

FDA New Drug Approvals August,2018

Brand name	Active Ingredient	Dosage form	Company	Treatment for	US FDA Approval Date
Tigecycline	tigecycline	powder; intravenous	AMNEAL PHARMS LLC	Complicated skin infections; complicated intra-abdominal infections & community-acquired bacterial pneumonia	08/02/2018
Orkambi	ivacaftor; lumacaftor	granule; oral	VERTEX PHARMS INC	It is indicated for the treatment of cystic fibrosis (CF)	08/07/2018
Soluprep	chlorhexidine gluconate; isopropyl alcohol	solution; topical	3M HEALTH CARE	It helps to reduce bacteria that can potentially cause skin infection.	08/08/2018
Jornay pm	methylphenidate hydrochloride	capsule, extended release; oral	IRONSHORE PHARMS	It is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older	08/08/2018
Arakoda	tafenoquine succinate	tablet; oral	60 DEGREES PHARMS	It is indicated as the prophylaxis of malaria in patients aged 18 years and older.	08/08/2018
Poteligeo	mogamulizumab-kpjc	injectable; injection	KYOWA KIRIN	It is indicated for the treatment of adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome	08/08/2018
Galafold	migalastat hydrochloride	capsule; oral	AMICUS THERAPS US	It is indicated for the treatment of adults with Fabry disease and an amenable galactosidase alpha gene (GLA)	08/10/2018
Annovera	Ethinyl estradiol; segesterone acetate	ring; vaginal	THERAPEUTICSMD INC	It is indicated for females to prevent pregnancy	08/10/2018

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Onpattro	patisiran sodium	solution; intravenous	ALNYLAM PHARMS INC	It is indicated for the treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults	08/10/2018
Lamivudine, nevirapine and zidovudine	lamivudine; nevirapine; zidovudine	tablet; oral	MICRO LABS	It is indicated alone or in combination with other antiretroviral drugs for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg	08/13/2018
Cequa	cyclosporine	solution; ophthalmic	SUN PHARMA GLOBAL	It is indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye)	08/14/2018
Efavirenz, lamivudine and tenofovir disoproxil fumarate	efavirenz; lamivudine; tenofovir disoproxil fumarate	tablet; oral	AUROBINDO PHARMA LTD	It is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 40 kg.	08/15/2018
Diacomit	stiripentol	capsule; oral	BIOCODEX SA	It is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older taking clobazam.	08/16/2018
Inveltys	loteprednol etabonate	suspension/drops; ophthalmic	KALA PHARMS INC	It is indicated for the treatment of post-operative inflammation and pain following ocular surgery	08/22/2018
Oxervate	cenegermin-bkjb	solution; ophthalmic	DOMPE FARMACEUTICI	It indicated for the treatment of neurotrophic keratitis	08/22/2018

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Altreno	tretinoin	lotion; topical	DOW PHARM	It is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older	08/23/2018
Takhzyro	lanadelumab (shp643)	injectable; injection	DYAX CORP.	It is indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older	08/23/2018
Universal industrial gases, inc	oxygen, usp	gas; inhalation	UNIVERSAL INDUSTRIAL GASES, INC	Label is not available	08/24/2018
Nitrogen, nf	nitrogen, nf	gas; inhalation	UNIVERSAL INDUSTRIAL GASES, INC	Label is not available	08/24/2018
Xerava	eravacycline dihydrochloride		TETRA PHASE PHARMS	It is indicated for the treatment of complicated intra-abdominal infections in patients 18 years of age and older.	08/27/2018
Lutrate depot kit	leuprolide acetate	for suspension; intramuscular	GP-PHARM SA	It is indicated for Palliative treatment of advanced prostatic cancer	08/28/2018
Pifeltro	doravirine	tablet; oral	MSD MERCK CO	It is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adult patients	08/30/2018
Delstrigo	doravirine; lamivudine; tenofovir disoproxil fumarate	tablet; oral	MSD MERCK CO	It is indicated as a complete regimen for the treatment of HIV-1 infection in adult patients	08/30/2018
Sympazan	clobazam	film; oral	AQUESTIVE THERAPEUTICS	Label is not available	08/31/2018

<https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=reportsSearch.process>

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