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Generic Name:

Drospirenone

Trade Name:

Slynd

Company:

Exeltis USA

Notes:

In a June 6 [news release](#), Exeltis USA announced FDA approval of drospirenone 4 mg, an oral contraceptive tablet for pregnancy prevention.

The progestin-only pill (POP) is a novel estrogen-free oral contraceptive with a dosing regimen of 24 active with 4 inactive tablets. It also allows a 24-hour missed-pill window.

In clinical trials, drospirenone, a synthetic form of progesterone that has a similar pharmacological profile to the natural hormone progesterone, showed no instances of thromboembolic events experienced by some women taking combined oral contraceptives, which by definition contain estrogen. It was approved with no black box warning, unlike other combined oral contraceptives. But for females with conditions that predispose to hyperkalemia (e.g., renal impairment, hepatic impairment, and adrenal insufficiency), drospirenone is contraindicated because of its anti-mineralocorticoid activity.

This safety profile was demonstrated for all patients, including higher-risk populations such as smokers, older women, and those with a BMI greater than 30.

Contraindications include renal impairment, adrenal insufficiency, presence or history of progestin-sensitive cancers, liver tumors (benign or malignant) or hepatic impairment, or undiagnosed abnormal uterine bleeding.

A commercial launch is planned for early fall 2019.

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