**Nuvexa™**
**A Fat-Complexing Fiber**

**DESCRIPTION**
Nuvexa™ is a dietary supplement containing the soluble fiber alpha-cyclodextrin patented as FBCTX®. Decades of preclinical and clinical research have established its supportive effects on insulin sensitivity, serum lipid levels, and body weight. It also improves insulin sensitivity. Nuvexa™ supports healthy lipid and glucose metabolism as well as contributing to healthy body weight maintenance.

**OVERVIEW**
Nuvexa™ is a cyclic oligosaccharide composed of six α-1,4-linked glucose molecules organized into the shape of a doughnut or truncated cone. The exterior of Nuvexa™ is hydrophilic, easily soluble in water, while the interior is a relatively hydrophobic space, which efficiently complexes dietary fats. Most dietary fats are in the form of di- and triglycerides. This fat must be broken down by pancreatic lipase. This process yields free fatty acids that are absorbed in the small intestine. Fatty acids are then reassembled into triglycerides, and when not needed metabolically, are deposited into fat tissue. Nuvexa™ prevents dietary fat absorption by surrounding and sequestering the fatty acid tails of di- and triglycerides within its conical structure. Nuvexa™-fat inclusion complex cannot be broken down by human digestive enzymes and so it passes through the small intestine unabsorbed into the colon. Microbial α-amylases hydrolyze Nuvexa™ in the colon and both Nuvexa™ and the triglycerides are largely fermented by the colonic microbiota. Unlike lipase inhibitors, when used as directed in clinical trials, Nuvexa™ did not cause excessive fat in the stool (steatorrhea). Nuvexa™ promotes healthy body weight and favorably supports serum lipids by inhibiting dietary fat absorption. Some portion of its favorable impact on serum lipids may be due to a prebiotic effect with fermentation into short-chain fatty acids. The mechanism of Nuvexa™’s improvement of insulin sensitivity is presently unknown, but is speculated to be due to inhibition of salivary and pancreatic α-amylase.

**Support for Healthy Weight**
Clinical studies demonstrate favorable effects of Nuvexa™ on weight management. In one trial, 66 subjects were randomized to take two 1-gram tablets of Nuvexa™ (FBCTX®) or placebo with every fat-containing meal and followed for three months. All participants had been gaining weight at the rate of 2.2 ± 0.88 lbs per month before entry into the study. People who received Nuvexa™ stabilized their weight while those on placebo continued to gain weight. When weight change was normalized for dietary energy intake, people receiving Nuvexa™ lost weight. The most weight loss occurred in people consuming Nuvexa™ in conjunction with reduced energy intake. Nuvexa™ had less impact on weight in subjects taking insulin although it still reduced daily energy intake by 237 calories as compared to 522 calories for non-insulin users. In a double-blind, crossover study involving 41 healthy, overweight adults, Nuvexa™ (FBCTX®) alone facilitated significant weight loss over 2 months without diet or exercise. Although none of the participants reduced their energy intake, people receiving Nuvexa™ lost on average a little less than 1 lb during the treatment period compared to controls.

**Glucose Tolerance and Insulin Sensitivity**
Nuvexa™ has a dose-dependent effect on glucose tolerance and insulin sensitivity. When taken by healthy people with 50 grams of digestible starch, 5- and 10-gram doses support healthy incremental area under the curve (iAUC) for postprandial glucose. A 2-gram dose also flattened the glucose iAUC, although there were too few subjects to reach statistical significance. Studies show that cyclodextrins sequester and inhibit pancreatic α-amylase indicating a mechanism whereby Nuvexa™ can support healthy postprandial glucose. Among healthy, overweight people, Nuvexa™ significantly supported insulin levels to be more consistent with healthy insulin sensitivity. In a sub-group of subjects, Nuvexa™ supported healthy adiponectin levels especially in those not using insulin. Higher adiponectin levels favorably impact insulin tolerance, glucose regulation, and healthy weight.
**INDICATIONS**

Nuvexa™ is a dietary supplement intended to provide significant support to manage a healthy weight. It supports healthy lipid metabolism and insulin sensitivity.

**FORMULA**

**Supplement Facts**

<table>
<thead>
<tr>
<th>Serving Size</th>
<th>2 Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amount Per 2 Tablets</strong></td>
<td></td>
</tr>
<tr>
<td><strong>FBCx®</strong> Alpha-cyclodextrin</td>
<td>2 g*</td>
</tr>
</tbody>
</table>

*Daily Value not established.

Other ingredients: Stearic acid, magnesium stearate, silicon dioxide, croscarmellose sodium, glycerin, and hypromellose.

**FBCx®** Nuvexa™ may be used in the methods of U.S. Patents 6890549, 8101201 and 8586076 owned by SOHO Floridis International Pty Ltd.

**SUGGESTED USE**

Adults take 2 tablets with meals or snacks three times per day. Ensure adequate intake of water when taking Nuvexa™. Best supportive results will be observed when Nuvexa™ is combined with a sensible calorie restricting diet and exercise program.

**ADVERSE REACTIONS**

None reported when used as directed.

**DRUG INTERACTIONS**

None reported. In one human study, it had no effect on serum vitamin D₃ levels.

**CONTRA-INDICATIONS**

None.

**HOW SUPPLIED**

90 or 180 tablets per bottle.

**STORAGE**

Store in a cool, dry place (59°F-85°F) away from direct light. Keep out of reach of children.

**REFERENCES**


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

For ordering information, please contact:
ProThera, Inc.
10439 Double R Blvd
Reno, NV 89521
Phone Toll Free 888-488-2488
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