

Drug	Date of Exclusivity	Sponsor	Indication(s)	Notes
Abacavir	12/14/1998	Glaxo	HIV Infection	
Abatacept	2/14/2017	BMS	Polyarticular juvenile idiopathic arthritis (pJIA)	
Acetaminophen	7/11/2016	Mallinckrodt	Mild to moderate pain, management of moderate to severe pain with adjunctive opioid analgesics, and reduction of fever	
Albuterol	8/27/2008	GSK	Bronchospasm in children with obstructive airway disease	
Alendronate	4/28/2003	Merck	Osteogenesis imperfecta	
Alfuzosin	9/7/2010	Sanofi Aventis	Elevated detrusor leak point pressure associated with a known neurological disorder (e.g., spina bifida)	
Aliskiren	10/3/2017	Noden Pharma DAC	Hypertension	
Almotriptan	1/13/2009	Johnson & Johnson	Acute treatment of migraine headache	
Amlodipine	11/27/2001	Pfizer	Hypertension	
Ammonium Lactate	10/1/1999	Westwood-Squibb	Ichthyosis vulgaris candidiasis	
Amphetamine Mixed Salts	10/28/2004	Shire	Attention Deficit Hyperactivity Disorder	
Anagrelide	5/25/2004	Shire	Thrombocythemia secondary to myeloproliferative disorders	

Anastrozole	11/14/2007	AstraZeneca	Male pubertal patients with gynecomastia and female pediatric patients with McCune-Albright syndrome with progressive precocious puberty.	
Aripiprazole	11/14/2007	Otsuka	Schizophrenia & Bipolar Depression	
Asenapine	3/3/2015	Forest Labs	Schizophrenia & bipolar disorder	
Atazanavir	6/23/2015	Bristol-Myers Squibb	HIV-1 Infection	
Atomoxetine	12/18/2001	Lilly	Attention Deficit Hyperactivity Disorder	
Atorvastatin	2/22/2002	Pfizer	Hypercholesterolemia	
Atovaquone/Proguanil	8/6/2003	GSK	Malaria	
Azelastine	8/11/1999	Asta	Itching associated with allergic conjunctivitis	
Azelastine	3/23/2015	Meda	Perennial and seasonal allergic rhinitis	A second period of Pediatric Exclusivity was granted for this moiety.
Azelastine/Fluticasone	3/23/2015	Meda	Perennial and seasonal allergic rhinitis	
Balsalazide	8/23/2006	Salix	Ulcerative colitis	
Benazepril	7/2/2003	Novartis	Hypertension	
Bendamustine	5/24/2012	Cephalon	Relapsed or refractory acute leukemia	
Betaxolol	2/28/2007	Falcon	Elevated intraocular pressure	A second period of Pediatric Exclusivity was granted for this moiety (effective 6/07 when it received Hatch-Waxman exclusivity)

Bicalutamide	9/19/2008	AstraZeneca	Gonadotropin-independent precocious puberty in boys with testotoxicosis	
Bisoprolol	4/19/2000	Lederle	Hypertension	
Bivalirudin	6/17/2009	The Medicines Company	Use as an anticoagulant in children during percutaneous intravascular procedures for the management of congenital heart disease	
Bortezomib	8/14/2015	Millennium	Acute lymphocytic leukemia (ALL)	
Brimonidine	10/10/2001	Allergan	Lower intraocular pressure	
Brinzolamide	6/28/2006	Alcon	Elevated intraocular pressure	
Budesonide	11/12/2002	AstraZeneca	Asthma & allergic rhinitis	
Budesonide/ Formoterol	1/25/2017	AstraZeneca	Asthma	
Buspirone	5/22/2000	Bristol-Myers	Generalized anxiety disorder	
Busulfan	3/12/2002	Orphan Medical	Conditioning regimen for allogeneic bone marrow transplant	
Cabazitaxel	5/18/2017	Sanofi-Aventis	Recurrent or refractory solid tumors, including high grade glioma or diffuse intrinsic pontine glioma	
Calcitriol	2/16/2001	Abbott	Hypocalcemia management in patients on hemodialysis	
Candesartan	7/20/2009	AstraZeneca	Reduce blood pressure	
Capecitabine	8/28/2013	Hoffman-La Roche	Non-disseminated intrinsic diffuse brain stem gliomas	
Carboplatin	4/30/2004	BMS	Refractory tumors	
Carvedilol	11/8/2006	GSK	Heart failure	
Caspofungin	4/15/2008	Merck & Co	Fungal Infections	
Celecoxib	8/23/2006	Pfizer	JRA	
Cetirizine	3/13/2002	Pfizer	Allergic rhinitis/urticaria	

Cetirizine	8/29/2016	Nicox	Ocular itching associated with allergic conjunctivitis	
Ciprofloxacin	12/18/2003	Bayer	Complicated UTI, Acute pyelonephritis	
Ciprofloxacin Ophth	1/10/2003	Alcon	Bacterial conjunctivitis	
Citalopram	7/12/2002	Forest	Depression	
Clofarabine	7/14/2004	Ilex	Refractory Leukemias	
Clopidogrel	1/20/2011	Sanofi Aventis	Reduction of the incidence of thrombosis in children with systemic to pulmonary artery shunts for palliation of cyanotic congenital heart disease	
Colesevelam	2/17/2009	Daiichi Sankyo	Heterozygous familial hypercholesterolemia (heFH)	
Cromolyn sodium	11/2/1999	Pharmacia & Upjohn	Allergic rhinitis	
Cysteamine	12/12/2017	Horizon	Nephropathic cystinosis	
Darunavir	6/7/2011	Tibotec	HIV-1 Infection	
Dasatinib	9/27/2018	BMS	Philadelphia chromosome positive (Ph+) leukemias, including acute lymphoblastic leukemia (ALL) & chronic myeloid leukemia (CML)	
Desflurane	9/13/2006	Baxter	Anesthesia	
Desloratadine	2/12/2003	Schering	Allergic rhinitis/urticaria	
Dexmedetomidine	3/12/2013	Hospira	Loading and maintenance infusion for sedation in intubated and mechanically ventilated pediatric patients	
Didanosine	8/13/2001	Bristol-Myers	HIV-1 Infection	

Difluprednate	3/21/2013	Alcon	Post-operative inflammation following cataract surgery	
Docetaxel	3/17/2010	Sanofi Aventis	Solid Tumors	
Dorzolamide	1/5/2004	Merck	Reduction in intraocular pressure	
Duloxetine	7/2/2012	Eli Lilly	Major depressive disorder (MDD)	
Efavirenz	1/29/2013	BMS	HIV-1 Infection	
Eltrombopag	8/14/2015	Novartis	Thrombocytopenia in children with chronic idiopathic thrombocytopenia purpura (ITP)	
Emtricitabine	5/24/2006	Gilead	HIV-1 Infection	
Enalapril	2/2/2000	Merck	Hypertension	
Entecavir	12/5/2013	BMS	Chronic Hepatitis B Virus Infection	
Eplerenone	10/24/2007	Pfizer	Hypertension	
Erlotinib	3/18/2015	OSI Pharmaceuticals	Cancer (recurrent ependymoma)	
Ertapenem	2/11/2005	Merck	Meningitis; hospital acquired pneumonia, intra-abdominal infection, or acute pelvic infection; CAP, cUTI, or skin and soft tissue infection	
Esmolol	8/22/2003	Baxter	Hypertension	
Esomeprazole	5/1/2009	AstraZeneca	Treatment of gastroesophageal reflux disease (GERD)	A second period of Pediatric Exclusivity was granted for this moiety.
Eszopiclone	6/29/2012	Sunovion	Insomnia in children with ADHD	
Etodolac	12/6/1999	Wyeth Ayerst	Juvenile Rheum/Arthritis	
Etravirine	6/21/2018	Janssen	HIV-1 infection	

Everolimus	7/10/2012	Novartis	Tuberous sclerosis complex (TSC) who have subependymal giant cell astrocytoma (SEGA)	
Ezetimibe	2/14/2008	MSP Singapore	Heterozygous familial hypercholesterolemia	
Famciclovir	9/21/2009	Novartis	Treatment of children 1 month – 12 years of age w/ herpes simplex (HSV) & 1 – 12 years w/ varicella zoster (VSV)	
Famotidine	11/21/2000	Merck	Gastro-esophageal reflux	
Felodipine	8/30/2001	Astra Zeneca	Hypertension	
Fentanyl	1/29/2003	Alza	Chronic pain	
Fexofenadine	1/27/2003	Aventis	Allergic rhinitis/urticaria	
Fluorouracil	8/25/2014	Alcon	Acute otitis externa (AOE)	
Fingolimod	4/16/2018	Novartis	Multiple sclerosis (MS)	
Fluconazole	1/21/2004	Pfizer	Tinea capitis	
Fludarabine	4/3/2003	Berlex	Refractory/relapse acute leukemia	
Fluoxetine	11/15/2000	Lilly	Depression & Obsessive Compulsive Disorder	
Fluticasone	2/25/2003	GSK	Asthma & atopic dermatitis	
Fluvastatin	12/15/2005	Novartis	Familial Hypercholesterolemia	
Fluvoxamine	1/3/2000	Solvay	Obsessive Compulsive Disorder	
Fosamprenavir	1/10/2012	ViiV	HIV-1 Infection	
Fosaprepitant	3/23/2018	Merck	Postoperative Nausea and Vomiting (PONV) & Chemotherapy-Induced Nausea and Vomiting (CINV)	
Fosinopril	1/27/2003	Bristol-Myers Squibb	Hypertension	
Fulvestrant	2/1/2011	AstraZeneca	Progressive precocious puberty in girls with McCune-Albright Syndrome	

Gabapentin	2/2/2000	Parke Davis	Epilepsy	
Gatifloxacin	5/19/2009	Allergan	Bacterial conjunctivitis in peds 0 - 1 month of age	
Gemcitabine	1/27/2005	Lilly	Refractory or relapsed leukemia and non-Hodgkin's lymphoma	
Glimepiride	6/9/2005	Aventis	Type II Diabetes	
Glyburide/Metformin	10/8/2003	BMS	Diabetes Mellitus	This is the first period of Pediatric Exclusivity for glyburide and a second period for metformin.
Guanfacine	10/17/2014	Shire	Attention Deficit Hyperactivity Disorder (ADHD)	
Ibuprofen	7/1/1998	McNeil	Fever, aches/pains cold symptoms	
Ibuprofen	7/1/1998	Whitehall	Fever, aches/pains cold symptoms	A second period of Pediatric Exclusivity was granted for this moiety.
Ibuprofen/Pseudoephedrine	9/19/2001	Whitehall	Cold, flu, sinus symptoms	
Imatinib Mesylate	6/9/2006	Novartis	Philadelphia positive (Ph+) leukemia	
Imiquimod	12/13/2006	3M	Molluscum contagiosum	
Insulin Aspart Recombinant	5/24/2005	Novo Nordisk	Type I Diabetes	
Insulin Glargine	7/12/1999	Aventis	Diabetes Mellitus	
Ipilimumab	7/20/2017	BMS	Unresectable or metastatic melanoma	
Irbesartan	9/16/2004	Sanofi-Synthelabo	Hypertension	

Irinotecan	3/10/2004	Pharmacia & Upjohn	Refractory tumors	
Isotretinoin	6/12/2001	Hoffman-La Roche	Severe recalcitrant nodular acne	
Ivabradine	3/30/2019	Amgen	Dilated cardiomyopathy (DCM)	
Ixabepilone	4/5/2011	BMS	Solid Tumors	
Ketorolac	9/6/2001	Allergan	Itching associated with allergic conjunctivitis	
Lamivudine	9/22/2000	Glaxo	HIV-1 Infection	
Lamivudine	7/25/2001	Glaxo/SK	Hepatitis B	A second period of Pediatric Exclusivity was granted for this moiety.
Lamotrigine	2/14/2007	GSK	Partial seizures	
Lansoprazole	7/15/2008	Tap Pharmaceutical Products, Inc.	Gastroesophageal Reflux Disease (GERD)	
Leflunomide	11/10/2003	Aventis	JRA	
Levetiracetam	6/3/2008	UCB Inc.	Partial seizures	
Levobetaxolol	6/28/2006	Alcon	Elevated intraocular pressure	
Levocetirizine	8/25/2009	UCB	Allergic rhinitis and urticaria in children 6 months to < 6 years of age	
Levofloxacin	3/14/2007	Ortho McNeil	Community acquired pneumonia	
Linezolid	2/11/2005	Pharmacia Upjohn	Skin and skin structure infections; suspected resistant gram positive infections; VRE infections; CSF shunts	
Liraglutide	5/1/2019	Novo Nordisk	Type 2 diabetes mellitus	
Lisinopril	11/19/2001	Astra Zeneca	Hypertension	
Lisinopril	11/19/2001	Merck	Hypertension	



Lopinavir/Ritonavir	3/7/2008	Abbott	HIV-1 Infection	This is the first period of Pediatric Exclusivity for lopinavir and a second period for ritonavir.
Loratadine	8/14/2000	Schering	Allergic rhinitis/urticaria	
Losartan	3/20/2002	Merck	Hypertension	
Loteprednol/ Tobramycin	12/28/2010	Bausch & Lomb	Superficial bacterial ocular infection	
Lovastatin	7/17/2001	Merck	Hypercholesterolemia	
Lurasidone	12/20/2016	Sunovion	Schizophrenia & irritability associated with autistic disorder	
Meloxicam	4/15/2005	Boehringer Ingelheim	JRA	
Memantine	6/16/2014	Forest Labs	Autism & Autism Spectrum Disorder (ASD)	
Metformin	3/15/2000	Bristol-Myers	Diabetes Mellitus	
Methylphenidate	12/4/2003	McNeil	ADHD	
Methylphenidate	3/15/2019	Rhodes	ADHD	
Metoprolol	7/27/2006	AstraZeneca	Hypertension	
Midazolam	9/18/1998	Hoffman-La Roche	Sedation/anxiolysis Amnesia	
Milrinone	9/24/2001	Sanofi- Sythelabo	Prevent heart failure after cardiopulmonary bypass	
Modafinil	3/21/2006	Cephalon	Narcolepsy	
Mometasone	11/7/2001	Schering	Corticosteroid responsive dermatoses/ Allergic rhinitis	
Montelukast	12/10/2001	Merck	Asthma	
Moxifloxacin Ophth	1/10/2003	Alcon	Bacterial conjunctivitis	
Nabumetone	8/30/2001	Glaxo/SK	Juvenile Rheum/Arthritis	
Nefazodone	6/27/2002	Bristol-Myers	Depression	
Nelfinavir	9/4/2003	Agouron	HIV-1 Infection	
Nevirapine	12/17/2001	Boehringer Ingelheim	Perinatal transmission of HIV infection	

Nilotinib	3/20/2018	Novartis	Philadelphia chromosome positive (Ph+) hematologic malignancies	
Nitric Oxide	11/2/2010	INO Therapeutics	Provide ventilatory assistance to preterm neonates with respiratory distress and reduce the risk of chronic lung disease (CLD) in preterm neonates at high risk of developing CLD	
Norgestimate/Ethinyl Estradiol	12/18/2003	Johnson & Johnson	Bone mineral density in anorexia nervosa patients	
Octreotide	1/12/2006	Novartis	Hypothalamic obesity	
Ofloxacin	3/12/2003	Allergan	Bacterial conjunctivitis	
Olanzapine	1/10/2007	Lilly	Adolescent-Onset Bipolar disorder and Adolescent-Onset Schizophrenia	
Olmesartan	10/7/2009	Daiichi Sankyo	Hypertension in pediatric patients 1 – 16 years of age	
Olopatadine	8/12/2009	Alcon	Allergic rhinitis	
Olopatadine	12/16/2014	Alcon	Allergic conjunctivitis	A second period of Pediatric Exclusivity was granted for this moiety.
Omeprazole	5/1/2001	Astra Zeneca	Gastro-esophageal reflux	
Ondansetron	12/1/2004	Glaxo	Nausea	
Orlistat	9/12/2003	Roche	Obesity	
Oseltamivir	3/22/2004	Roche	Influenza A & B	
Oxaliplatin	9/27/2006	Sanofi-Aventis	Refractory tumors	
Oxaprozin	12/6/1999	Searle	Juvenile Rheum/Arthritis	
Oxcarbazepine	3/2/2005	Novartis	Partial seizures	
Oxybutynin	2/8/2002	Alza	Detrusor hyperreflexia	
Paliperidone	1/5/2011	Ortho-McNeil-Janssen	Adolescent schizophrenia	

Palonosetron	4/10/2014	Helsinn	Prevention of postoperative nausea and vomiting (PONV) and chemotherapy induced nausea and vomiting (CINV)	
Pantoprazole	2/17/2009	Wyeth	Short-term treatment of Symptomatic GERD in pediatric patients	
Paricalcitol	12/8/2003	Abbott	End Stage Renal Disease	
Paroxetine	6/27/2002	GSK	Depression & OCD	
Pemetrexed	12/3/2010	Eli Lilly	Refractory and recurrent solid tumors, including osteosarcoma, Ewing sarcoma/peripheral PNET, rhabdomyosarcoma, and neuroblastoma	
Pemirolast	8/11/1999	Santen	Allergic conjunctivitis	
Phenylephrine-Ketorolac	12/6/2017	Omeros	Intraoperative mydriasis & reduction of ocular pain in patients who have undergone cataract surgery	
Pimecrolimus	9/24/2001	Novartis	Atopic dermatitis	
Pitavastatin	3/30/2019	Kowa Research Institute	Heterozygous Familial Hypercholesterolemia (HeFH)	
Prasugrel	5/23/2016	Eli Lilly	Vaso-occlusive crises (VOC) in pediatric patients with sickle cell disease (SCD)	
Pravastatin	7/10/2002	Bristol-Myers	Hypercholesterolemia	
Pregabalin	11/21/2018	Pfizer	Partial seizures	
Propofol	8/11/1999	Zeneca	Anesthetic	
Quetiapine	1/23/2009	AstraZeneca	Schizophrenia and bipolar mania	
Quinapril	6/7/2002	Parke-Davis	Hypertension	

Rabeprazole	12/4/2012	Eisai	Healing & maintenance of healing of GERD & improvement of GERD symptoms	
Raltegravir	8/14/2017	Merck	HIV Infection	
Ranitidine	1/19/1999	Glaxo	Gastro-esophageal reflux	
Remifentanyl	3/15/2000	Abbott	Anesthetic	
Ribavirin/Intron A	5/9/2001	Schering	Chronic Hepatitis C	
Risedronate	4/24/2009	Procter & Gamble	Prevent vertebral and non-vertebral fractures in children with moderate-to-severe osteogenesis imperfecta (OI)	
Risperidone	2/28/2007	Janssen	Adolescent-Onset Schizophrenia; Bipolar Disorder	
Ritonavir	6/14/2005	Abbott	HIV-1 Infection	
Rizatriptan	9/20/2011	Merck	Migraine headaches	
Rocuronium	4/3/2008	Organon	Anesthesia	
Rofecoxib	2/18/2004	Merck	JRA	
Rosiglitazone	12/9/2004	SB Pharmco	Type II Diabetes	
Rosuvastatin	7/7/2009	AstraZeneca	Adjunct to diet to reduce cholesterol and ApoB levels	
Rufinamide	1/13/2015	Eisai	Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS)	
Salmeterol	3/9/2006	GSK	Asthma	
Sapropterin	3/13/2014	BioMarin	Reduce blood phenylalanine (Phe) levels in patients with hyperphenylalaninemia (HPA) due to BH4-responsive phenylketonuria (PKU)	
Saquinavir	10/26/2010	Hoffman-La Roche Inc.	HIV-1 Infection	
Sertraline	2/1/2002	Pfizer	Depression	
Sevoflurane	8/2/2000	Abbott	Anesthetic	

Sibutramine	10/6/2004	Abbott	Pediatric Obesity	
Sildenafil	2/9/2012	Pfizer	Pulmonary arterial hypertension (PAH)	
Simvastatin	2/22/2002	Merck	Hypercholesterolemia	
Sirolimus	11/17/2004	Wyeth	Prevention of organ rejection following renal transplantation	
Sodium ferric gluconate complex	3/24/04	Watson	Iron deficiency due to chronic hemodialysis	
Sodium oxybate	10/24/2018	Jazz	Cataplexy in narcolepsy	
Solifenacin	7/20/2017	Astellas	Neurogenic detrusor overactivity (NDO)	
Sotalol	1/6/2000	Berlex Lab	Arrhythmias	
Stavudine	8/13/2001	Bristol-Myers	HIV-1 Infection	
Sumatriptan	2/18/2004	GSK	Migraine	
Sumatriptan/ Naproxen	4/16/2015	GSK/Pernix	Migraine	
Sunitinib	2/7/2019	CP Pharmaceuticals	Refractory solid & CNS tumors	
Tadalafil	11/16/2017	Eli Lilly	Duchenne muscular dystrophy (DMD)	
Tamoxifen	5/16/2002	AstraZeneca	McCune-Albright Syndrome	
Tamsulosin	9/17/2009	Boehringer Ingelheim	Elevated detrusor leak point pressure associated w/ a known neurological disorder (e.g., spina bifida)	
Tavaborole	7/18/2018	Anacor	Onychomycosis of the toenail	

Tbo-filgrastim	7/18/2018	Sicor	Reduction of duration of severe neutropenia in pediatric patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia	
Technetium Tc99 sestamibi	1/11/2008	BMS	Kawasaki's disease	
Teduglutide	3/7/2019	Shire-NPS	Short Bowel Syndrome (SBS)	
Temozolomide	11/20/2002	Schering	Refractory/relapse malignancies	
Temsirolimus	2/28/2012	Pfizer	Treatment of relapsed/refractory solid tumors	
Tenofovir	9/6/2011	Gilead	HIV-1 Infection	
Tenofovir	11/15/2018	Gilead	HBV Infection	A second period of Pediatric Exclusivity was granted for this moiety.
Terbinafine	12/4/2006	Novartis	Tinea capitis	
Testosterone	8/22/2007	Unimed Pharmaceuticals,	Delayed onset of puberty in boys	
Timolol	2/28/2007	Alcon	Elevated intraocular pressure	
Tiotropium	12/14/2016	Boehringer Ingelheim	Asthma	
Tipranavir	3/7/2008	Boehringer Ingelheim	HIV-1 Infection	
Tocilizumab	7/18/2018	Genentech/ Hoffmann-La Roche	Systemic Juvenile Idiopathic Arthritis (SJIA) and Polyarticular Course Juvenile Idiopathic Arthritis (PcJIA)	

Tolterodine	1/5/2004	Pfizer	Detrusor hyperreflexia/ overactive bladder	
Topiramate	7/24/2008	Ortho-McNeil-Janssen Pharmaceuticals, Inc.	Mono- and adjunctive therapy for partial onset or primary generalized tonic-clonic seizures (epilepsy) & adjunctive therapy for seizures associated w/ Lennox-Gastaut syndrome	
Topotecan	11/20/2002	GlaxoSK	Refractory/relapse malignancies	
Trabectedin	6/12/2018	Janssen	Relapsed or refractory solid tumors	
Tramadol	4/19/2000	R.W. Johnson	Post-surgical pain	
Valacyclovir	2/26/2008	GSK	Herpes simplex virus infection	
Valganciclovir	7/24/2008	Hoffman-La Roche Inc.	Cytomegalovirus (CMV) Disease	
Valproic acid	12/14/2007	Abbott	Migraine, Bipolar disorder, Epilepsy	
Valsartan	8/8/2007	Novartis	Hypertension	
Varenicline	11/15/2018	Pfizer	Smoking cessation	
Venlafaxine	12/2/2002	Wyeth-Ayerst	Depression/OCD	
Vigabatrin	10/3/2013	Lundbeck	Intractable Complex Partial Seizures & Infantile Spasm	
Vinorelbine	8/15/2002	GSK	Leukemia/lymphoma	
Zoledronic acid	12/21/2007	Novartis	Severe osteogenesis imperfecta	
Zolmitriptan	12/18/2003	AstraZeneca	Migraine	
Zolpidem	11/20/2006	Sanofi Aventis	Insomnia	