

Absorica[®] LD[™] (isotretinoin) – New formulation approval

- On November 5, 2019, the [FDA approved](#) Sun Pharmaceuticals' [Absorica LD \(isotretinoin\)](#) capsules, for the treatment of severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5 mm or greater. Because of significant adverse reactions associated with its use, Absorica LD is reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics.
 - If a second course of Absorica LD therapy is needed, it is not recommended before a two-month waiting period because the patient's acne may continue to improve following a 15 to 20-week course of therapy.
- Absorica is also available as capsules carrying the same indication as Absorica LD.
 - Given that the bioavailability and the recommended dosage of Absorica and Absorica LD are different, Absorica and Absorica LD are not substitutable. For example, Absorica and Absorica LD have a 20 mg strength; however, these strengths have different bioavailability and are not substitutable.
- The FDA approval of Absorica LD was based on a clinical study conducted in 925 patients 12 years and older with severe recalcitrant nodular acne who received Absorica or another isotretinoin product. Efficacy was evaluated by a change from baseline to week 20 in total nodular lesion count and proportion of subjects with at least a 90% reduction in total nodular lesion count.
 - Mean reduction in nodular lesions was -15.68 for patients treated with Absorica vs. -15.62 for patients treated with the other isotretinoin product.
 - A total of 70% of patients treated with Absorica vs. 75% of patients treated with the other isotretinoin product experienced a 90% reduction in total nodular lesion count.
- Absorica LD carries a boxed warning for embryo-fetal toxicity – contraindicated in pregnancy.
- Warnings and precautions of Absorica LD include iPLEDGE program, Absorica and Absorica LD are not substitutable, psychiatric disorders, intracranial hypertension (pseudotumor cerebri), serious skin reactions, pancreatitis, lipid abnormalities, hearing impairment, hepatotoxicity, inflammatory bowel disease, musculoskeletal abnormalities, ocular abnormalities, hypersensitivity reactions, and laboratory abnormalities and laboratory monitoring for adverse reactions.
- The most common adverse reactions ($\geq 5\%$) with Absorica LD use were dry lips, dry skin, back pain, dry eye, arthralgia, epistaxis, headache, nasopharyngitis, chapped lips, dermatitis, increased creatine kinase, cheilitis, musculoskeletal discomfort, upper respiratory tract infection, and reduced visual acuity.
- The recommended dose of Absorica LD is 0.4 to 0.8 mg/kg/day given in two divided doses orally with or without meals for 15 to 20 weeks.
 - During treatment, the dosage may be adjusted according to response of the disease and/or adverse reactions, some of which may be dose-related.
 - Adult patients whose disease is very severe with scarring or is primarily manifested on the trunk may require dosage adjustments up to 1.6 mg/kg/day in divided doses, as tolerated.
 - The safety and effectiveness of once daily dosing has not been established and is not recommended.

- Sun Pharmaceuticals' launch plans for Absorica LD are pending. Absorica LD will be available as 8 mg, 16 mg, 20 mg, 24 mg, 28 mg, and 32 mg capsules.



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