

New Drug Approvals

Naltrexone for Extended-Release Injectable Suspension 380mg/vial

Approved: July 6, 2023 - Teva Pharmaceuticals USA, Inc.

Treatment for: Alcohol Dependence; Opioid Dependence

Sugammadex Sodium Intravenous Solution 200 mg (base)/2 mL and 500 mg (base)/5 mL

Approved: June 9, 2023 - Aspiro Pharma Ltd.

Treatment for: Reversal of Neuromuscular Blockade

Tipiracil Hydrochloride and Trifluridine Tablets 6.14 mg (base)/15 mg and 8.19 mg (base)/20 mg

Approved: June 13, 2023 - Natco Pharma Ltd.

Treatment for: Colorectal Cancer/Gastric Cancer

Amlodipine Benzoate Oral Suspension 1 mg (base)/mL

Approved: June 13, 2023 - Amneal Pharmaceuticals LLC

Treatment for: Hypertension/Coronary Artery Disease

Safinamide Mesylate Tablets 50mg (base) and 100 mg (base)

Approved: June 14, 2023 - Aurobindo Pharma Limited

Treatment for: Parkinson's Disease

Mometasone Furoate Metered Nasal Spray 0.05 mg/spray (OTC)

Approved: June 14, 2023 - Amneal Pharmaceuticals LLC

Treatment for: Allergic Rhinitis

Tiotropium Bromide Inhalation Powder 0.018mg (base) per inhalation

Approved: June 20, 2023 - Lupin Pharmaceuticals, Inc.

Treatment for: COPD

Amphetamine Extended-Release Orally Disintegrating Tablets 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg and 18.8 mg

Approved: June 22, 2023 - Actavis Pharma, Inc.

Treatment for: ADHD

Alcaftadine Ophthalmic Solution 0.25%

Approved: June 23, 2023 - Eugia Pharma Specialities Limited

Treatment for: Allergic Conjunctivitis

Cyanocobalamin Metered Nasal Spray 0.5mg/spray

Approved: June 30, 2023 - Lupin Pharmaceuticals, Inc.

Treatment for: Vitamin B12 Deficiency

Methsuximide Capsules 300 mg

Approved: May 1, 2023 - Novitium Pharma LLC

Treatment for: Seizures

Obeticholic Acid Tablets 5 mg and 10 mg

Approved: May 30, 2023 - Apotex Corp.; Lupin Pharmaceuticals, Inc.; MSN Laboratories Private Limited

Treatment for: Primary Biliary Cholangitis

Diazepam Rectal Gel 10mg/2mL (5mg/mL) and 20mg/4mL (5mg/mL)

Approved: May 30, 2023 - Novel Laboratories, Inc.

Treatment for: Seizures

Budesonide Rectal Foam 2mg/actuation

Approved: April 12, 2023 - Padagis Israel Pharmaceuticals Ltd.

Treatment for: Ulcerative Colitis

Loteprednol Etabonate Ophthalmic Suspension 0.2%

Approved: April 12, 2023 - Akorn Operating Company LLC

Treatment for: Seasonal Allergic Conjunctivitis

Estradiol Transdermal System 0.014mg/24hr

Approved: April 17, 2023 - Zydus Pharmaceuticals USA, Inc.

Treatment for: Prevention of Postmenopausal Osteoporosis

Thalidomide Capsules 150 mg

Approved: April 27, 2023 - Natco Pharma Limited

Treatment for: Multiple Myeloma and Erythema Nodosum Leprosum

Bismuth Subcitrate Potassium, Metronidazole and Tetracycline Hydrochloride Capsules 140mg / 125mg / 125mg

Approved: March 6, 2023 - Par Pharmaceutical Inc.

Treatment for: Helicobacter Pylori Infection

Betamethasone Dipropionate and Calcipotriene Topical Aerosol Foam 0.064% / 0.005%

Approved: March 21, 2023 - Glenmark Pharmaceuticals Ltd.

Treatment for: Plaque Psoriasis

Tenofovir Alafenamide Fumarate Tablets 25 mg (base)

Approved: March 30, 2023 - Lupin Pharmaceuticals, Inc.

Treatment for: Hepatitis B

Doxepin Hydrochloride Topical Cream 5%

Approved: February 17, 2023 - Teva Pharmaceuticals USA, Inc.

Treatment for: Pruritus

Tiopronin Delayed Release Tablets 100 mg and 300 mg

Approved: February 24, 2023 - Par Pharmaceutical, Inc.

Treatment for: Cystinuria

Acetaminophen and Ibuprofen Tablets 250 mg / 125 mg

Approved: February 28, 2023 - L. Perrigo Company

Treatment for: Pain / Fever

References: www.drugs.com/generic-approvals

References: www.drugs.com/news

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