

Alerts and Recalls

Generic Name (Trade Name—Company)

September 4, 2018

Montelukast

(No trade name—Camber Pharmaceuticals)

Bottles labeled as montelukast contain different drug

Uses/Notes

[FDA is warning](#) consumers and health professionals about a voluntary recall of one lot of montelukast sodium tablets (lot #MON17384, expiration 12/31/2019) by Camber Pharmaceuticals. Sealed bottles labeled as montelukast sodium tablets, 10 mg, 30-count bottle were found to instead contain 90 tablets of losartan potassium tablets, 50 mg.

This tablet mix-up may pose a safety risk because taking losartan tablets when not prescribed has the potential to cause renal dysfunction, elevated potassium levels, and low blood pressure. 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.

FDA recommends that consumers who have this recalled product contact their health care provider or pharmacist immediately.

Montelukast sodium tablets are beige, rounded square-shaped, film coated tablets that are imprinted with “I” on one side and “114” on the reverse. Losartan tablets are white and oval-shaped with the letter “I” imprinted on one side and the number “5” imprinted on the reverse.

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

To date, Camber has not received adverse event reports associated with this recall.

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<http://www.aphanet.org/alerts-and-recalls/bottles-labeled-montelukast-contain-different-drug>

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