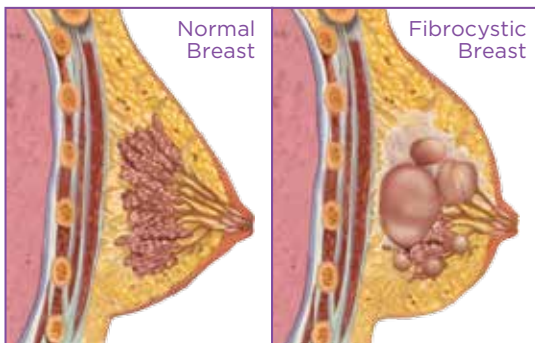


# The Effects of Iodine on Fibrocystic Breast Changes

## Overview of Fibrocystic Breast Changes (FBC)

Fibrocystic breast changes is a benign condition of breast tissue affecting an estimated 50% of women during their childbearing years.<sup>(1)</sup> It is characterized by non-cancerous lumps in the breast, which can sometimes cause cyclic mastalgia, tenderness, aches and swelling. It is generally related to hormonal influences from the menstrual cycle.



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### Fibrocystic Manifestation

Atypical palpatory findings, diffuse small inhomogeneities, discrete masses, lumpiness, nodules, cysts, breast thickening

### Cyclic Mastalgia

Breast pain often related to hormonal influences from the menstrual cycle, tenderness, swelling and inflammation

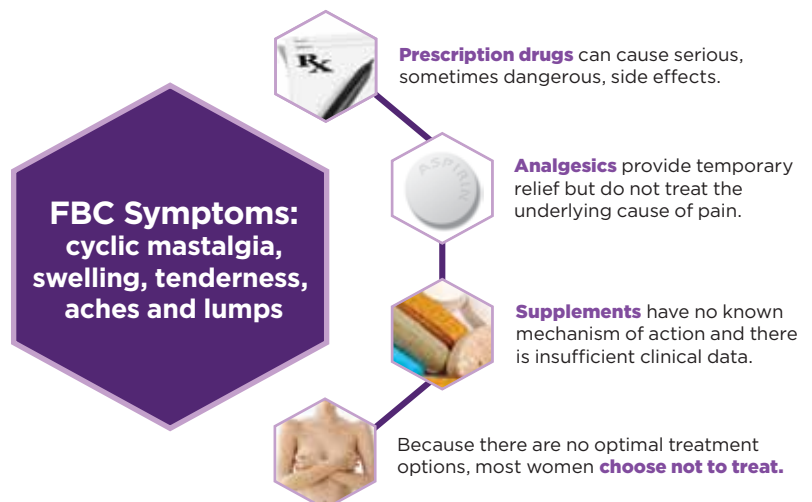
## Causes of FBC

The cause of FBC has been linked to the imbalance of estrogen and progesterone levels, in favor of estrogen. Estrogen has a mitotic (cell proliferative) effect on breast ductal epithelial cells.<sup>(1,2)</sup> Prolactin has been shown in mice to increase the sensitivity of these tissues to estrogen through regulating the estrogen receptor expression.

Scientists believe the combination of high serum levels of estrogen and prolactin (as well as a higher sensitivity to prolactin) may cause an imbalance between cell growth and apoptosis, thus driving natural cell turnover out of balance.<sup>(1-5)</sup> This leads to fibrocystic breast tissue, which presents with a progressing range of severity until menopause. This fibrotic tissue can increase in density and volume, which can cause pain by exerting pressure on the surrounding nerves.<sup>(1)</sup>

## Common Treatments

Many treatments are available to treat FBC or mitigate its symptoms. Unfortunately, treatments that are effective often have severe side effect profiles and those with few side effects do not treat the condition but rather mask the symptoms. Because there is no optimal treatment, most women choose to live with FBC and its symptoms.



# Iodine A New Treatment for FBC

## Clinical Results

Clinical studies have demonstrated safety and efficacy of molecular iodine (I<sub>2</sub>).<sup>(6,7)</sup> One of these studies involved 2,242 women who were given one of three treatment protocols. This study clinically examined different forms of iodine for treatment of fibrocystic breast changes and demonstrated safety differences between molecular iodine and iodide.<sup>(7)</sup>

Protocol	Clinical	Result
1.	Tested two forms of iodide in 821 women over two to five years	"70% of subjects treated with sodium <b>iodide</b> had clinical improvement in their breast disease, but the rate of side effects was high."
2.	Treated 1,365 women with molecular iodine	Objective improvement was noted in up to 74% of those who received <b>molecular iodine</b> .
3.	Treated 56 women in a placebo-controlled, double-blind study of molecular iodine. Clinical measurements included fibrosis resolution and pain assessment by the subject.	<p><b>For fibrosis resolution:</b> Numerical scores for subjects in the <b>molecular iodine</b> treatment improved by an average of 65% in comparison to a degradation of 3% for those in the placebo group.</p> <p><b>For symptom resolution:</b> 65% of subjects in the <b>molecular iodine</b> treatment group showed subjective improvement in symptoms compared to 33% in the placebo group.</p>

## Safety

- Excess iodine does not build up; it is instead flushed from the body.<sup>(8)</sup>
- Clinical studies have demonstrated safety and efficacy of molecular iodine over multi-month and multi-year daily use. These studies include placebo-controlled, double-blind studies.<sup>(6,7)</sup>

## Summary

I<sub>2</sub> is clinically demonstrated to help alleviate many of the common symptoms associated with FBC including: cyclic mastalgia, tenderness, swelling and aches.<sup>\*(6,7)</sup> Increased fluids, cell number and cell size all lead to swelling of breast tissue. When taken up by breast tissue, I<sub>2</sub> restores the natural, healthy balance of breast cells, resulting in a decrease in the swelling.<sup>\*(6,7)</sup> Additionally, with consistent daily use, I<sub>2</sub> has been shown to help maintain overall breast health.<sup>\*(6,7)</sup>

Taken daily,  
I<sub>2</sub> restores the  
natural, healthy  
balance of  
breast cells.\*

VIOLET  
I<sub>2</sub>



\* These statements have not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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