Inter-Agency Agreement Between the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and the U.S. Food and Drug Administration (FDA)

Final Report

The objective of this Interagency Agreement (IAA) was to develop formulation approaches that will provide optimal approaches for pediatric drug delivery. The availability of publically available oral pediatric drug delivery approaches would have the corollary benefit of reducing the unregulated extemporaneous compounding of pediatric dosage forms, using dosage forms designed for adult patient populations, which have been responsible for numerous adverse events in the pediatric patient population. An ideal pediatric dosage form is an orally dissolvable solid; tasteless; in an appropriate dose amount that would be appropriate for pediatric patients, ranging from infant to adolescent; contain minimal amounts of safe excipients; stable in light, humidity and heat; and have the necessary release and stability characteristics, as applicable.

As part of this IAA, a list of about 400 best-selling, commercially available, drug products was compiled. These drug products are available in a wide verity of dosage forms, e.g., tablets, capsules, injections, solutions, suspensions, etc., many of which are also suitable for administration to pediatric patients. However, a large number of these drugs are currently not approved for use in the pediatric patients. Excluding these, and a few combination drug products (i.e., those containing more than one drug), reduced the list to 222 drugs, that has information on pediatric use as part of the approved product label. For these 222 drugs, information of the approved dosage forms and their suitability in pediatric patients was determined using the information available on the FDA (Drugs@FDA) and NIH (DailyMed) websites. 184 out of these 222 drugs are available in one or more orally administered dosage from (tablet, capsule, solution, syrup, elixir, suspension, granules, etc.), with many drugs being available in more than one oral dosage from. A further analysis show tablets to be the most popular dosage form with 154 of these drugs being available as tablet for oral administration (A review of the approved product labeling for these drugs showed a significant variation the pediatric use labeling among these 222 drugs. The minimum age for which these drugs were approved ranged from neonates to 16 years old, while, in some cases, different dosage forms had different minimum age or sometime only select dosage forms were approved for use in the pediatric patient population above a certain minimum age. A list of approved dosage forms, with respective minimum age for pediatric use, for these 222 drugs and the permanent link to prescribing information (Dailymed) is present in Appendix I. An MS Excel file of the list is also enclosed with this report.

The list in Appendix I include drugs that may be administered orally as tablet, capsule, solution, suspension, etc., or via other route of administration, such as, parenteral, topical, ophthalmic, nasal, etc. Some of these dosage forms, e.g., parenteral, capsules, etc. may be difficult to administer to pediatric patients, especially those that are very young. The oral dosage forms that

are most suitable for pediatric patients include chewable tablet, ODT, solution, syrup, suspension and elixir dosage forms. Topical, nasal and ophthalmic dosage forms may also be suitable for use in pediatric patients to treat certain medical conditions. However, only 138 out of these 222 drugs are available in one of these pediatric friendly dosage forms. The availability of these dosage forms for individual drugs has also been identified in Appendix I.

Table 1). Many of these drugs, that are available as tablets, are also available other oral dosage forms, e.g., capsule, solution, syrup, elixir, suspension, chewable tablet, orally disintegrating tablet (ODT), etc (Figure 1).

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The list in Appendix I include drugs that may be administered orally as tablet, capsule, solution, suspension, etc., or via other route of administration, such as, parenteral, topical, ophthalmic, nasal, etc. Some of these dosage forms, e.g., parenteral, capsules, etc. may be difficult to administer to pediatric patients, especially those that are very young. The oral dosage forms that are most suitable for pediatric patients include chewable tablet, ODT, solution, syrup, suspension and elixir dosage forms. Topical, nasal and ophthalmic dosage forms may also be suitable for use in pediatric patients to treat certain medical conditions. However, only 138 out of these 222 drugs are available in one of these pediatric friendly dosage forms. The availability of these dosage forms for individual drugs has also been identified in Appendix I.

Table 1. Available dosage forms for 222 drugs that have pediatric use information as part of product labeling

Dosage Form	Number of Drugs
Tablet (Oral)	154
Injection	78
Capsule (Oral)	65
Solution/Syrup (Oral)	54
Suspension (Oral)	47
Topical	22

Chewable Tablet (Oral)	15
Nasal	12
Ophthalmic	12
Orally Disintegrating Tablet (ODT)	11
Granules/Pellets/Powder (Oral)	10
Rectal	7
Elixir	3
Vaginal	3
Transdermal	3
Sublingual	2

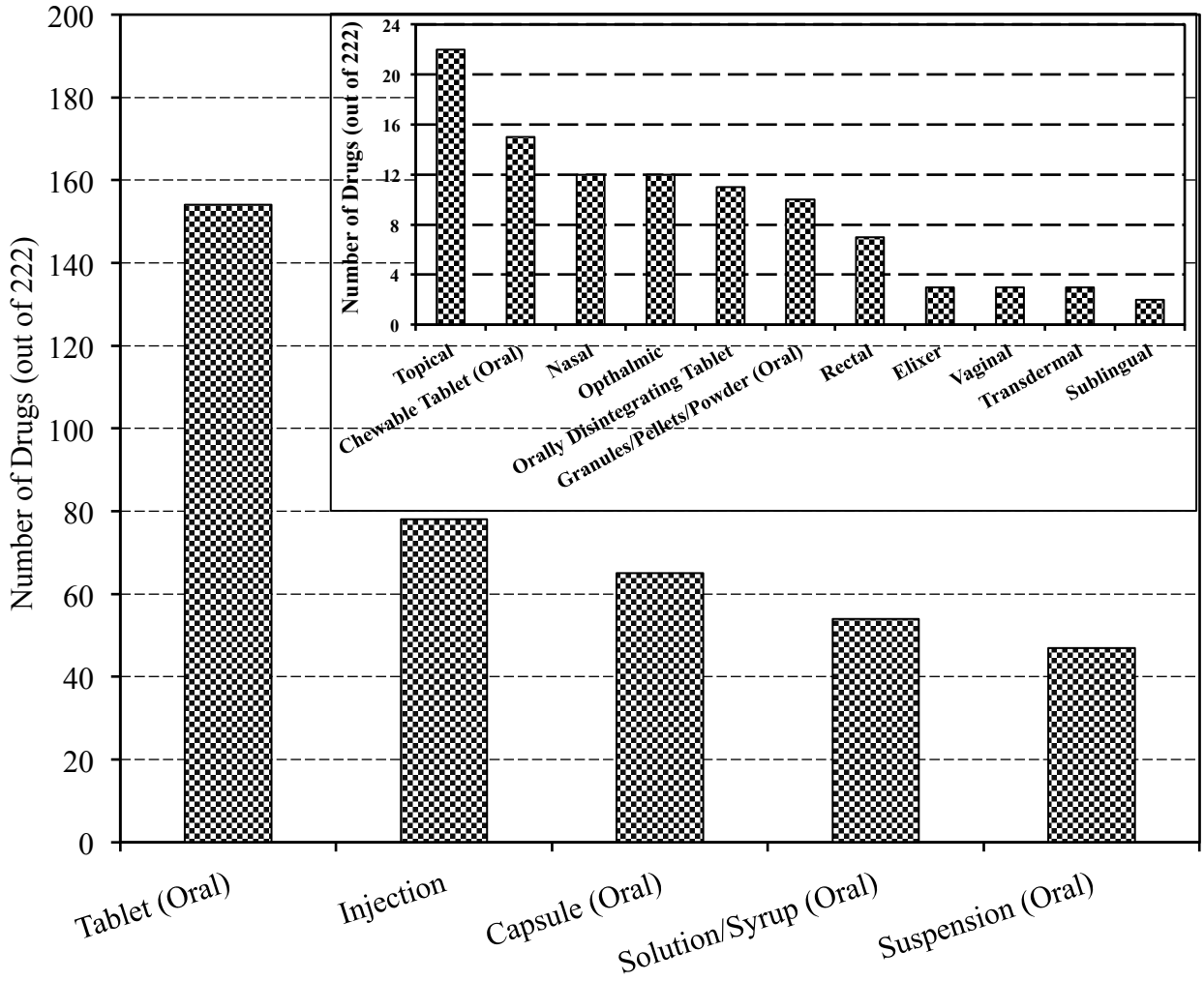

Figure 1. Approved dosage forms for the 222 drugs with pediatric use information in product labeling.

To identify attributes that may be contributing to the ability of a drug to be formulated in a pediatric friendly dosage from, these drugs were categorized based on their molecular characteristics such as solubility, permeability, pH stability, etc. However, no attribute could be identified that may be hindering or contributing to the formulation of a drug in one or more of these pediatric friendly dosage forms. Since the pediatric dosage forms should ideally be tasteless, taste-masking of the drug is essential for oral drug delivery for pediatric patients. Hence, a number of formulation approaches, including various taste-making approaches, were evaluated and used to prepare prototype formulations suitable for pediatric patients. The findings of these studies and the knowledge gained have been published in peer-reviewed scientific journals. A summary of the formulation approaches used is provided below, and the corresponding published manuscript, containing details of the individual formulation approach, is included as an attachment to this report.

The formulation approaches used include:

1. **Taste-masking by complexation**:
   1.1. Abstract: The purpose of the study was to investigate the complexation between a weakly basic drug (risperidone) and an ion exchange resin (amberlite IRP-64) used as a taste-masking agent via two preparation methods: physical mixture and solvent evaporation. Both methods were prepared in different drug-to-resin ratios by weight (1:1, 1:2, 1:4, 1:6). Physicochemical characterizations were performed using differential scanning calorimetry, x-ray diffraction, infra-red spectroscopy, Raman spectroscopy, near infra-red spectroscopy, chemical imaging and drug release studies. These physicochemical techniques revealed that risperidone formed complex with the resin via the solvent evaporation method where enhanced dissolution occurred but not with the physical mixtures. (Published in *Pharm. Dev. Tech.* 2009; 14(4): 409-421).

   1.2. Abstract: The aim of this investigation was to evaluate the complexation potential of brompheniramine maleate (BPM) and tannic acid (TA) for sustained release and taste masking effects. The complexes (1:1‑1:7 TA to BPM ratio) were prepared by the solvent evaporation method using methanol, phosphate buffer pH 6.8 or 0.1 N HCl as common solvents. The complexes were characterized microscopically by scanning electron microscopy (SEM), chemically by Fourier transform infrared (FTIR) and solid-state NMR (SSNMR), thermally by differential scanning calorimetry (DSC), for crystallinity by powder X-ray powder diffraction (PXRD), for organoleptic evaluation by electronic tongue (e-tongue), and for solubility in 0.1 N HCl and phosphate buffer pH 6.8. The dissolution studies were carried out using the USP II method at 50 rpm in 500 ml of dissolution media (0.1 N HCl or phosphate buffer pH 6.8). SEM images revealed that the morphology of complexes were completely different from the individual

components, and all complexes had the same morphological characteristics, irrespective of the solvent used for their preparation, pH or ratio of BPM and TA. The FTIR spectra showed the presence of chemical interactions between the TA and BPM. DSC, PXRD and SSNMR indicated that the drug lost its crystalline nature by formation of the complex. Complexation has significantly reduced the solubility of BPM and sustained the drug release up to 24 h in phosphate buffer pH 6.8 media. The bitter taste of the BPM was completely masked which was indicated by Euclidean distance values which was far from the drug but near to its placebo in the complexes in all ratios studied. The taste masked complexes can be potentially developed as suitable dosage forms for pediatric use. In summary, complexation of BPM and TA effectively sustained the dissolution and masked the bitter taste of drug for the development of suitable dosage forms for pediatric use. (Published in *Int. J. Pharm.* 2012: 422(1-2):91-100).

1.3. Abstract: The focus of present investigation was to evaluate the tannic acid (TA) complexes of cholorpheniramine maleate (CPM) and characterize it by a variety of physicochemical, dissolution, and electronic tongue methods. The complexes were prepared in various molar ratios by solvent evaporation method. They were characterized by spectroscopic, thermal, powder X-ray, electronic tongue, solubility and dissolution methods. FTIR (infrared red) spectra showed complex formation between the TA and CPM. Complex formation has significantly lowered the drug solubility and sustained its release for more than 24 h in phosphate buffer pH 6.8. On the contrary, the release was much faster in the presence of Avicel PH 113 in the same molar ratio complex. The complex formulation has suppressed the bitter taste of CPM as indicated by Euclidean distance in electronic tongue evaluation. NIR-CI (near infrared chemical imaging) showed lower skew value that indicated the homogenous distribution of formulation components. The chemometric models were also developed using the NIR data. The model based on second derivative data was better in predicting the TA and CPM loading as indicated by higher values of R, R2 and lower values of root mean square error and standard errors. Furthermore, it has a better accuracy and less biased in comparison to other models. In conclusion, the CPM tannate has a sustained release behavior and excipients play a major role in modifying its release. Additionally, the complexes with varying molar ratio of tannate to CPM have differential taste masking abilities than that of the pure drug. (Published in *Int. J. Pharm.* 2012: 436(1-2):582-592).

1.4. Abstract: The objective of the present work was to evaluate and characterize a pediatric friendly formulation of a bitter tasting drug, oseltamivir phosphate (drug). Amberlite IRP64 (resin) was used to make ionic complexes for masking its bitterness. Complexes of four drug-toresin ratios, 1:1, 1:2, 1:4, and 1:6 (w/w), were prepared and characterized. At buccal pH of 6.8, drug–resin complexes of 1:1, 1:2, 1:4, and 1:6 ratios released 42.13%, 23.26%, 4.13%, and 14.94%, respectively, of loaded drug after 20 s. However,

at stomach pH of 1.2 (0.1 N HCl), 61.96%, 70.18%, 85.88%, and 91.42% of drug was released from the same complexes in 6 min. Nearinfrared (NIR) chemical imaging of the complexes showed homogeneous distribution of drug in the resin. Chemometric partial least squares model using NIR data of the drug showed a high correlation between calibration and predicted data (R2 > 0.998). Overall, these results indicated the complex formation between drug and resin. The pH dependence of drug release from these complexes could minimize drug release in the mouth, whereas immediately releasing it in the stomach. Electronic tongue used to evaluate taste indicated that conductivity taste signals were different from control, suggesting taste masking of the drug. (Published in *J. Pharm. Sci.* 2013; 102(6):1800-1812).

2. **Niosomes for pediatric dug delivery**:
   2.1. Abstract: A variety of factors were systemically evaluated in order to establish the characteristics of the niosomes obtained with a high-pressure homogenizer. The vesicular sizing parameters, electrical properties, drug entrapment data and drug release characteristics were investigated using two groups of factors. The first group presented the physical process variables such as pressure of the homogenizer and the times that the samples were processed (cycles). The second group encompassed the compositional variables such as the drug loading, surfactant chain length, cholesterol level and the level of the charge imparting agent. The obtained data showed that the drug distributed within both the aqueous and lipid phases of the formed niosomes. Saturation-like behaviors for both the effect of homogenization cycles on the produced size and the effect of the pressure on the size homogeneity were recorded. In contrast to the drug entrapment and conductivity of the niosomal suspension, the vesicular size parameters as well as the zeta potential were inversely proportional with the homogenization parameters. Drug release was significantly affected by the compositional factors rather than the physical ones. The current study demonstrated the usefulness of the microfluidization for the production and further scale-up of anti-HIV niosomes with very small mean vesicular sizes. (Published in *Eur. J. Pharm. Sci.* 2011; 44(1-2): 93-102).

3. **Salt engineering for pediatric dug delivery**:
   3.1. Abstract: The focus of the present investigation was to evaluate the feasibility of using cyclamic salt of lamotrigine in order to improve its solubility and intrinsic dissolution rate (IDR). The salt was prepared by solution crystallization method and characterized chemically by fourier transform infrared spectroscopy (FTIR), proton (1H) and carbon (13C) nuclear magnetic resonance (liquid and solid, NMR) spectroscopy, physically by powder X-ray diffraction (PXRD), thermally by differential scanning calorimetry (DSC) and thermogravimetric analysis (TGA), physicochemically for solubility, IDR, solution and solid-state stability, and polymorphism by solution recrystallization and slurry conversion studies. The FTIR, NMR, PXRD, DSC, and TGA spectra and thermograms

indicated the salt formation. The salt formation increased lamotrigine solubility by 19-fold and IDR by 4.9-fold in water. The solution and solid-state stability were similar to parent molecule and were resistant to polymorphic transformation. In conclusion, cyclamic salt of lamotrigine provides another potential avenue for the pharmaceutical development of lamotrigine with improved physicochemical properties especially for pediatric population. It is also possible that appropriate dosage forms can be formulated with much lower drug amount and better safety profile than existing products. (Published in *AAPS PharmSciTech* 2012; 13(3):793-801).

3.2. Abstract: The aim of present research was to design and evaluate orally disintegrating tablet (ODT) of novel lamotrigine- cyclamate salt. Box‑Behnken response surface methodology was selected to design the optimized formulation. The independent factors selected were tablet hardness (X1), disintegrant (X2) and lubricant (X3) levels, and responses chosen were disintegration time (DT, Y1), friability (Y2), T50 (Y3), and T90 (Y4). The tablets were also characterized for drug uniformity by near infrared chemical imaging (NIR-CI) and taste masking evaluation by electronic tongue. All the selected independent variables were statistically ($p < 0.05$) effect the Y1 while Y2, Y3, and Y4 affected only by X2. The optimized ODT was found to meet the regulatory requirement of DT and friability specification. The NIR-CI images indicated uniform distribution of active and inactive ingredients within the tablets. The electronic tongue results were analyzed by principle component analysis (PCA). It indicated that novel salt of lamotrigine and its ODT formulation have a taste similar to cyclamic acid which is indicated by close proximity on PCA score plot, lower Euclidean distance, and high discrimination index values. Furthermore, these parameters were very close to ODT placebo formulation. On the other hand, lamotrigine, its ODT, and placebo formulation were far from each other. In summary, lamotrigine salt provides another avenue for pediatric friendly formulation for children and will enhance patience compliance. (Published in *Eur. J. Pharm.Biopharm.*2013; 85(3):1300-1309).

4. Taste masking by coating:

4.1. Abstract: The purpose of this research was to develop an orally disintegrating tablet (ODT) dosage form containing taste-masked beads of clindamycin HCl. Several formulation strategies were evaluated and a taste-masked ODT of clindamycin HCl was prepared without the use of a waxy cushioning agent. Clindamycin HCl (ca. 46% w/w) was coated onto microcrystalline cellulose beads (Cellets 200) followed by the addition of a taste-masking layer of amino methacrylate copolymer, NF (Eudragit EPO (EPO)) coating suspension. The efficiency of both the drug coating process and the taste-masking polymer coating process, as well as the taste masking ODTs was determined using potency and drug release analysis. Magnesium stearate was found to be advantageous over talc in improving the efficiency of the EPO coating suspension. A

response surface methodology using a Box–Behnken design for the tablets revealed compression force and levels of both disintegrant and talc to be the main factors influencing the ODT properties. Blending of talc to the EPO-coated beads was found to be the most critical factor in ensuring that ODTs disintegrate within 30 s. The optimized ODTs formulation also showed negligible (50.5%) drug release in 1 min using phosphate buffer, pH 6.8 (which is analogous to the residence time and pH in the oral cavity). By carefully adjusting the levels of coating polymers, the amounts of disintegrant and talc, as well as the compression force, robust ODTs can be obtained to improve pediatric and geriatric patient compliance for clindamycin oral dosage forms. (Published in *Drug Dev. Ind. Pharm.* 2014. DOI 10.310903639045.201, Epub ahead of print).

List of publications:

1. Cantor SL, Khan MA, Gupta A. Development and optimization of taste-masked orally disintegrating tablets (ODTs) of clindamycin hydrochloride. *Drug Dev Ind Pharm.* 2014. . DOI 10.310903639045.201. [Epub ahead of print]
2. Gupta A, Khan MA. Challenges of pediatric formulations: a FDA science perspective. *Int J Pharm.* 2013;457(1):346-8. doi: 10.1016/j.ijpharm.2013.08.064.
3. Rahman Z, Siddiqui A, Khan MA. Orally disintegrating tablet of novel salt of antiepileptic drug: formulation strategy and evaluation. *Eur J Pharm Biopharm*. 2013;85(3 Pt B):1300-9. doi: 10.1016/j.ejpb.2013.06.006.
4. Zajicek A, Fossler MJ, Barrett JS, Worthington JH, Ternik R, Charkoftaki G, Lum S, Breitkreutz J, Baltezor M, Macheras P, Khan M, Agharkar S, MacLaren DD. A report from the pediatric formulations task force: perspectives on the state of child-friendly oral dosage forms. *AAPS J.* 2013;15(4):1072-81. doi:10.1208/s12248-013-9511-5.
5. Siddiqui A, Shah RB, Khan MA. Oseltamivir phosphate-amberlite(TM) IRP 64 ionic complex for taste masking: preparation and chemometric evaluation. *J Pharm Sci.* 2013;102(6):1800-12. doi: 10.1002/jps.23518.
6. Rahman Z, Zidan AS, Khan SR, Reddy IK, Khan MA. Cholorpheniramine tannate complexes: physicochemical, chemometric, and taste masking evaluation. *Int J Pharm*. 2012;436(1-2):582-92. doi: 10.1016/j.ijpharm.2012.07.037.
7. Khan MA, Wu K, Gupta A. FDA: contribution to developing pediatric formulations and transatlantic collaboration. *Int J Pharm*. 2012;435(2):146-8. doi:10.1016/j.ijpharm.2012.05.060.
8. Rahman Z, Zidan AS, Samy R, Sayeed VA, Khan MA. Improvement of physicochemical properties of an antiepileptic drug by salt engineering. *AAPS PharmSciTech*. 2012;13(3):793-801. doi: 10.1208/s12249-012-9800-9.
9. Rahman Z, Zidan AS, Berendt RT, Khan MA. Tannate complexes of antihistaminic drug: sustained release and taste masking approaches. *Int J Pharm*. 2012;422(1-2):91-100. doi: 10.1016/j.ijpharm.2011.10.033.

10. Zidan AS, Rahman Z, Khan MA. Product and process understanding of a novel pediatric anti-HIV tenofovir niosomes with a high-pressure homogenizer. *Eur J Pharm Sci*. 2011;44(1-2):93-102. doi: 10.1016/j.ejps.2011.06.012.
11. Tawakkul MA, Shah RB, Zidan A, Sayeed VA, Khan MA. Complexation of risperidone with a taste-masking resin: novel application of near infra-red and chemical imaging to evaluate complexes. *Pharm Dev Technol*. 2009;14(4):409-21. doi:10.1080/1083745080271266.

Appendix I: List of available dosage forms for drugs with pediatric use information as part of product labeling until Dec 2014.

	Generic Name	Trade Name	BCS Class	Down to Age (years)[1]	Pediatric Dosage Form Available?	Dosage Forms suitable for Pediatric	Tablet (Oral)	Injection	Capsule (Oral)	Solution/Syrup (Oral)	Suspension (Oral)	Topical	Chewable Tablet	Nasal	Ophthalmic	Orally Disintegrating Tablet (ODT)	Granules/Pellets/Powder	Rectal	Elixir	Vaginal	Transdermal	Sublingual	Dailymed Permanent Link to Prescribing Information (http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=)
1	Abacavir Sulfate	Ziagen	3	0.25	Y	Oral Solution	x			x													ca73b519-015a-436d-aa3c-af53492825a1
2	Abatacept	Orencia		6	N			x															0836c6ac-ee37-5640-2fed-a3185a0b16eb
3	Acetaminophen		3	2/Oral 3/Rectal	Y	Oral Solution/ Suspension, Chewable Tablet	x		x	x	x		x					x					0027e3a2-862a-474d-8c33-dda1a2264b27 32bbe845-7f0e-c33d-adb2-659f18fedfa9
4	Acyclovir	Sitavig, Zovirax	3	2 (Sublingual not approved for Ped)	Y	Oral Suspension, Topical	x		x		x	x										x	f94a46a2-2e86-4d98-ec89-9483a41d290a 00f7425a-6236-47ff-a087-f28f8cdb1aec
5	Adalimumab	Humira		4	N			x															608d4f0d-b19f-46d3-749a-7159aa5f933d
6	Albuterol Sulfate	Ventolin HFA Vospire ER	3	2/Syrup 4/Inhalation 6/Oral Tablets	Y	Syrup, Metered Nasal Aerosol	x			x				x									8a9b20e4-82e6-4151-9c9d-39aaf2a767e2 d92c5d6b-ff10-4087-36a2-1cfc464cb967 16efdd16-04db-4874-92de-d1de22aee074
7	Allopurinol	Aloprim, Zyloprim	3	6	N		x	x															10cc918f-aa44-415b-932d-2404695ac449 342832b5-1a32-4bea-bc49-ab0fd152154e
8	Amlodipine Besylate	Norvasc	1	6	N		x																abd6a2ca-40c2-485c-bc53-db1c652505ed
9	Amoxicillin	Amoxil/Trimox	3	0	Y	Oral Suspension, Chewable Tablet	x		x		x		x										4c0f348a-a65d-409c-8668-207c82a5e3cb

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10	Amphetamine Mixed Salts	Adderall	3	3/Tablets 6/Capsule	N		x		x														24af5ced-ed01-4188-95f0-b6b8e4f70aab aff45863-ffe1-4d4f-8acf-c7081512a6c0
11	Aripiprazole	Abilify	2	6	Y	ODT, Oral Solution	x	x		x						x							c040bd1d-45b7-49f2-93ea-aed7220b30ac
12	Aspirin	Halfprin	3	12	Y	Chewable Tablet, Oral Powder	x		x				x				x						46f1c9a8-590f-47db-a060-4be0c59f55ca
13	Atazanavir	Reyataz	2	0.25	N				x														165cff62-b284-4a27-a65d-9ec8a5bfcdd8
14	Atomoxetine Hydrochloride	Strattera	1?	6	N				x														309de576-c318-404a-bc15-660c2b1876fb
15	Atorvastatin Calcium	Lipitor	2	10	N		x																c6e131fe-e7df-4876-83f7-9156fc4e8228
16	Azelastine Hydrochloride	Astelin, Optivar	1	5/Inhalation 3/Opthalmic	Y	Metered Nasal Spray, Ophthalmic								x	x								46b2ddff-d40a-43ac-b027-4fac9fc2f4b9 f4b9597c-5b50-4889-be41-20bd1f13aaa5
17	Azithromycin	Zithromax, Zmax, Azasite,	2	0.5/Oral 1/Opthalmic (Injection not approved for Ped)	Y	Oral Suspension, Ophthalmic	x	x			x				x								db52b91e-79f7-4cc1-9564-f2eee8e31c45 14ae4c07-b042-452a-b069-2b41bc646e04 8d24bacb-feff-4c6a-b8df-625e1435387a
18	Benazepril Hydrochloride	Lotensin	1	6	N		x																4d954024-a191-46e3-ba71-2a7d5b0c65d5
19	Benzonatate	Tessalon	3	10	N				x														8edd07a0-5f5b-9000-bafb-dbf8ff7609d4
20	Benztropine Mesylate	Cogentin	?	3	N		x	x															b707bc17-3ab4-47a9-a83e-ebd1d384a9d8
21	Brimonidine Tartrate	Alphagan	?	2	Y	Topical,						x			x								264c4494-c225-486f-888a-

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		P, Mirvaso				Ophthalmic																	caaf36be46b3 f6a4353f-ae69-4214-901f-e5d42a6fbde7
22	Busulfan	Busulfex, Myleran	?	Not established	N		x	x															5cb9d285-1803-4a99-946a-d0b239b32df6 bf456fc7-3a79-47f7-8acc-600b5e2f0dc2
23	Caffeine Citrate	Cafcit	3	0	Y	Oral Solution		x		x													fbcd234e-57e1-4da2-a96c-e3f7b7cf6ec0
24	Calcitriol	Rocaltrol, Calcijex Vertical	2/4	1/Oral 13/Injection (Topical not approved for Ped)	Y	Oral Solution		x	x	x		x											d1013494-bf62-4e68-9f0c-e6571137f20f 63d26a82-4b79-44ce-52a4-395e4368acd4 a1567da9-af74-4afd-9ac5-8b53ec5d7cbf
25	Canakinumab	Ilaris		2	N			x															7d271f3b-e4f9-4d80-8dcf-28d49123f80e
26	Candesartan Cilexetil	Atacand	2	1	N		x																a73e1339-9643-4eea-2cbe-e879c88fb50e
27	Carbamazepine	Tegretol, Carbatrol	2	6	Y	Oral Suspension, Chewable Tablet	x		x		x		x										536811ab-308b-4866-9185-9e4149483512 bc03e499-5bac-4293-bff4-6864153a624d
28	Cefaclor	Ceclor	3	0.08/Capsule and For Oral Suspension 16/Tablet	Y	Oral Suspension	x		x		x												9f919252-7a87-4386-a64c-5d8213f7e881 0878bdc2-0410-4938-9890-96523aa81c2f
29	Cefadroxil	Duricef	?	0.08	Y	Oral Suspension	x		x		x												4ad759f3-72dd-412e-9500-055335cda6cf
30	Cefdinir	Omnicef	4	0.5	Y	Oral Suspension			x		x												5fb3c464-ab1a-4e2f-ba7a-9aa59b94ca00

	Generic Name	Trade Name	BCS Class	Down to Age (years)[1]	Pediatric Dosage Form Available?	Dosage Forms suitable for Pediatric	Tablet (Oral)	Injection	Capsule (Oral)	Solution/Syrup (Oral)	Suspension (Oral)	Topical	Chewable Tablet	Nasal	Ophthalmic	Orally Disintegrating Tablet (ODT)	Granules/Pellets/Powder	Rectal	Elixir	Vaginal	Transdermal	Sublingual	Dailymed Permanent Link to Prescribing Information (http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=)
31	Cefprozil	Cefzil	?	0.5	Y	Oral Suspension	x				x												3ec55c0a-1456-412e-972f-352b3135c8f2
32	Ceftibuten	Cedax	?	0.5	Y	Oral Suspension			x		x												756d627b-021d-4609-aa08-af6cab80a812
33	Ceftriaxone Sodium	Rocephin	3	0	N			x															9467f6c9-3e59-45c6-a1be-77200f2d4554
34	Cefuroxime Axetil	Ceftin	4	0.25	Y	Oral Suspension	x				x												2f439b86-59d6-4350-aeb4-c904b3781db4
35	Celecoxib	Celebrex	2	2	N				x														8d52185d-421f-4e34-8db7-f7676db2a226
36	Cephalexin	Keflex	4	1	Y	Oral Suspension	x		x		x												19307ff0-71de-477b-965d-ea243e5ede3a
37	Cetirizine Hydrochloride	Zyrtec	1	6	Y	ODT, Chewable Tablet, Syrup	x		x	x			x			x							6a962a1c-c197-492b-bfa6-e0c28eda1533
38	Chloroquine Phosphate	Aralen	1	0.25	N		x																9b585ad5-ae86-4403-b83f-8d8363d43da5
39	Chlorothiazide	Diuril	4	0.08/Oral (Injection not approved for Ped)	Y	Oral Suspension	x	x			x												bd936e35-1af8-42da-bcc0-f22489d68574
40	Ciclesonide	Alvesco		12	Y	Metered Aerosol								x									a1a31258-d164-4369-91f0-52900bbd1509
41	Ciprofloxacin Hydrochloride	Cipro	3	1	Y	Ophthalmic	x	x							x								888dc7f9-ad9c-4c00-8d50-8ddfd9bd27c0
42	Clarithromycin	Biaxin	2	0.5	Y	Oral Suspension	x				x												aa44552c-3cfe-4111-8aa5-4251aeed9be9
43	Clindamycin	Cleocin	1	0	Y	Oral Solution, Topical		x	x	x		x								x			7d72c291-d96f-468d-b3bb-8c255c4906b1
44	Clobazam	Onfi		2	Y	Oral Suspension	x				x												de03bd69-2dca-459c-93b4-541fd3e9571c

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45	Clonazepam	Klonopin	?	1	Y	ODT	x									x							1aef0069-80ea-483d-ac70-c8d485462c5b
46	Clorazepate Dipotassium	Tranxene	?	9	N		x																9c7ab45c-7461-6e4e-ee6d-f0ebe3eb4a28
47	Colesevelam Hydrochloride	Welchol	?	10	Y	Oral Suspension	x				x												4a06d3b2-7229-4398-baba-5d0a72f63821
48	Cyclophosphamide	Cytoxan	3	6	N		x	x	x														367b47d7-c4de-4b39-bd3a-69c29d80396f
49	Dantrolene Sodium	Dantrium	?	5	N			x	x														146f7be7-5cd4-4279-a482-794d0cd554e1
50	Dapsone	Aczone	4	12	Y	Topical	x					x											b7d605cf-bf84-461b-939b-1f773a4cba65
51	Darbepoetin Alfa	Aranesp		1	N			x															0fd36cb9-c4f6-4167-93c9-8530865db3f9
52	Darunavir	Prezista	2	3	N		x				x												814301f9-c990-46a5-b481-2879a521a16f
53	Denosumab	Xgeva		13	N			x															628f0998-1206-4001-aeee-18133aa9f3bf
54	Desloratadine	Clarinex	1	0.5	Y	ODT, Oral Solution	x			x						x							5b79aff4-9bed-429d-8def-a7929293387d
55	Desmopressin Acetate	Stimate, DDAVP	?	1/Nasal 4/Oral	Y	Metered Nasal Spray	x	x						x									30d4c387-b99c-49f8-a8bd-de23fdafb739 1bb9b8d5-eed6-45cb-b1b9-e43d3ee6fecd
56	Desonide	Desonate		0.25	Y	Topical, Elixir						x											8d7c46ed-e6c3-465b-be3d-16ecab43a9e7
57	Dexamethasone	Decadron	1	1	Y	Oral Solution, Elixir, Ophthalmic	x	x		x					x				x				537b424a-3e07-4c81-978c-1ad99014032a
58	Dexmethylphenidate Hydrochloride	Focalin	?	6	N		x		x														7c552f11-e24a-4d9b-bb8d-be10c928eca8

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59	Diazepam	Valium	1	0.08/Injection 0.5/Oral 2/Rectal	Y	Oral Solution	x	x		x								x					7e7dd743-a87b-4ab3-b6ae-f116cd0c8b0f 554baee5-b171-4452-a50a-41a0946f956c 88e0f275-dd7b-447d-b9d3-316a06da934f
60	Diazoxide	Proglycem		0.08	Y	Oral Suspension					x												b16c7832-2fd9-49af-b923-1dc0d91fd6e2
61	Didanosine	Videx	3	0.04	Y	Oral Solution			x	x													d4401ca0-98ae-af38-84c7-2f615d0706b9
62	Digoxin	Lanoxin	3	0	N		x	x															58678fd6-afe3-4a4c-a37f-356444194cd6
63	Diphenhydramine Hydrochloride		1	6	Y	Oral Solution/ Syrup, Elixir, Topical	x	x	x	x		x							x				0b624128-5f68-47b6-b837-81ff6f064ddd
64	Divalproex Sodium	Depakote	?	10	Y	Pellets	x		x								x						4619aff4-0f80-444f-858d-42e4137aa809
65	Docusate	Colace, Diocto, Enemeez	?	2	Y	Oral Solution/ Syrup	x		x	x								x					7793fced-e8ee-44e2-b212-dd2a59a5f462 afac6c3d-a513-4655-9545-3e489f26558a 0b06445d-0839-497e-bdff-e0fe224a7738
66	Dolutegravir Sodium	Tivicay	2	12	N		x																63df5af3-b8ac-4e76-9830-2dbb340af922
67	Doxycycline	Vibramycin	3	8	Y	Syrup, Oral Suspension	x	x	x	x	x												d6f98d3c-5a20-4cbf-9a9c-abef10b9e465
68	Emtricitabine	Emtriva	1	0	Y	Oral Solution			x	x													d6599395-3944-44f9-97f2-e0424c6b6a1f
69	Enalapril Maleate	Epaned, Vasotec	3	0	Y	Oral Solution	x			x													94c9a9d6-957f-4667-8f09-509e99bac777

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																							39631f1f-5d19-43c1-b504-bf56d991ed97
70	Epoetin Alfa	Epogen		0.08	N			x															1f2d0b28-9cc5-4523-80b8-637fdaf3f7a5
71	Ergocalciferol	Calciferol	3/1	0	N				x														0d501431-82d3-4f8e-94c4-5eabcefc00ad
72	Ertapenem sodium	Invanz		0.25	N			x															33f3b99b-fa82-42e0-26bf-f49891ae3d22
73	Erythromycin		1	0.08	Y	Oral Suspension, Topical, Ophthalmic	x		x		x	x			x								b455bbdb-a3f1-470f-aa5f-ed83ac2e228d
74	Erythropoietin	Procrit		0.08	N			x															0c721ba4-ae19-417f-aae1-221ed1a0866a
75	Escitalopram Oxalate	Lexapro	1	6	Y	Oral Solution	x			x													13bb8267-1cab-43e5-acae-55a4d957630a
76	Esomeprazole Magnesium	Nexium	3	0.08	Y	Oral Suspension		x	x		x												f4853677-1622-4037-688b-fdf533a11d96
77	Etanercept	Enbrel		68 lb	N			x															a002b40c-097d-47a5-957f-7a7b1807af7f
78	Ethosuximide	Zarontin	1/3	3	Y	Syrup			x	x													7bf3e616-45e8-4469-a75d-4d824ce951ea
79	Etravirine	Intelence	4	6	N		x																6a9cbc29-9f15-4b24-8d86-206b82887f3d
80	Everolimus	Afinitor		1	Y	Oral Suspension	x				x												2150f73a-179b-4afc-b8ce-67c85cc72f04
81	Ezetimibe	Zetia	2	10	N		x																a773b0b2-d31c-4ff4-b9e8-1eb2d3a4d62a
82	Famotidine	Pepcid	3	0	Y	Oral Suspension, Chewable Tablet	x	x			x		x										4f1a0b58-f7c8-485e-a317-432e1c374d2f
83	Felbamate	Felbatol	2	2	Y	Oral Suspension	x				x												2f522701-397a-11de-8a39-

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																							0800200c9a66
84	Fentanyl	Duragesic, Sublimaze, Actiq, Lazanda, Subsys	?	2/ Transdermal, Injection 16/Oral (Nasal Spray not approved for Ped)	Y	Sublingual, Transdermal	x	x						x							x	x	d7aade83-9e69-4cd5-8dab-dbf1d7b89bb4 8944ea18-016e-4971-876d-2365fac190ea 90b94524-f913-48b3-3771-7b2fcffd888a 9dcaff31-1653-11e3-8ffd-0800200c9a66 18a413e9-11e0-4a8f-86c0-d33b37b7b771
85	Fexofenadine Hydrochloride	Allegra	1	0.5	Y	ODT, Oral Suspension	x				x					x							7c25b695-bbed-4ad1-aa47-de47091bc808
86	Fluconazole	Diflucan	3	0.5	Y	Oral Suspension	x	x			x												f694c617-3383-416c-91b6-b94fda371204
87	Fluocinonide	Lidex		12	Y	Topical						x											95cb19a0-4b71-4c66-92bd-901cfd223301
88	Fluoxetine Hydrochloride	Prozac	1	7	Y	Oral Solution	x		x	x													c88f33ed-6dfb-4c5e-bc01-d8e36dd97299
89	Fluticasone	Cutivate Veramyst Flonase Flovent	?	1/Topical 2/Nasal (furoate salt) 4/Nasal (propionate salt)	Y	Metered Nasal Spray/ Aerosol/ Powder, Topical						x		x									9953df12-a2b4-4d22-b204-746fc29f7a5f f16a9f33-45ca-4e16-0ebe-157b71abb8df d4a424f4-5661-41da-31ae-304d79fd16ad 001f22f8-a83d-495f-9196-d0264ef4d76e
90	Fluvoxamine Maleate	Luvox	1	8 (ER tablets not approved for Ped)	N		x		x														e57814e3-9507-4a2f-858f-a845ad18f029

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91	Folic Acid		3	0	N		x	x															a37e08c3-92cb-4bfb-901f-219c6cdcffe2
92	Fosamprenavir Calcium	Lexiva	2	0.08	Y	Oral Suspension	x				x												24feb9be-32a6-45fd-a896-f3e202edd8a9
93	Fosinopril Sodium		1or3?	6	N		x																3c91edcd-b11a-4289-a1c5-d5054b18f54d
94	Furosemide	Lasix	2	0	Y	Oral Solution	x	x		x													eadfe464-720b-4dcd-a0d8-45dba706bd33
95	Gabapentin	Neurontin	3	3	Y	Oral Solution	x		x	x													ee9ad9ed-6d9f-4ee1-9d7f-cfad438df388
96	Gatifloxacin	Zymaxid	?	1	Y	Ophthalmic									x								1160b16c-929a-4e85-9c0b-1d8c96a7678b
97	Glycerol Phenylbutyrate	Ravicti		2	Y	Oral Solution				x													73bc6b83-2513-11e1-bfc2-0800200c9a66
98	Glycopyrrolate	Cuvposa, Robinul	?	3/Solution (Tablet not approved for Ped)	Y	Oral Solution	x	x		x													d200bd44-9856-4104-a29e-a4cca3db6737 bd65ee5e-2000-423c-b0a6-72eb213455c4
99	Griseofulvin	Gris-peg	2	2	Y	Oral Suspension	x				x												20aa6571-ee10-4dc1-9be9-018aa0a680fc
100	Guanfacine	Intuniv	1	6	N		x																b972af81-3a37-40be-9fe1-3ddf59852528
101	Human Papillomavirus Recombinant	Gardasil		9	N			x															30952400-0572-4431-9150-3a41affffb9a
102	Hydroxychloroquine Sulfate	Plaquenil	2	0.08	N		x																1959d645-6b82-4f4d-b1f2-af644dec7c8f
103	Hydroxyzine	Atarax, Vistaril	2	0.08	Y	Oral Solution/ Syrup, Oral Suspension	x	x	x	x	x												7eaf5043-5c73-47af-904b-8e1fae02af2e c271f97f-040e-492b-9194-

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																							2c8b74675a95
104	Ibuprofen	Advil, Motrin	2	0.5	Y	Oral Suspension, Chewable Tablet	x	x	x		x		x										db5ed801-7a7e-3c83-0172-77f914daaa5a c57f6ded-c0bd-45ae-823a-4c02ce334d98
105	Idursulfase	Elaprase		1.33	N			x															60cba843-5aab-4dd7-96dc-66648d413be3
106	Imatinib Mesylate	Gleevec		1	N		x																211ef2da-2868-4a77-8055-1cb2cd78e24b
107	Imipramine	Tofranil	1	6	N		x	x	x														1827a5aa-733a-49d9-89d9-48ea0367b230
108	Indomethacin	Indocin	2	14	Y	Oral Suspension		x	x		x							x					06de3c9d-63bf-47c1-f78c-4fbdd482928a
109	Infliximab	Remicade		6	N			x															a0a046c1-056d-45a9-bfd9-13b47c24f257
110	Insulin	Novolin R, Novolog, Humalog, Lantus, Levemir		2/(human,aspart,detemir) 3/(lispro) 6/(glargine)	N			x															aee7f1f3-612c-4027-8ce9-4fd1f41eed71 3a1e73a2-3009-40d0-876c-b4cb2be56fc5 d38d65c1-25bf-401d-9c7e-a2c3222da8af c8ecbd7a-0e22-4fc7-a503-faa58c1b6f3f d5e07a0c-7e14-4756-9152-9fea485d654a
111	Irbesartan	Avapro	2	6	N		x																b7f1a9ef-c7bb-465c-e4d7-a41395205cad
112	Isoniazid	Isoniazid	3	0	Y	Oral Solution	x	x		x													db8a3ae7-fb5b-47a9-a9f7-f57cd90501c2
113	Ivermectin	Sklice, Stromecto	2/4	0.5/Topical 33 lb/Oral	Y	Topical	x					x											4c5557cd-c4cf-11df-851a-0800200c9a66

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		I																					681888c9-af79-4b7d-ae80-c3f4f6f1effd
114	Lactulose	Enulose	2?	0.25	Y	Oral Solution				x								x					00c42c5c-d19e-4130-aa08-a8bbd47d3e5b
115	Lamivudine	Epivir	3	0.25	Y	Oral Solution	x			x													786992bd-13a0-4a00-dfb2-6c135ecd349b
116	Lamotrigine	Lamictal	2	2	Y	ODT, Chewable Tablet	x						x			x							d7e3572d-56fe-4727-2bb4-013ccca22678
117	Lansoprazole	Prevacid	2	1	Y	ODT	x		x							x							28ae35c3-bce3-4a63-a4e4-085ffca92aef
118	Laronidase	Aldurazyme		0.5	N			x															a80ac249-cae4-41f3-88bb-344088b20e60
119	Levalbuterol Hydrochloride	Xopenex HFA	?	4	Y	Metered Nasal Aerosol								x									218ab3f0-4d1e-4c33-a7e8-27807f029d83
120	Levetiracetam	Keppra	3	0.08/ Oral (Injection not approved for Ped)	Y	Oral Solution	x	x		x													3ca9df05-a506-4ec8-a4fe-320f1219ab21
121	Levocarnitine	Carnitor	?	0.25	Y	Oral Solution	x	x		x													b2cbc620-59fd-47b6-9e4b-7e3e31533a1c
122	Levocetirizine Dihydrochloride	Xyzal	3	0.5	Y	Oral Solution	x			x													9cc60ce2-2806-4bdf-9b89-b630e8f3a159
123	Levofloxacin	Levaquin	3	0.5	Y	Oral Solution, Ophthalmic	x	x		x					x								a1f01e8e-97e9-11de-b91d-553856d89593
124	Levothyroxine Sodium	Synthroid	1	0	N		x	x															1e11ad30-1041-4520-10b0-8f9d30d30fcc
125	Lidocaine	Lidoderm	1	0 (Patch not approved for Ped)	Y	Topical		x				x									x		f1c40164-4626-4290-9012-c00e33420a33

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126	Linezolid	Zyvox	4	0	Y	Oral Suspension	x	x			x												6e70e63b-bfd5-478d-a8ee-8ba22c9efabd
127	Lisdexamfetamine Dimesylate	Vyvanse	?	6	N				x														704e4378-ca83-445c-8b45-3cfa51c1ecad
128	Lisinopril	Zestril	3	6	N		x																46f17ba7-a78c-4a9e-7597-27654f097bd3
129	Loperamide Hydrochloride	Imodium	4	6	Y	Oral Solution, Chewable Tablet	x		x	x			x										d011ae1a-680c-4476-a489-5407df13648f
130	Loratadine	Claritin	2	2	Y	ODT, Chewable Tablet, Oral Solution	x		x	x			x			x							3e267980-115b-4672-9c4c-0807e475034f
131	Losartan Potassium	Cozaar	1	6	N		x																9199238d-8b24-4ca8-bd24-c200853416f6
132	Lovastatin	Altoprev	2	10	N		x																0a680e13-0356-4e08-a7fe-78b96ba51b9d
133	Mebendazole	Vermox	2	2	Y	Chewable Tablet	x						x										fa778759-2b9a-4446-ba06-d3c486019e79
134	Mefenamic Acid	Ponstel	2	14	N		x																d77e13db-d1b1-4dbf-9de8-80827018cf43
135	Meloxicam	Mobic	2/4	2	Y	Oral Suspension	x				x												676e73fb-51d2-449a-8749-1a7bcc257b11
136	Meperidine Hydrochloride	Demerol	1	Not established but may be used	Y	Oral Solution	x	x		x													6c2b41c3-732c-477f-8790-0eecea43b2da b31d1308-28c3-43f4-e0a6-2f3ed76b8975
137	Mercaptopurine	Purinethol	4	0.08	N		x																f9af557d-37bf-4078-888e-37c086dfc6e9
138	Meropenem	Merrem IV		0.25	N			x															c15e88d3-d903-4e7a-f683-e29f51afa848
139	Metaxalone	Skelaxin	2	12	N		x																7a4163f2-c553-4d14-7e98-

	Generic Name	Trade Name	BCS Class	Down to Age (years)[1]	Pediatric Dosage Form Available?	Dosage Forms suitable for Pediatric	Tablet (Oral)	Injection	Capsule (Oral)	Solution/Syrup (Oral)	Suspension (Oral)	Topical	Chewable Tablet	Nasal	Ophthalmic	Orally Disintegrating Tablet (ODT)	Granules/Pellets/Powder	Rectal	Elixir	Vaginal	Transdermal	Sublingual	Dailymed Permanent Link to Prescribing Information (http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=)
																							d14c5c7f772a
140	Metformin Hydrochloride	Glucophage, Riomet	3	10	Y	Oral Solution	x			x													4a0166c7-7097-4e4a-9036-6c9a60d08fc6 05d4df4b-dfe8-4828-b423-a3d4f2c4114a
141	Methotrexate Hydrochloride	Trexall, Otrexup	3	2	N		x	x															e942f8db-510f-44d6-acb5-b822196f5e8c
142	Methyldopa		3	2	N		x																bb1c7c3f-9e6f-4d0e-aea1-6974558659ef
143	Methylphenidate Hydrochloride	Concerta, Daytrana, Metadate, Methylin, Quillivant XR, Retalin LA	2	6	Y	Oral Solution, Oral Suspension, Chewable Tablet, Transdermal	x		x	x	x		x								x		1a88218c-5b18-4220-8f56-526de1a276cd 2c312c31-3198-4775-91ab-294e0b4b9e7f a6aedc40-5725-4bd3-9037-033746e8599e 09f13452-8f90-426e-9687-d30be75db9d7 e0157005-6e3e-4763-b910-9eb0937608c9 effd952d-ac94-47bb-b107-589a4934dcca
144	Metronidazole	Flagyl	3	0 (Injection not approved for Ped)	Y	Topical	x	x	x			x								x			a2883ca1-5a9a-4259-9d80-46ab67274384
145	Midazolam Hydrochloride	Midazolam	1	0.5	Y	Syrup		x		x													a833c24b-6dca-44d7-a0d6-20012fa1ea77
146	Minoxidil	Loniten	3	1	Y	Topical						x											e29270d6-0a99-4161-918f-26b3fcad548d
147	Mometasone Furoate	Elocon, Asmanex	?	2/Topical 12/Aerosol	Y	Topical, Nasal Aerosol						x		x									43f51e9d-8f80-4aba-9b2f-de36d302f8d6

	Generic Name	Trade Name	BCS Class	Down to Age (years)[1]	Pediatric Dosage Form Available?	Dosage Forms suitable for Pediatric	Tablet (Oral)	Injection	Capsule (Oral)	Solution/Syrup (Oral)	Suspension (Oral)	Topical	Chewable Tablet	Nasal	Ophthalmic	Orally Disintegrating Tablet (ODT)	Granules/Pellets/Powder	Rectal	Elixir	Vaginal	Transdermal	Sublingual	Dailymed Permanent Link to Prescribing Information (http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=)
		HFA, Nasonex																					1f608abd-d414-41e9-89bd-32dd2ef33cb8 12df48a0-fd2e-4e1c-b135-e616a1f31f42
148	Montelukast Sodium	Singulair	1	0.5	Y	Chewable Tablet, Granules	x						x				x						8c166755-7711-4df9-d689-8836a1a70885
149	Mupirocin	Bactroban, Centany	?	0.17	Y	Topical						x											6dd5868f-0bc2-48c8-238b-e857f5bd812f 90cfa2dc-3904-4bd3-b951-dcdb141883bf
150	Mycophenolate Mofetil	CellCept	2	0.25	Y	Oral Suspension	x	x	x		x												37241e87-4af4-4dc3-a1aa-ea6f20d8dc40
151	Mycophenolic Acid	Myfortic	2	5	N		x																eed26501-890d-4ff6-88e7-6dbea4726e53
152	Naproxen	Naprosyn	2	2	Y	Oral Suspension	x		x		x												68848217-03c9-4377-9be6-6f567e629129
153	Nedocromil Sodium	Tilade		3	Y	Ophthalmic									x								2fe8d7ad-2158-4169-94b0-719ad20242b7
154	Nelfinavir Mesylate	Viracept	2	2	Y	Oral Powder	x										x						e72c2bc6-9462-4a2e-8e1d-b97592376cbd
155	Nevirapine	Viramune	2	0.04	Y	Oral Suspension	x				x												5ec05500-6333-4bd0-ac83-464fad0d5162
156	Nitazoxanide	Alinia		1/Oral suspension 12/Oral Tablet	Y	Oral Suspension					x												56b1575a-dff4-4c5a-a159-2f858e7a0cb8
157	Nitrofurantoin	Furandantin Macrobid, Macrodantin	2	0.08	Y	Oral Suspension			x		x												6bdf87ae-daf1-4912-9d45-e06fa9eaaf1a 1971e893-5fdb-41e3-a1e9-5e52deed03d1 ec86b651-d77d-4a42-b493-

	Generic Name	Trade Name	BCS Class	Down to Age (years)[1]	Pediatric Dosage Form Available?	Dosage Forms suitable for Pediatric	Tablet (Oral)	Injection	Capsule (Oral)	Solution/Syrup (Oral)	Suspension (Oral)	Topical	Chewable Tablet	Nasal	Ophthalmic	Orally Disintegrating Tablet (ODT)	Granules/Pellets/Powder	Rectal	Elixir	Vaginal	Transdermal	Sublingual	Dailymed Permanent Link to Prescribing Information (http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=)
																							24244456b3f6
158	Nystatin	Nystain	4	0	Y	Oral Suspension, Topical	x				x	x								x			c9e28323-21fa-4547-b70c-27dc13a5bd7e
159	Olanzapine	Zyprexa	2	13	Y	ODT	x	x								x							d5051fbc-846b-4946-82df-341fb1216341
160	Olmesartan Medoxomil	Benicar	?	6	N		x																33770d80-754f-11de-8dba-0002a5d5c51b
161	Olopatadine Hydrochloride	Pataday, Patanase,	3/1	2/Opthalmic 6/Inhalation	Y	Metered Nasal Spray, Ophthalmic								x	x								e1eb5130-e59d-4590-8b04-7b1a6adae5bd c4cffabd-774b-4cfd-b312-c86cf5206402
162	Omalizumab	Xolair		12	N			x															7f6a2191-adfb-48b9-9bfa-0d9920479f0d
163	Omeprazole	Prilosec	2	1	Y	Granules, Oral Suspension	x		x		x						x						a1b077e6-b070-43f2-a98e-380cc635419d
164	Ondansetron Hydrochloride	Zofran	3/1	4/Oral 0.08/Injection	Y	Oral Solution, ODT	x	x		x						x							c7d61d98-fe86-4340-9b86-47eb92acaa0e d9a71b42-ddfc-49d5-7280-0fc0041dba41
165	Oseltamivir Phosphate	Tamiflu	1/3	1	Y	Oral Suspension			x		x												ee3c9555-60f2-4f82-a760-11983c86e97b
166	Oxaprozin	Daypro	2	6	N		x																ea1de47e-3101-4414-817c-0a098af8988c
167	Oxcarbazepine	Trileptal	4	2	Y	Oral Suspension	x				x												4c5c86c8-ab7f-4fcf-bc1b-5a0b1fd0691b
168	Oxcarbazepine	Oxtellar XR	4	6	N		x																aa610e56-1d1d-11e1-8bc2-0800200c9a66
169	Paliperidone	Invega		12/Oral (Injection not approved for	N		x	x															7b8e5b26-b9e4-4704-921b-3c3c0d159916 1af14e42-951d-414d-8564-

	Generic Name	Trade Name	BCS Class	Down to Age (years)[1]	Pediatric Dosage Form Available?	Dosage Forms suitable for Pediatric	Tablet (Oral)	Injection	Capsule (Oral)	Solution/Syrup (Oral)	Suspension (Oral)	Topical	Chewable Tablet	Nasal	Ophthalmic	Orally Disintegrating Tablet (ODT)	Granules/Pellets/Powder	Rectal	Elixir	Vaginal	Transdermal	Sublingual	Dailymed Permanent Link to Prescribing Information (http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=)
				Ped)																			5d5fce138554
170	Pancrelipase	Creon, Pancreaze (Not interchangeable)	?	0.33/Creon 0.5/Pancreaze (Tablets not approved for Ped)	N		x		x														073201aa-556d-4a70-918e-84e9616fd88d e1431edd-0fc5-4ebc-8c10-53deb0db0d23 d85c7e20-4e1d-43cd-a64b-ced3bda70eed
171	Pantoprazole Sodium	Protonix	3	1/ Oral (Injection not approved for Ped)	Y	Oral Suspension	x	x			x												08098cb2-c048-4640-f387-6beec4a38936
172	Penicillin vK	Betapen-VK, Pen-Vee K	3/1	0	N		x																012d46f1-d0a0-4676-a879-cd320297ab16
173	Perampanel	Fycompa		12	N		x																71cf3309-e182-473c-8b0b-280cabd0e122
174	Phenytoin Sodium	Dilantin	2	0.08	Y	Oral Suspension, Chewable Tablet	x	x	x		x		x										051742b5-b0f0-44a5-8d31-3288527b0638
175	Pneumococcal 13-Valent Conjugate	Prevnar 13		0.12	N			x															5d49181b-b974-a5da-3b38-12a3a87bb96b
176	Pravastatin Sodium	Pravachol	1	8	N		x																897ad8b7-921d-eb02-a61c-3419e662a2da
177	Prednisolone	Orapred	1	2	Y	Syrup, ODT, Oral Suspension, Ophthalmic	x	x		x	x				x	x							1e379543-c4cf-4e72-953b-db15b7f0c2a1
178	Prednisone	Rayos	1?	2	Y	Oral Solution	x			x													281ab967-7565-4bef-9c0c-a646589c671e
179	Primidone	Mysoline	2	0.08	N		x																af593171-dabb-4ea3-b44c-89ed457b2c46
180	Prochlorperazine	Compazine	2	2	N		x	x										x					95b54f0a-5e38-4bfa-8c5e-f9c826774da0

	Generic Name	Trade Name	BCS Class	Down to Age (years)[1]	Pediatric Dosage Form Available?	Dosage Forms suitable for Pediatric	Tablet (Oral)	Injection	Capsule (Oral)	Solution/Syrup (Oral)	Suspension (Oral)	Topical	Chewable Tablet	Nasal	Ophthalmic	Orally Disintegrating Tablet (ODT)	Granules/Pellets/Powder	Rectal	Elixir	Vaginal	Transdermal	Sublingual	Dailymed Permanent Link to Prescribing Information (http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=)
181	Promethazine Hydrochloride	Phenergan	1	2	Y	Syrup	x	x		x								x					6f7e47cc-f823-4336-8107-f980e3049617
182	Pyrazinamide	Pyrazinamide	3	2	N		x																257bd8cf-74d7-45db-bf25-354a8d26634e
183	Pyrimethamine	Daraprim	4/2	0	N		x																3e4d5027-7939-480f-ae19-82e764d9fa97
184	Quetiapine Fumarate	Seroquel	2	10	N		x																0584dda8-bc3c-48fe-1a90-79608f78e8a0
185	Quinidine		1	0.08	N		x	x															11d14362-8f69-4c30-b487-5d05f6462bd7
186	Rabeprazole Sodium	Aciphex	1/3	1	Y	Granules	x		x								x						5d103551-978f-472a-9c62-51e6e4dea068
187	Raltegravir	Isentress	2/4	0.08	Y	Oral Suspension, Chewable Tablet	x				x		x										89a5ec53-d956-4329-8004-0f40f51c88a3
188	Ranitidine Hydrochloride	Zantac	3	0.08	Y	Syrup	x	x	x	x													08010bf7-1f61-48b3-e1b5-7cecb72ba863
189	Retapamulin	Altabax		0.75	Y	Topical						x											7acc17e7-7041-46bf-f2b2-a615cbf99da6
190	Ribavirin	Virazole, Rebetrol, Copegus	3	0/Inhalation 3/Capsule and Solution 5/Tablet	Y	Inhalation Solution, Oral Solution	x		x	x				x									adf16e64-345f-469a-b987-3fbdd17e0ac2 04d2b6f4-bd9b-4871-9527-92c81aa2d4d0 d370635f-5530-4d42-a019-d76b61639787
191	Rifampin	Rifadin	2	0.08	N			x	x														036ab68e-5085-4edc-bd83-784b43d64eab
192	Rifaximin	Xifaxan		12	N		x																c5e8e2fd-7087-4b78-9181-cc259c0be2f1
193	Risperidone	Risperdal	2	5 (Injection not	Y	Oral Solution, ODT	x	x		x						x							7e117c7e-02fc-4343-92a1-230061dfc5e0

	Generic Name	Trade Name	BCS Class	Down to Age (years)[1]	Pediatric Dosage Form Available?	Dosage Forms suitable for Pediatric	Tablet (Oral)	Injection	Capsule (Oral)	Solution/Syrup (Oral)	Suspension (Oral)	Topical	Chewable Tablet	Nasal	Ophthalmic	Orally Disintegrating Tablet (ODT)	Granules/Pellets/Powder	Rectal	Elixir	Vaginal	Transdermal	Sublingual	Dailymed Permanent Link to Prescribing Information (http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=)
				approved for Ped)																			bb34ee82-d2c2-43b8-ba21-2825c0954691
194	Ritonavir	Norvir	2	0.08	Y	Oral Solution	x		x	x													2849298e-de6e-47bb-8194-56e075b33fc3
195	Rosuvastatin Calcium	Crestor	3	10	N		x																bb0f3b5e-4bc6-41c9-66b9-6257e2513512
196	Rufinamide	Banzel		4	Y	Oral Suspension	x				x												0a3fa925-1abd-458a-bd57-4ae780a1ef2d
197	Sertraline Hydrochloride	Zoloft	1	6	Y	Oral Solution	x			x													fe9e8b7d-61ea-409d-84aa-3ebd79a046b5
198	Simvastatin	Zocor	2	10	N		x																fdbfe194-b845-42c5-bb87-a48118bc72e7
199	Sodium Bicarbonate		1	2	Y	Oral Powder	x	x									x						79ddec3b-ef04-425d-478f-76f6b54a22a5
200	Sotalol Hydrochloride	Betapace	1	0	N		x																c4caf469-f684-4f6d-98e8-b6a2fff1de98
201	Stavudine	Zerit	1,3	0	Y	Oral Solution			x	x													7745cad8-720d-4755-87c7-9147c0915b0f
202	Sulfasalazine	Azulfidine	2,4	2	N		x																ddbe69f3-bd55-45f3-a64f-f60226c744c4
203	Tacrolimus	Prograf, Protopic	2	2	Y	Topical		x	x			x											7f667de1-9dfa-4bd6-8ba0-15ee2d78873b 8c2e5036-5f1b-4e71-bf87-5faef295fa96
204	Tenofovir Disoproxil Fumarate	Viread	3	2	Y	Oral Powder	x										x						33fd6418-fbdc-42ca-a50d-ce2a476a5418
205	Terbinafine Hydrochloride	Lamisil	1	4/Granules 12/Topical	Y	Granules, Topical	x					x					x						bc7d43f0-8a4a-4d40-b0fd-70a37dc5faad de5def4a-f77f-4ea6-a497-24f041c1f123

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206	Tetracycline Hydrochloride	Achromycin V, Acnecycline	3	8/Oral ?/Topical	Y	Topical			x			x											eaecd9a1-e13e-49b1-8b3c-8e1ef016cacd 3a5e4a8e-20bb-4bf8-8a2e-8dfd7f2afb49
207	Theophylline	Elixophyllin	3,1	0	Y	Oral Solution, Oral Suspension, Elixir	x	x	x	x									x				2676f761-4fe5-40a9-a07d-ed2542847883
208	Thiamine Hydrochloride		3	0	N			x															c3c9db74-95d4-487c-90c3-c810786fbaec
209	Tinidazole	Tindamax		3	N		x																a0d01539-8413-4703-94cc-d221918630a1
210	Tipranavir	Aptivus	2	2	Y	Oral Solution			x	x													08982e49-d2eb-4b25-b01a-1be52fd669ef
211	Tobramycin	Tobi	?	6	Y	Inhalation Solution/ Powder								x									94f9e516-6bf6-4e30-8dde-8833c25c2560
212	Tocilizumab	Actemra		2	N			x															2e5365ff-cb2a-4b16-b2c7-e35c6bf2de13
213	Tolmetin Sodium		2	2	N		x		x														6e0228a8-e3d3-4ae9-8873-d7aa3e0dcfee
214	Topiramate	Topamax, Qudexy XR, Trokendi XR	3	2	Y	Pellets	x		x								x						21628112-0c47-11df-95b3-498d55d89593 46f54677-3a22-4c38-9b92-923020164e15 2dc7957e-a3e5-46bb-aa66-f3250f872f5e
215	Triamcinolone Acetonide	Kenalog-40, Kenalog, Nasacort	4	0.08/Injection 2/Inhalation (Not Established for Topical)	Y	Nasal Aerosol, Metered Nasal Spray		x				x		x									ec04ecbb-2896-3feb-85fd-a64aba93b289 cdf6c80c-ddbd-498f-8897-3c0feebafe31 f0dbc2a3-ca5e-428f-a2e5-0ce0bf954dd1

	Generic Name	Trade Name	BCS Class	Down to Age (years)[1]	Pediatric Dosage Form Available?	Dosage Forms suitable for Pediatric	Tablet (Oral)	Injection	Capsule (Oral)	Solution/Syrup (Oral)	Suspension (Oral)	Topical	Chewable Tablet	Nasal	Ophthalmic	Orally Disintegrating Tablet (ODT)	Granules/Pellets/Powder	Rectal	Elixir	Vaginal	Transdermal	Sublingual	Dailymed Permanent Link to Prescribing Information (http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=)
216	Trifluridine	Viroptic		6	Y	Ophthalmic									x								f3a14d86-0ff2-4535-318c-ac8bc8ede42c
217	Valacyclovir Hydrochloride	Valtrex	3	2	N		x																f8e0d8f8-cb73-4206-a484-88f5c4fbd719
218	Valganciclovir	Valcyte	3	0.25	Y	Oral Solution	x			x													dc548ff9-e8ea-4d6e-b9b4-e31f53ac4078
219	Valproic Acid	Depakene	1,2	1	Y	Syrup			x	x													6b4331f5-4475-417a-6a9d-09c2f8334235
220	Valsartan	Diovan	2	6	N		x																5ddba454-f3e6-43c2-a7a6-58365d297213
221	Vigabatrin	Sabril		10	Y	Oral Solution	x			x													a88ac1b4-e2c9-45c0-b321-4785902172e3
221	Vigabatrin	Sabril		10	Y	Oral Solution	x			x													a88ac1b4-e2c9-45c0-b321-4785902172e3
222	Zidovudine	Retrovir	1,3	0.08	Y	Syrup	x	x	x	x													6df09f15-b102-431c-adde-d7aeef6f5d84

Table last updated on: Dec 28, 2014

[1]?: Minimum age not established but may be used in pediatrics; 0.04: 2 weeks; 0.08: 4 weeks or 1 month; 0.12: 6 weeks; 0.17: 2 months;

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