

Lupin – Recall of Mibelas[™] 24 Fe (norethindrone/ethinyl estradiol and ferrous fumarate)

- On May 25, 2017, <u>Lupin announced</u> a consumer-level recall of one lot of <u>Mibelas 24 Fe</u>
 (<u>norethindrone/ethinyl estradiol and ferrous fumarate</u>) tablets due to a packaging error, where one
 blister was rotated 180 degrees within the wallet, reversing the weekly tablet orientation and making
 the lot number and expiry date no longer visible. The first four days of therapy would have four non-hormonal placebo tablets instead of four active tablets.
- As a result of this error, the daily regimen for these oral contraceptives may be incorrect, which could leave women without adequate contraception and at risk for unintended pregnancy.
- The recalled lot was distributed on March 15, 2017.

Product Description	NDC #	Lot # (Expiration date)
Mibelas 24 Fe (norethindrone/ethinyl estradiol and ferrous fumarate) 1 mg/0.02 mg and 75 mg tablets	68180-911-11, 68180-911-13	L600518 (5/31/2018)

- Mibelas 24 Fe is indicated for use by females of reproductive age to prevent pregnancy.
- Anyone with an existing inventory of the recalled product should stop use and distribution, and
 quarantine the product immediately. Patients should contact their healthcare provider if they have
 experienced any problems that may be related to using the recalled product.
- For questions regarding this recall, contact Genco, the appointed company for Lupin, at 1-855-633-1428.



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