

FIRST TIME GENERIC APPROVAL

Brand Name	Butrans®
Generic Name	buprenorphine transdermal system
Drug Manufacturer	Amneal Pharmaceuticals LLC

New Drug Approval

Dosage form(s): 5 mcg/hr, 7.5 mcg/hr, 10 mcg/hr, 15 mcg/hr, and 20 mcg/hr Transdermal System Therapeutic equivalent code: AB

FDA Approval Date: April 14, 2020

Indications for Use

buprenorphine transdermal system is indicated for:

• Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate

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