



Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Natazia™

Common Name: Estradiol Valerate/ Dienogest Tablets

PDL Category: Contraceptives- Multi-Phasic Combinations

<u>Comparable Products</u>	<u>Preferred Drug List Status</u>
Ortho Novum® 7/7/7	Preferred
Ortho Tri-Cyclen®	Preferred

Summary

Indications and Usage: Prevention of Pregnancy¹

Mechanism of Action: Suppresses ovulation, modifies cervical mucus and endometrium.¹

Dosage Forms: Tablets; 2 tablets each containing 3 mg estradiol valerate, 5 tablets each containing 2 mg estradiol valerate and 2 mg dienogest, 17 tablets each containing 2 mg estradiol valerate and 3 mg dienogest, 2 tablets each containing 1 mg estradiol valerate, 2 inert tablets.¹

Recommended Dosage: 1 tablet by mouth once daily¹

Common Adverse Drug Reactions: Irregular uterine bleeding, breast tenderness, headaches, nausea and vomiting, increased weight, acne.¹

Contraindications: A high risk of arterial or venous thrombotic diseases, undiagnosed abnormal genital bleeding, breast cancer or other estrogen- or progestin-sensitive cancer, liver tumors or liver disease, pregnancy.¹

Manufacturer: Bayer HealthCare Pharmaceuticals, Inc.

Analysis: Natazia™ is the first four-phasic oral contraceptive containing varying doses of estradiol valerate and dienogest. In the trials used to gain FDA approval, the effectiveness of Natazia™ was similar to other combination oral contraceptives. It appears to cause less withdrawal bleeding than ethinyl estradiol/levonorgestrel products, most likely due to its short hormone free period. Other preferred oral contraceptive products exist on the PDL, with varying hormone doses, that are equally effective at preventing pregnancy and that are more cost effective. Therefore, it is recommended that Natazia™ 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. Natazia™ [package insert]. Wayne, NJ: Bayer HealthCare Pharmaceuticals, Inc.; 2010.