

Lupin – Recall of Tydemy™ (drospirenone/ethinyl estradiol and levomefolate)

- On July 28, 2023, Lupin announced a consumer level recall of two lots of Tydemy (drospirenone/ethinyl estradiol and levomefolate) tablets because of an out of specification result observed in inactive content and results of an impurity test.
- The recalled lots were distributed between June 3, 2022 to May 31, 2023.

Product Description	NDC Number (Package Size)	Lot Number (Exp Date)
Tydemy (drospirenone/ethinyl estradiol and levomefolate calcium) 3 mg/0.03 mg/0.451 mg and 0.451 mg tablets	68180-904-71 (1 blister of 28 tablets each)	L200183 (1/2024); L201560 (9/2024)
	68180-904-73 (3 blister of 28 tablets each)	

- Tydemy is indicated for use by women to prevent pregnancy. It is also indicated in women who choose to use an oral contraceptive as their method of contraception, to raise folate levels for the purpose of reducing the risk of a neural tube defect in a pregnancy conceived while take the product or shortly after discontinuing the product.
- Per Lupin, significant reduction in the amount of inactive content could potentially impact the effectiveness of Tydemy.
- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using the recalled drug products.
- Anyone with the affected lots on hand should stop use and distribution and return to place of purchase.
- Contact Inmar (appointed company for Lupin) at 1-866-480-8206 for questions regarding this recall