



## Preferred Drug List

### NEW DRUG REVIEW

**Proprietary Name:** Lysteda™

**Common Name:** Tranexamic Acid

**PDL Category:** Hemostatic

<u>Comparable Products</u>	<u>Preferred Drug List Status</u>
Ponstel®	Non-Preferred with Conditions

#### Summary

**Indications and Usage:** Indicated for the treatment of cyclic heavy menstrual bleeding.<sup>1</sup>

**Mechanism of Action:** Lysine amino acid derivative which occupies the lysine binding sites of plasmin for fibrin, preventing binding to fibrin monomers, thus preserving and stabilizing fibrin's matrix structure.<sup>1</sup>

**Dosage Forms:** Tablets: 650mg

**Recommended Dosage:** 1,300 mg (two 650 mg tablets) three times a day (3,900 mg/day) for a maximum of 5 days during monthly menstruation. Dosage adjustment is needed if serum creatinine concentration (Cr) is higher than 1.4 mg/dL.<sup>1</sup>

**Common Adverse Drug Reactions:** Headache, sinus and nasal symptoms, back pain, abdominal pain, muscle and joint pain, muscle cramps, anemia, fatigue.<sup>1</sup>

**Contraindications:** Women with active thromboembolic disease or a history or intrinsic risk of thrombosis or thromboembolism, including retinal vein or artery occlusion.<sup>1</sup>

**Manufacturer:** Xanodyne Pharmaceutical, Inc.

**Analysis:** Lysteda™ is the first non-hormonal therapy indicated for the treatment of women suffering from cyclic heavy menstrual bleeding (HMB), also known as menorrhagia. In the trials used to gain FDA approval, Lysteda™ was compared to placebo. In the clinical trials, there was a statistically significant reduction in menstrual blood loss in women who received Lysteda™, as compared to placebo. In addition, there was a statistically significant reduction of limitations on social, leisure, and physical activities, which were the secondary outcome measures. There is no clinical data concerning the concomitant use of Lysteda™ and hormonal contraceptives, thus it should be used with caution for women using hormonal contraception. It is recommended that Lysteda™ be added to the Preferred Drug List as a non-preferred drug.

**IME Recommendation:**

<input type="checkbox"/> Preferred Drug	<input type="checkbox"/> Recommended Drug
<input checked="" type="checkbox"/> Non-Preferred Drug	<input type="checkbox"/> Non-Recommended Drug
<input type="checkbox"/> Non-Preferred Drug with Conditions	

1. Lysteda™ [package insert]. Newport, KY: Xanodyne Pharmaceutical, Inc.; 2009.