Supplemental Approvals

Generic Name (Trade Nameâ€"Company)

Uses/Notes

September 11, 2018

Buprenorphine and naloxone

(Cassipa—Teva)

FDA approves new sublingual formulation for maintenance treatment of opioid dependence

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.

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