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Lupin's oral contraceptive Kurvelo gets FDA approval

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Mumbai: Lupin's subsidiary, Lupin Pharmaceuticals, received final approval for its oral contraceptive Kurvelo tablets (levonorgestrel and ethinyl estradiol tablets) 0.15 mg/0.03 mg from the US FDA to market a generic version of Teva's branded pharmaceuticals (Teva) Nordette tablets (levonorgestrel and ethinyl estradiol tablets) 0.15 mg/0.03 mg.

Kurvelo tablets are the AB-rated generic equivalent of Teva's Nordette tablets. Lupin's Kurvelo 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, which recorded annual US sales of approximately $59 million, according to IMS.