URGENT NOTICE

# TYPE: Drug Recall

*Label Mix-Up Prompts Montelukast Recall*


Drug Name: **Montelukast**
NDC#: 31722-726-30 Lot#: MON17384

Audience: Consumer, Health Professional, Pharmacy

Date: **08/31/2018**

**ISSUE**
Camber Pharmaceuticals is recalling one lot of montelukast sodium tablets because the bottles are labeled "montelukast sodium tables, 10mg, 30-count" but actually contain 90 tablets of losartan potassium, 50mg.

The lot number for the recalled product is MON1734, the expiration date is 12/31/2019, and the national drug code is 31722-726-30.

**BACKGROUND**
This tablet mix-up may pose a safety risk, as taking losartan tablets when not prescribed has the potential to cause renal dysfunction, elevated potassium levels, and low blood sugar. This risk is especially high for pregnant women taking the allergy and asthma medication montelukast because losartan, which is indicated to treat high blood pressure, could harm or kill the fetus.

**RECOMMENDATION**
Patients who take montelukast must be made aware of this recall due to the serious risks associated with taking losartan in its place.

The FDA is asking patients to contact their healthcare provider or pharmacist to determine whether their montelukast medication has been recalled.

To date, Camber has not received adverse even reports associated with this recall. The FDA encourages healthcare professionals and consumers to report adverse events to the FDA's MedWatch Adverse Event Reporting Program.

This recall is not related to the recent valsartan recalls that were due to an impurity, *N*-nitrosodimethylamine.