



Lysodren® (mitotane) – New warning

- On May 9, 2017, the FDA approved an update to the *Warnings and Precautions* section of the [Lysodren \(mitotane\)](#) drug label, regarding ovarian macrocysts in premenopausal women.
- Lysodren is indicated for the treatment of patients with inoperable, functional or nonfunctional, adrenal cortical carcinoma.
- Ovarian macrocysts, often bilateral and multiple, have been reported in premenopausal patients receiving Lysodren. Complications from these cysts, including adnexal torsion and hemorrhagic cyst rupture, have been reported. In some cases, improvement after Lysodren discontinuation has been described.
- Patients should seek medical care if they experience gynecological symptoms such as vaginal bleeding and/or pelvic pain.
- Lysodren carries a boxed warning for adrenal crisis in the setting of shock or severe trauma.



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