RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Limbrel Recall Alert

Date of Notice: 04/13/2020

Brief Description of Recall

On April 13, 2020, the FDA has requested a recall of all lots of Limbrel® due to rare but serious and reversible side effects associated with Limbrel®.

Between January 1, 2007, and November 9, 2017, the FDA has received 30 adverse event reports of elevated liver function tests or acute hypersensitivity pneumonitis associated with the use of Limbrel® products. These conditions present in rare cases with varying degrees of severity in patients taking Limbrel® for the first time in the initial weeks of exposure, and may go unnoticed by the patient until they consult with their physician or until symptoms develop that require hospitalization. There have been no deaths reported with the use of Limbrel®, and in all reported cases adverse effects resolved without residual effects after discontinuing use of the product.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
Limbrel® capsules, 250mg	68040-601-16 68040-605-16	All lots	All dates
Limbrel® capsules, 500mg	68040-602-16 68040-606-16	All lots	All dates

Prescriber Information

Health care professionals with extensive experience with Limbrel® have provided written testimony to FDA confirming the benefits and safety of Limbrel® for managing osteoarthritis and to establish the medical necessity of Limbrel® for elderly patients with comorbidities who cannot use NSAIDs and have a strong desire to avoid opioid use if possible. For these and other patients and their medical professionals who have stated their desire for continued access to Limbrel®, Primus will seek to work with FDA to return Limbrel® to the market as quickly as possible. For updates about access to Limbrel® go to Limbrel.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online
- Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Member Information

Members who wish to return unopened bottles or who have questions regarding this recall should go to Limbrel.com or contact Primus by calling (480-483-1410) on Monday through Friday, 9 AM to 5 PM Mountain Time. Members should contact their prescriber if they have experienced any adverse event that may be related to taking Limbrel®.

RxAdvance Response

RxAdvance is in the process of contacting members and prescribers to advise them of this recall.