

Supplemental Approvals

Generic Name (Trade Name—Company)

September 11, 2018

Buprenorphine and naloxone

(Cassipa—Teva)

FDA approves new sublingual formulation for maintenance treatment of opioid dependence

Uses/Notes

FDA has [approved](#) buprenorphine and naloxone sublingual film under the trade name Cassipa for maintenance treatment of opioid dependence. This action provides a new dosage strength (16 mg/4 mg) of the sublingual film, which is also approved in both brand name and generic versions and in various strengths.

Cassipa should be used as part of a complete treatment plan that includes counseling and psychosocial support and should be used only after patient induction and stabilization up to a dose of 16 mg of buprenorphine using another marketed product.

Common adverse events are oral numbness, burning mouth, inflammation of oral mucous membrane, headache, nausea, vomiting, excessive sweating, constipation, signs and symptoms of withdrawal, insomnia, pain, and peripheral edema.

These products may only be prescribed by Drug Addiction Treatment Act–certified prescribers.

Source URL:

<http://blog.pharmacist.com/supplemental-approvals/fda-approves-new-sublingual-formulation-maintenance-treatment-opioid>

APhA DrugInfoLine is an official publication of, and is owned and copyrighted by the American Pharmacists Association, the national professional society of pharmacists. Materials in APhA DrugInfoLine do not necessarily represent the policy, recommendations, or endorsement of APhA. The publisher, authors, editors, reviewers, and contributors have taken care to ensure that information contained in APhA DrugInfoLine is accurate and current; however, they shall have no liability to any person or entity with regard to claims, losses, or damages caused or alleged to be caused, directly or indirectly, by use of any information contained in the publication. All decisions about drug therapy must be based on the independent judgment of the clinician. Copyright © 2000–2011, American Pharmacists Association. All rights reserved.