

Lupin gets approval for oral contraceptive

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Bangalore: Pharma major, Lupin, announced that its subsidiary Lupin Pharmaceuticals Inc. (collectively Lupin) has received final approval for its oral contraceptive Kurvelo® Tablets (Levonorgestrel and Ethinyl Estradiol Tablets, USP) 0.15 mg/0.03 mg from the United States Food and Drugs Administration (FDA) to market a generic version of Teva Branded Pharmaceuticals (Teva) Nordette® Tablets (Levonorgestrel and Ethinyl Estradiol Tablets, USP), 0.15 mg/0.03 mg.

Lupin's Kurvelo® Tablets are the AB-rated generic equivalent of Teva's Nordette® Tablets. Lupin's Kurvelo® tablets is a Levonorgestrel and Ethinyl estradiol combined oral contraceptive indicated for the prevention of pregnancy in women who elect to use this product as a method of contraception. Lupin is marketing its Kurvelo® tablets in 21 light orange colored active tablets containing 0.15 mg Levonorgestrel and 0.03 mg Ethinyl estradiol and seven pink inert tablets (without hormones). This dosage regimen is identical to that of Nordette®.

Nordette® Tablets had annual U.S sales of approximately USD 59 million (IMS MAT Jun 2012 sales).

The OC market in the U.S is valued at close to USD 5.0 Bn. It's a very niche segment and requires a high level of R&D expertise, API strengths and manufacturing competencies and as such, is a much less competed for space. The 5th largest Generic player by prescription, Lupin is the most vertically integrated generic OC player for the US market and has a dedicated OC facility in Indore. Lupin's current ANDA filings for OC's stand at 30, which is the largest product pipeline for the

US Generic OC market.