Medical Food for Osteoarthritis
Medical Foods

- An FDA regulated category of products that are intended for the dietary management of a disease or condition that has distinct nutritional requirements.
  - FDA category in between dietary supplements and drugs
- Used under supervision of a medical professional
- Requires a higher level of science than dietary supplements
  - Adequate to justify the claim that they are beneficial for management of a disease or condition
- Ingredients must be Generally recognized as safe (GRAS)
**NSAID Side Effects**

- GI complaints – nausea, heartburn, dyspepsia, abdominal pain
  - May occur in up to 40% patients with chronic NSAID use
- Bleeding ulcer
- Kidney damage that may persist even after drug withdrawal
- Cardiovascular events (MI, stroke)
- Congestive heart failure
- NSAIDs responsible for ≈19% of hospital admissions with CHF
  - The burden of illness from NSAID-related CHF may exceed that from gastrointestinal tract damage.
- Hospitalization and death:
  - Approximately 107,000 patients are hospitalized annually for NSAID-related GI complications
  - At least 16,500 NSAID-related deaths occur each year among arthritis patients alone
  - Statistics do not include deaths ascribed to the use of over-the-counter NSAIDS

**Acetaminophen side effects:**

- The leading cause of acute liver failure
- Kidney toxicity

“**A large majority of patients with serious GI complications due to NSAIDs do not even have preceding mild side effects.**” - *Arch Inter Med.* Vol. 156;1530-1536; July 1996
Normal

Ulceration
Dyspepsia
Renal Dysfunction

Edema
Hypertension
CV Dysfunction

Arachidonic Acid Metabolism

Burnett et al., 2006
Reduced Inflammation; Virtually No Side Effects with Flavocoxid (mixed extract of natural flavonoids)
<table>
<thead>
<tr>
<th>Products</th>
<th>Ratio of COX-1/COX-2 inhibition</th>
<th>Inhibits 5-LOX</th>
<th>Antioxidant</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin</td>
<td>15:1</td>
<td>NO</td>
<td>NO</td>
<td>causes blood thinning, reduces GI repair</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>8:1</td>
<td>NO</td>
<td>NO</td>
<td>increases blood pressure, dyspepsia, GI bleeding, inhibit mitochondrial function</td>
</tr>
<tr>
<td>Flavocoxid</td>
<td>1:1</td>
<td>YES</td>
<td>YES</td>
<td>virtually no side effects observed in clinical trials</td>
</tr>
<tr>
<td>Rofecoxib</td>
<td>1:250</td>
<td>NO</td>
<td>NO</td>
<td>increases blood clotting, risk of heart attack</td>
</tr>
<tr>
<td>Celecoxib</td>
<td>1:432</td>
<td>NO</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>No COX1/COX2 inhibition</td>
<td>NO</td>
<td>NO (depletes glutathione)</td>
<td>liver toxicity</td>
</tr>
</tbody>
</table>
As Effective as Naproxen in Managing Knee Osteoarthritis

...without the negative side effects
Evolution in Joint Care Therapy

**FIRST GENERATION**

- **Pain killers and anti-inflammatory medicine:**
  - Addressed symptoms and some short term relief and improved mobility

**SECOND GENERATION**

- **Chondroitin and Glucosamine:**
  - Anti-inflammatory effect and pain relief
  - Suggested to stimulate proteoglycan synthesis

**THIRD GENERATION**

- **Collagen Peptides**
  - Evidence of collagen AND proteoglycan synthesis, exerting an effect on total cartilage mass
  - Counteracting causes AND symptoms of cartilage degeneration
  - Improving physical performance & mobility

* FORTIGEL®
© 2011 GELITA AG. Any copies need to be authorized by GELITA
Change in joint cartilage after 3 months (tissue sections)

Benefits of Arthroben™

- Reduces inflammation
  - Balanced inhibition of COX-1, COX-2, 5-LOX
- Offers potent antioxidant protection to reduce joint deterioration
- Increases joint mobility and function
- Stimulates joint repair, and provides nutritional building blocks for cartilage, ligaments (and skin)
- Not associated with the negative side effects that are commonly seen with NSAIDs & other drugs
- Safe for patients on warfarin (Coumadin)
  - Little or no effect on prothrombin times (PT)
Recommended Use

- Mix 11 grams (approx. 1 1/2 tablespoons) in 8 ounces of water
- 1 serving daily
- Initially may use 2 servings daily (loading phase)
- 2 to 12 weeks depending on patient response

<table>
<thead>
<tr>
<th>Serving size</th>
<th>20 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flavocoxid</td>
<td>250 mg</td>
</tr>
<tr>
<td>Fortigel</td>
<td>5.0 g</td>
</tr>
<tr>
<td>Verisol</td>
<td>2.5 g</td>
</tr>
</tbody>
</table>

Arthroben™ is available in a delicious tasting apple flavored powder.
Understanding Osteoarthritis

What is osteoarthritis?
Osteoarthritis (OA), also called arthritis, currently affecting as many as 40 million people in the U.S. It is characterized by a gradual loss of cartilage and overgrowth of bone within one or more joints. The cartilage surface, once firm and smooth, begins to thin and wear down. OA can occur in almost any joint, most commonly the knees, hips, spine, hands or feet.

What causes osteoarthritis?
OA is a slow, progressive disease that begins at the cellular level in the joint cartilage, often with a traumatic event. The exact cause of cartilage deterioration is unknown, but is generally related to single or repetitive joint use, causing cartilage to degenerate.

Why can most NSAIDS cause serious side effects?
The main reason why most NSAIDS (nonsteroidal anti-inflammatory drugs), prescription or OTC, work to reduce pain and swelling from OA symptoms by inhibiting the COX-1 and COX-2 enzymes that produce key inflammatory molecules. However, these molecules also have other functions, such as protecting the stomach and intestines, and maintaining the balance between these molecules or reduce their levels below what is required for other normal body functions.

NSAIDS do not inhibit 5-LOX, they leave leukotriene levels unchecked, and therefore potential side effects can arise.

What can I do to minimize the side effect risks for me?
It is possible to minimize side effects. Your practitioner can work with you to weigh the benefits and risks of any therapy for your OA. Follow your practitioner's directions on lifestyle changes and non-medicinal approaches, such as heat and massage. Always tell your practitioner what non-prescription and other prescription medications you are taking. Ask your physician what possible side effects you should be aware of from your prescriptions. When evaluating a prescription for osteoarthritis, ask your physician if it is an NSAID and if it works on the 5-LOX or leukotriene pathway.

Patient Education Materials

Wall Poster

Patient Brochure