What should I know about side effects?
Limbrel represents a new approach to managing osteoarthritis (OA) by addressing the dietary imbalances of the metabolic processes involved in joint disease, rather than merely focusing on the symptoms of OA. The fact that Limbrel is neither a drug nor an alternative to any drug is reassuring to many physicians and patients. (See Limbrel's key ingredients for its Generally Recognized As Safe or GRAS status.) Safe flavonoid ingredients combined with unique effects on dual inhibition and antioxidant action are the foundations of Limbrel’s safety.

The most common side effects of Limbrel are nausea, diarrhea and flatulence, which are often mild and do not usually require discontinued use of Limbrel. If this should happen to you, take Limbrel with food. Serious upper GI reactions are rare, and in fact, clinical experience by physicians has shown Limbrel to be well tolerated in patients with a history of mild ulceration.

Mild elevations in liver tests and rare cases of severe liver reaction symptoms (e.g. jaundice) have been reported, and were resolved within 2-4 weeks after Limbrel was discontinued. Liver abnormalities may be the result of a hypersensitivity reaction to one of the components of Limbrel. Extremely rare cases of allergic lung reactions that required treatments have also been reported. No kidney toxicity has been reported.

If you experience any discomfort while taking Limbrel, inform your doctor immediately.

Who should not take Limbrel?
Limbrel is not intended for patients with hypersensitivity to flavonoids or allergic to zinc. Flavonoids are a family of beneficial ingredients generally found in colored vegetables, fruits, red wine and green tea. Limbrel has not been tested among pregnant or lactating women, pediatric patients, or patients with an active bleeding gastrointestinal ulcer.
Frequently Asked Questions

Is osteoarthritis (OA) a degenerative or a metabolic disease?
It is both. Osteoarthritis (OA) is traditionally known as a degenerative joint disease caused by traumatic injury or wear and tear. OA is characterized by the breakdown of cartilage in the joints, leading to discomfort, stiffness, and loss of movement. However, after the initial damage, the progression of OA generally worsened by metabolic imbalances of arachidonic acid derived fatty acids which regulate the inflammatory processes in the body. Arachidonic acid is essential to build membranes in the body, but it is also inflammatory when in excess and could lead to further deterioration of cartilage over time. OA is the most common type of arthritis, and it can affect any joint, especially weight-bearing joints such as knees, hips, feet or back.

How does Limbrel work?
Limbrel works through dietary management to restore the underlying metabolic balance of inflammatory fatty acids in OA, rather than “treating symptoms” as drugs do. Limbrel’s dietary management approach to OA ultimately results in dual inhibition as well as antioxidant action, and both effects are important to managing OA.

Dual Inhibition refers to inhibition of COX (cyclooxygenase) and LOX (lipoxygenase) enzyme systems, two major inflammatory pathways involved in OA that process arachidonic acid into inflammatory metabolites. Limbrel is the first and only marketed prescription product that balances COX-1 & COX-2 metabolism by inhibiting both enzymes relatively equally, in addition to inhibiting 5-LOX. Limbrel is not a selective COX-2 inhibitor. The COX & LOX dual inhibition action of Limbrel helps to minimize systemic side effects while effectively managing the metabolic imbalances of OA.

Antioxidant Action refers to the “absorption” of free radicals (or reactive oxygen species). Free radicals in the joints have been found to directly break down cartilage over time and trigger other inflammatory processes in OA. Limbrel is a potent antioxidant that helps to “absorb” free radicals in the joints. The antioxidant potency score of Limbrel is higher than many well-known antioxidants such as Vitamin C and E, as well as concentrated sources of antioxidants such as blueberry juice.

What are Limbrel’s key ingredients?
Limbrel consists of flavocoxid and citrated zinc bisglycinate. Flavocoxid is a proprietary blend of flavonoids, baikalin and catechin from the plants Scutellaria baicalensis and Acacia catechu, respectively. These plants have been used in foods and medicinal products for thousands of years in other countries, especially in Japan and China.

The two key flavonoids, baikalin and catechin, in Limbrel have been studied extensively around the world and are recognized for their anti-inflammatory and antioxidant properties, as well as their exceptional safety profile. Limbrel’s ingredients have achieved GRAS (Generally Recognized As Safe) status, a strict food safety standard set by the FDA.

Flavonoids in general are the healthful ingredients that give color to vegetables, fruits, cocoa, red wine and green tea. However, a simple change in diet would not provide enough flavonoids needed to manage the metabolic processes of OA. In practical terms, an OA patient would need to consume about 5 pounds of fruits and vegetables daily in order to obtain the high concentration levels of flavonoids in the body that Limbrel provides.

Each Limbrel capsule contains 50 mg citrated zinc bisglycinate, that provides approximately 10 mg of elemental zinc per capsule. Zinc is an essential mineral co-factor required by many enzymes in the body, including those related to both bone and cartilage metabolism, and has important physiological functions in other tissues throughout the body. The National Academy of Sciences upper acceptable limit for self-administration is 40 mg/day of elemental zinc, the equivalent of four Limbrel capsules per day.

Is Limbrel a drug or dietary supplement?
Limbrel is neither a drug nor a dietary supplement. Limbrel is a prescription medical food product. Medical foods are also regulated by the FDA, but are in a unique class separate from drugs and dietary supplements. The effectiveness of a medical food must be proven by acknowledged sound laboratory and clinical science. A medical food is intended for the dietary (metabolic) management of a disease and must be used under physician (MD or DO) supervision. Although the term “food” sounds deceptively common, it actually speaks to the safety of medical food products because they must contain only ingredients that have been designated as GRAS (Generally Recognized As Safe).

Can patients on warfarin (Coumadin™) take Limbrel?
Limbrel has been shown to be safe for patients who are also taking warfarin. However, following usual clinical practice, physicians are advised to check prothrombin time one to two weeks after adding any new prescriptions, including Limbrel, in patients anticoagulated with warfarin.

Can Limbrel be taken with NSAIDs?
It is okay to take Limbrel for short periods of time (7-10 days) with NSAIDs such as naproxen, ibuprofen, aspirin (except baby aspirin for cardio-protection), or with any selective COX-2 inhibitors. Long term, combining NSAIDs and selective COX-2 inhibitors with Limbrel will destroy Limbrel’s “balancing” effect on the COX and LOX pathways.

Drug interactions?
Preclinical test results suggest no major drug interactions with Limbrel. If any drug interaction is suspected, inform your doctor immediately.

Allergies?
Patients allergic to zinc should not take Limbrel. Patients with hypersensitivity to flavonoids should not take Limbrel. Some patients may experience indigestion while taking Limbrel, perhaps because the flavonoids in each capsule of Limbrel are in such high concentration levels, equivalent to about 5 pounds of fruits and vegetables.

Other (or “inactive”) ingredients of Limbrel are magnesium stearate, microcrystalline cellulose, Maltodextrin NF, gelatin (as the capsule material), and FD&C Blue #1 and Green #3 (approved food colorings). Limbrel does not contain fructose, glucose, sucrose, lactose, gluten or flavors. Limbrel does not contain any parts or ingredients of nuts, soy, corn, wheat, sugar, or any fruits and vegetables.

If you experience any discomfort while taking Limbrel, please inform your doctor immediately.

Why not available OTC if Limbrel is so safe?
Limbrel is only available by prescription, and not available over-the-counter (OTC). Limbrel is regulated by the FDA as a medical food product, which must be used under physician supervision according to federal statutes and regulations. Therefore, Limbrel is only available by prescription to prevent possible use without physician supervision.

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