (*Vitis vinifera*) and Olive oil (*Olea europaea*) BioEnhanced Extracts**

Both extracts provide: bioflavonoids' complexes, tannins, glycosides, pigments and a variety of vitamins and minerals.

- Helps to improve blood flow, circulation and to reduce muscle tension.
- Reduces muscle pain and stiffness, joints stiffness, numbness and parenthesesizes
- Provides relief of CFS and gastric pain, diarrhea, miction problems and edema related to water retention





## Fibromya®

- ❑ Instant effect, unique composition
- ❑ Restores balance of DHEA\*, Cortisol and Melatonin levels within the body.
- ❑ It relieves multiple symptoms of Fibromyalgia such as widespread tenderness and pain in the fibrous tissues of the muscles, tendons, ligaments and the sciatica.
- ❑ Reduces muscle tension and gives patients a feeling of greater energy and an improved sense of well-being
- ❑ A best seller; there is no competitive product worldwide

\*DeHydroEpiAndrostenone



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# Price & Regulatory status



1 package of 30  
blistered tablets

- Fibromya is a nutraceutic; it is also a dietetic preparation with therapeutic properties.
- It is accepted in the United States as a dietary supplement and by the Main Sanitary Inspector in Poland.
- It has found positive opinion with the Polish Food and Nutrition Institute.



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# **Fibromya<sup>®</sup>**

**A new therapeutic option for Fibromyalgia**



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# Preparation evaluation

- Presented results of twenty-one volunteers that have declared a positive result.
- There were fifteen women and six men\* ranging in age from thirty-four to sixty-nine years.
- The subjects have subjectively evaluated their symptoms on a scale from 0 to 4 before and after four weeks of product administration.
- Self-assessment scale:
  - 0 – no symptoms
  - 1 – light symptoms
  - 2 – moderate symptoms
  - 3 – intense symptoms
  - 4 – very intense symptoms

\*/ high proportion of men is related to the fact that the survey was administered over the internet where more men than women are available.

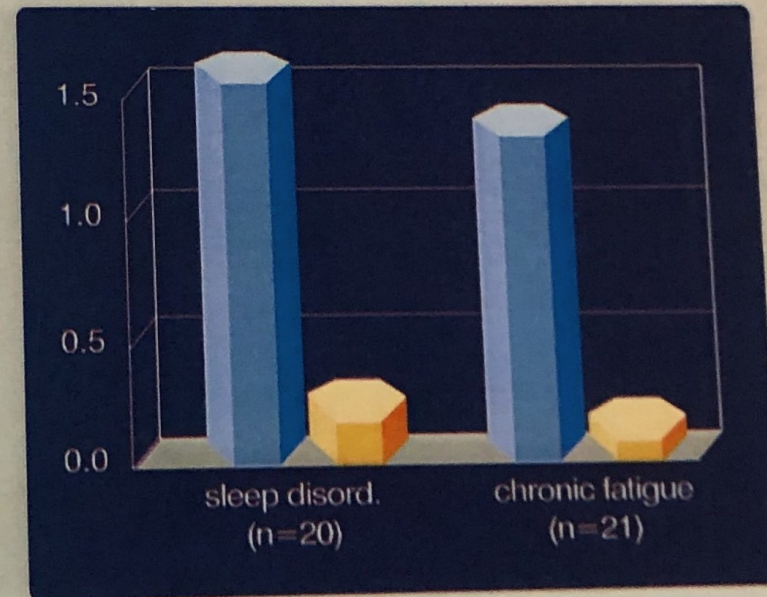
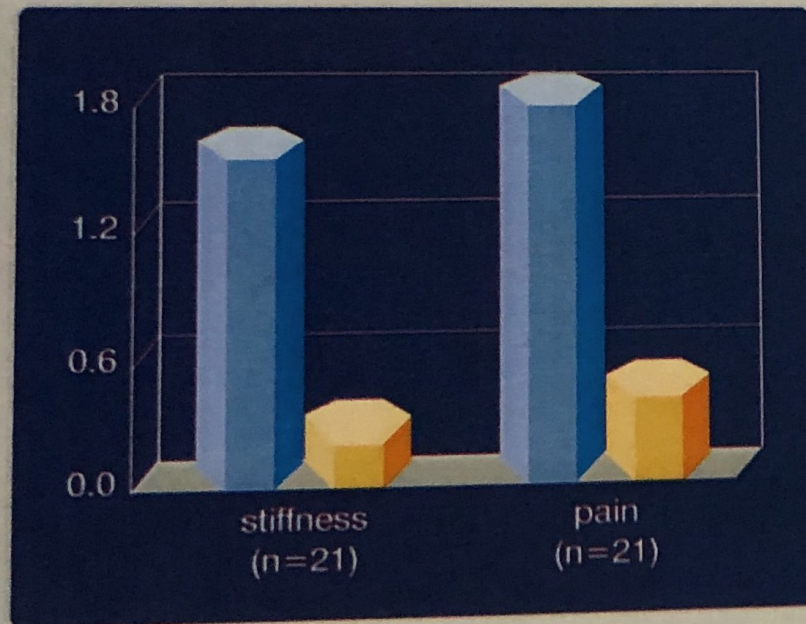


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## Results (1)

### Reduction of symptoms

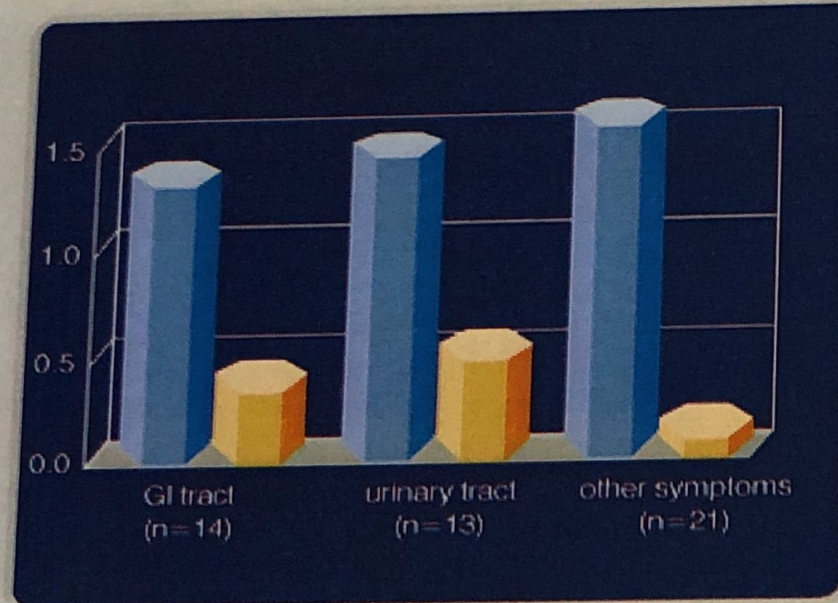


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## Results (2)

### Reduction of symptoms



**Other symptoms include:**

**Psychological symptoms:**  
Depression and anxiety

**Cardiovascular symptoms:**  
Rapid heart beat and  
Raynaud syndrome



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## Results (3)

Side effects have been noticed in two subjects.

- 1 person reported gastric pain\*
- 1 person reported flatulence

These side effects did not require discontinuation of treatment.

\*/ probably related to food ingestion



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# Fibromya® case story

- ❑ Forty-five year old woman suffering from Fibromyalgia for six years.
- ❑ The disease started with pain in the back.
- ❑ Pain gradually spread throughout the entire body and muscle stiffness occurred.
- ❑ The traditional painkillers, NSAIDs were ineffective.
- ❑ She visited a number of doctors and underwent several examinations without any major abnormalities (over a span of five years).
- ❑ Menopause related depression had been diagnosed.
- ❑ Anti-depressant therapy proved to have poor results.
- ❑ After discovering Fibromya she experienced dramatic betterment after only a couple days of treatment.



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