



Limbrel250[®] and Limbrel500[®] – Safety communication

- On December 4, 2017, the [FDA recommended](#) that Primus Pharmaceuticals voluntary recall [Limbrel \(flavocoxid/citrated zinc bisglycinate\)](#) due to serious adverse events, including drug-induced liver injury and hypersensitivity pneumonitis.
 - Primus has not yet acted to remove the product from the market.
- Limbrel is a medical food product for the clinical dietary management of the metabolic processes of osteoarthritis.
 - Although the product is marketed as a medical food, the preliminary determination of the FDA investigation is that Limbrel is an unapproved new drug. The agency does not have mandatory recall authority over drug products.
- Medical food products are often used in hospitals and outside of a hospital setting under a physician's care for the dietary management of diseases in patients with particular medical or metabolic needs due to their disease or condition.
- The FDA has received reports of serious adverse events, including drug-induced liver injury and a lung condition, hypersensitivity pneumonitis, involving Limbrel. In total, the FDA has received 194 adverse event reports regarding Limbrel. Thirty of these contained sufficient information for FDA medical experts to determine whether Limbrel was likely associated with these adverse events.
 - Symptoms of drug-induced liver injury can vary and may include jaundice, nausea, fatigue, and gastrointestinal discomfort.
 - Symptoms of hypersensitivity pneumonitis can vary and may include fever, chills, headache, cough, chronic bronchitis, shortness of breath or trouble breathing, weight loss, and fatigue.
 - The FDA continues to receive additional reports, which it is currently evaluating.
- The FDA advises the following:
 - Consumers should not use Limbrel because of the risk of drug-induced liver injury and hypersensitivity pneumonitis. Consumers who are taking this product should discontinue it immediately and contact their health care provider.
 - Health care providers who are aware that their patients are taking Limbrel should advise them to stop using it.



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