



STATE OF TENNESSEE
DEPARTMENT OF FINANCE AND ADMINISTRATION
DIVISION OF HEALTH CARE FINANCE AND ADMINISTRATION
BUREAU OF TENNCARE
310 Great Circle Road
NASHVILLE, TENNESSEE 37243

Memo

To: TennCare Providers

From: Bureau of TennCare

Date: June 21, 2017

Re: Important Voluntary Manufacturer Recall Information Regarding the Following Agent:

- **Mibelas 24 Fe Chewable Tablets (Lupin)**

Lupin Pharmaceuticals Inc. announced a **recall of Mibelas 24 Fe**, (Norethindrone Acetate and Ethinyl Estradiol 1 mg/0.02 mg chewable and ferrous fumarate 75 mg) Tablets associated with Lot# **L600518 and expiration date of 05/31/18** at the consumer level. A confirmed market complaint indicated a packaging error, where the blister was rotated 180 degrees within the wallet, reversing the weekly tablet orientation and making the lot number and expiration date no longer visible. The first four days of therapy would have had four non-hormonal placebo tablets as opposed to the active tablets.

The FDA is recommending consumers who have the affected product to notify their physician and return the product to the pharmacy or place of purchase and also inform their physician or healthcare provider if they have experienced any problems that may be related to taking this drug product.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online:
<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>
- Regular Mail or Fax: Download form: www.fda.gov/medwatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-address form, or submit by fax to 1-800-FDA-0178.

Additional Links:

FDA Communication:

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm560908.htm>

GUIDE FOR TENNCARE PHARMACIES: OVERRIDE CODES

OVERRIDE TYPE	OVERRIDE NCPDP FIELD	CODE
Emergency 3-Day Supply of Non-PDL Product	Prior Authorization Type Code (D.0 461-EU)	8
Hospice Patient (Exempt from Co-pay)	Patient Residence (D.0 384-4X)	11
Pregnant Patient (Exempt from Co-pay)	Pregnancy Indicator (D.0 335-2C)	2
Titration Dose Override for the following select drugs/drug classes: oral oncology agents, anticonvulsants, warfarin, low molecular weight heparins, theophylline, Selective Serotonin Reuptake Inhibitors (SSRIs), Selective Norepinephrine Reuptake Inhibitors (SNRIs), atypical antipsychotics (except clozapine/Clozaril®), Hizentra®, Vivaglobin® - process second Rx for the same drug within 21 days of initial Rx with an override code to avoid the second Rx counting as another prescription against the limit.	Submission Clarification Code (D.0 42Ø-DK)	2
Titration Dose Override for the following select drugs/drug classes: clozapine/Clozaril®, Suboxone®, Zubsolv® and buprenorphine- will allow up to five prescription fills to process for the same drug within a month of the initial prescription without the subsequent fills counting against the enrollee’s monthly RX limit.	Submission Clarification Code (D.0 42Ø-DK)	6

Important Phone Numbers:

TennCare Family Assistance Service Center	866-311-4287
TennCare Fraud and Abuse Hotline	800-433-3982
TennCare Pharmacy Program Fax	888-298-4130
Magellan Pharmacy Support Center	866-434-5520
Magellan Clinical Call Center	866-434-5524
Magellan Call Center Fax	866-434-5523

Helpful TennCare Internet Links:

Magellan: <https://tenncare.magellanhealth.com>
TennCare website: www.tn.gov/tenncare/

Please visit the Magellan TennCare website regularly to stay up-to-date on changes to the pharmacy program.

For additional information or updated payer specifications, please visit the Magellan website at:

<https://tenncare.magellanhealth.com> then click on pharmacy and choose program information from the drop down menu. Please forward or copy the information in this notice to all providers who may be affected by these processing changes.

Thank you for your valued participation in the TennCare program.