

THE TEDDY BEAR BOOK

Pediatric Injectable DRUGS

TENTH EDITION

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Dedication

This edition is dedicated to our families who sacrificed a tremendous amount of “quality time” to make it possible for us to participate in this project. We are forever indebted to them, and to our friends and loved ones for their patience, encouragement, motivation, and endless support.

Publisher's Note



This QR code will enable you to check for any updates or corrections that have been issued on this edition as well as information about the forthcoming mobile app. You can also visit www.ashp.org/teddybear to access updates, corrections, and information about the forthcoming mobile app.

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Preface

In the late 1930s, elixir sulfanilamide was marketed for the treatment of streptococcal infections. The poor solubility of the antibiotic made it difficult to create a liquid formulation; hence, the medication was mixed with diethylene glycol. Although the company tested the raspberry-flavored product for palatability, it was not tested for safety before distribution. *Unfortunately*, more than 100 individuals, including many children, died following its ingestion. In 1949, intravenous chloramphenicol, a bacteriostatic antimicrobial, became an important agent in the treatment of a variety of pediatric infectious diseases. *Unfortunately*, the medication caused significant vomiting, ashen-gray color of the skin, limp body tone, distended abdomen, hypotension, and cardiovascular collapse. This phenomenon, termed *gray-baby syndrome*, resulted in the death of hundreds of newborns who lacked the hepatic enzymes (i.e., UDP-glucuronyl transferase) necessary to metabolize large doses of the medication and the required renal maturity to excrete the unconjugated drug. Thalidomide was introduced in the late 1950s as a sleeping pill but was quickly noted to prevent nausea and vomiting during early pregnancy. *Unfortunately*, it was subsequently found to cause significant birth defects and was removed from the market. In 1983, the intravenous vitamin E supplement, E-Ferol, was marketed. *Unfortunately*, within 3 months, its use was associated with ascites, liver and renal failure, thrombocytopenia, and death in low birth weight infants. This tragedy was ultimately attributed to the polysorbates added as emulsifiers; a new drug application had not been submitted to the Food and Drug Administration (FDA) prior to use. *Unfortunately*, there are other noteworthy therapeutic disasters including valproate hepatotoxicity in young children, aspirin and Reye syndrome, benzyl alcohol and fatal gasping syndrome, and the list goes on. The negative effects of these therapeutic disasters have led to more structured drug regulations and control over drug use and development including passage of the 1938 Federal Food, Drug, and Cosmetic Act.

Regardless of profession, those practicing in pediatrics understand that the vast majority of medications given are used off label. In fact, as much as 75% of all medications used in this population are not approved by the FDA for use in either the specific age group or disease for which it is administered. Despite the National Institutes of Health's creation of the Pediatric Pharmacology Research Units (PPRUs) and the FDA Modernization Act (FDAMA), much of the necessary research to validate safety and efficacy of medications has yet to be conducted in all pediatric populations. The impact of FDAMA has been important as more than 100 industry-sponsored studies have been conducted, but much of the effort has not included premature and full-term neonates and infants.

The reasons for lack of information and subsequent FDA approval is multifactorial and relates to priorities in pharmaceutical industry and federal funding, the belief that we need to protect our most vulnerable from medication-associated harm, and ethical considerations such as voluntary participation and informed consent/assent, which in many cases is not possible to obtain due to the patient's young age. All stakeholders must continue to proactively discuss the issues that surround drug research and prevention of therapeutic misadventures in the pediatric population.

The tenth edition of *Pediatric Injectable Drugs (The Teddy Bear Book)* has three new editors. Collectively, these editors bring 75 years of pediatric pharmacy practice experience to the book and represent the practice approaches and philosophies of three different institutions. Beyond general pediatric pharmacotherapy, the specific expertise of the editors includes critical care medicine, hematology and oncology, infectious diseases, and neurology.

This edition of *Pediatric Injectable Drugs (The Teddy Bear Book)* has been revised to include 238 parenteral medications. Twenty new monographs, some of which are newly marketed drugs, have been added. Previously published monographs have been extensively reviewed and updated to include the most recent literature available. Information included in this text was compiled in an evidence-based manner from, in most cases, the primary literature

including case reports, observational reports, and comparative trials. Limited information is available for some of the frequently used older drugs in which case recommendations may come from textbooks. Importantly, the references are provided in the back of the book according to generic drug names, thereby allowing readers to access the source of the information provided and make independent decisions related to their specific patients.

With this edition, *Pediatric Injectable Drugs (The Teddy Bear Book)* will also be available as both a mobile app and as an eBook. For information on the mobile app, go to www.ashp.org/teddybear. The eBook version of *Pediatric Injectable Drugs (The Teddy Bear Book)* can be purchased through ASHP eBooks (ebooks.ashp.org) or from Amazon Kindle, the Apple iBookstore, or Barnes & Noble Nook.

We hope that this text improves your ability to safely and effectively use medications in all members of the pediatric community and that ultimately the information contained in this reference will not only facilitate their recovery, enhance their quality of life, and prevent *unfortunate* therapeutic misadventures, but also enable you to sleep better at night.

Stephanie J. Phelps
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2013

Introduction

The following guidelines were developed to provide a single authoritative source of information on the parenteral administration of medications to pediatric patients. All recommendations should be individualized in accordance with the clinical situation.

This tenth edition of ASHP's *Pediatric Injectable Drugs* has been updated to improve existing sections and to make them more user-friendly through their placement in the monograph and with the addition of more specific subheadings. The tenth edition provides the following information for updates to 238 drugs and all references that support information contained in the text.

Brand names	Common brand names and, if applicable, other names (synonyms) are listed.
Medication error potential	If the drug was included in the ISMP's <i>List of High-Alert Medications</i> , ISMP's <i>List of Confused Drug Names</i> , or the USP's <i>Findings of Look-alike and/or Sound-alike Drug Errors</i> at the time the monograph was written, it will be noted in this section. Tall man letters, per FDA and ISMP recommendations, will be used in this section, as well as in the monograph title and in the title in the references, if applicable.
Contraindications and warnings	While it may be noted in the monographs, it is understood that a drug would be contraindicated in a patient who has experienced a prior anaphylaxis or type I hypersensitivity reaction. U.S. Boxed Warnings, Contraindications, and Other Warnings, if applicable, will be described under subheadings in this section. The Other Warnings subheading will describe warnings deemed noteworthy and may not be the complete list of warnings included in the manufacturer's labeling. It is recommended to review the labeling for the most complete list.
Infusion-related cautions	Warnings are provided where appropriate. If a drug requires premedication or if the administration of the drug necessitates the availability of another drug (i.e., to have on hand), information regarding premedication or the drug to have on hand will be provided in this section. If a drug should be given only via central access, this will be noted here. If a drug carries an increased risk of thrombophlebitis, infiltration, or extravasation, it will be noted in this section. Appendix E provides information regarding extravasation treatment for medications known to cause effects from infiltration or extravasation.
Dosage	<p>Unless otherwise specified, dosages are for all age groups. These age groups are as follows: neonates (premature and term), up to 1 month; infants, 1–24 months; children, 2–12 years, and adolescents, 12–18 years. When applicable, <i>adult</i> dosing is also provided. While these age groups provide general guidelines for therapy in pediatric patients, it should be noted that changes in development, which affect drug pharmacokinetics and pharmacodynamics, and hence, dosing recommendations, are not confined to the limits of these defined age groups.</p> <p>Dosage is often expressed as X mg/kg/day divided q Y–Z hours, where the total daily dose (X) is given in equally divided doses at evenly spaced intervals. Dosage may also be expressed as X mg/m²/day divided q Y–Z hours, a calculation of body surface area (BSA) as determined from height and mass. See Appendix A for a BSA nomogram.</p> <p>The presence of obesity may require the practitioner to estimate ideal body mass/weight and calculate an adjusted weight for the dosing of some medications. Appendix B provides a nomogram for estimating total body mass/weight.</p>
Dosage adjustment in organ dysfunction	Drugs requiring dosage adjustment in patients with renal or hepatic dysfunction and serum drug concentration monitoring are indicated. The manufacturer's labeling and specialized references are provided when available. Information, if known, will also be included about dosage adjustment or therapeutic drug monitoring with dialysis, continuous renal replacement therapy, and with extracorporeal membrane oxygenation.



Maximum dosage

Maximum dosages are referenced to primary literature where available. However, maximum dosages for pediatric patients are often extrapolated from *adult* data because of a lack of documented experience with pediatric patients. Many manufacturers caution against exceeding the maximum recommended *adult* dosage (usually expressed as X g/day) in pediatric patients. In this reference, when the maximum dosage is expressed as "mg/kg/day, not to exceed X g/day," "X g/day" is typically the manufacturer's maximum recommended *adult* dosage and should be used only as an upper limit for pediatric dosing. It should not be inferred that use of these maximum dosages in pediatric patients is recommended and is without risk of toxicity. Readers should consult the references indicated for information on the use of these maximum dosages in the pediatric population.

Additives

Pertinent additives, including sodium and those with a potential for toxicity or adverse effects, are listed. Please see Appendix C for specific information on common additives with a potential for toxicity or adverse effects.

Suitable diluents

If a drug can be mixed or diluted with a fluid, the appropriate fluids will be listed here. Compatible drugs will NOT be listed.

Drug stability in some of the IV solutions listed is limited. The manufacturer's labeling and specialized references (e.g., Trissel LA. *Handbook on Injectable Drugs*. 17th ed. Bethesda, MD: American Society of Health-System Pharmacists; 2013) should be consulted for detailed stability information.

Maximum concentration

Generally, any concentration up to the maximum may be administered, taking into consideration the patient's fluid status (and potential for loss of vascular access), administration method (IV push vs. intermittent infusion), drug administration rate (and drug administration device flow rate range, if applicable), dose (and degree of accuracy required in dose measurement), and drug stability. However, some drugs, as indicated in these guidelines, should not be diluted.

For drugs available as solutions that may be administered undiluted, the maximum concentration is the commercially available concentration. For drugs that must be reconstituted prior to administration, the maximum concentration should serve as a guide for the minimum dilution required.

Concentrations listed are referenced to literature on drug use in pediatric patients to the extent possible. However, concentrations administered to *adults* are cited where documentation on use in pediatric patients is insufficient. The references should be consulted. The IV Push, Intermittent Infusion, Continuous Infusion, and Other Routes of Administration sections all begin with information concerning the concentration or concentration range usual for that method or route of administration.

Preparation and delivery

When pertinent, issues related to preparation and delivery are included in this section and, if applicable, will be described under the following subheadings: Preparation, Delivery, Stability, Compatibility, and Photosensitivity. If a drug has information regarding compatibility with parenteral nutrition solutions, a statement will be included. Appendix D provides information regarding compatibility of medications with parenteral nutrition solutions.

IV push

This rate is generally expressed as a period of time over which the dose should be administered (seconds or minutes) or as a quantity of drug per unit of time. In the latter case, the size of the dose determines the administration time. For the purpose of this text, IV push is defined as <5 minutes. Drugs for which IV push administration is contraindicated are noted.

Intermittent infusion

The recommended infusion rate is expressed as a period of time over which the dose should be administered (minutes to hours) or as a quantity of drug per unit of time (size of dose determines administration time).



Continuous infusion

The recommended infusion rate is usually expressed as a quantity of drug per unit of time; infusion is continued for 24 hours unless otherwise specified (e.g., until the desired therapeutic endpoint is achieved).

Other routes of administration

This section contains information on the appropriateness of other routes of administration, including IM, SC, ET, IT, and IO administration and the best site for administration. The terms *contraindicated* and *not recommended* will be used. *Contraindicated* implies that you do not administer the drug in that manner. *Not recommended* implies that it may have been administered in that manner, but it is not recommended to administer it in that manner. Drugs for which other routes of administration are contraindicated are noted.

Comments

Miscellaneous information is included when pertinent. Information pertaining to *adults* is sometimes included because, in the absence of reports on pediatric use, *adult* data may be relevant and may be cautiously extrapolated to the pediatric population.

When applicable, the following subheadings may be included in the comments section: Significant Adverse Effects, Rare Adverse Effects, Monitoring, Drug Interactions, Pharmacokinetic Considerations, Pharmacodynamic Considerations, Laboratory Interference, Osmolality, and Other.

Abbreviations

Solutions:

ABS	acrylonitrile, butadiene, and styrene
BW	bacteriostatic water for injection
D-LR	dextrose—Ringer’s injection, lactated, combinations
D-R	dextrose—Ringer’s injection combinations
D-S	dextrose—saline combinations
D10NS	dextrose 10% in sodium chloride 0.9%
D10W	dextrose 10% in water
D15W	dextrose 15% in water
D20W	dextrose 20% in water
D2.5W	dextrose 2.5% in water
D2.5½NS	dextrose 2.5% in sodium chloride 0.45%
D5LR	dextrose 5% in Ringer’s injection, lactated
D5NS	dextrose 5% in sodium chloride 0.9%
D5¼NS	dextrose 5% in sodium chloride 0.225%
D5⅓NS	dextrose 5% in sodium chloride 0.3%
D5½NS	dextrose 5% in sodium chloride 0.45%
D5R	dextrose 5% in Ringer’s injection
D5S	dextrose 5% in sodium chloride 0.9%, 0.45%, 0.3%, or 0.225%
D5W	dextrose 5% in water
LR	Ringer’s injection, lactated
NS	sodium chloride 0.9% (normal saline)
¼NS	sodium chloride 0.225% (¼ normal saline)
⅓NS	sodium chloride 0.3% (⅓ normal saline)
½NS	sodium chloride 0.45% (½ normal saline)
R	Ringer’s injection
SW	sterile water for injection

Terms:

AAP	American Academy of Pediatrics
ABCD	amphotericin B colloidal dispersion
ABS	acrylonitrile, butadiene, and styrene
ABW	actual body weight
ACCP	American College of Chest Physicians
ACLS	advanced cardiovascular life support
ACT	activated clotting time
ACTH	adrenocorticotrophic hormone
ADH	antidiuretic hormone
AED	antiepileptic drug
AHA	American Heart Association
AHF	antihemophilic factor
AIDS	acquired immunodeficiency syndrome
ALL	acute lymphocytic leukemia

xx Abbreviations

ALT	alanine transaminase (may be referred to as SGPT)
AML	acute myeloid leukemia
ANA	antinuclear antibody
ANC	absolute neutrophil count
APAP	acetaminophen
aPTT	activated partial thromboplastin time
ARDS	acute respiratory distress syndrome
ASPEN	American Society for Parenteral and Enteral Nutrition
AST	aspartate aminotransaminase (may be referred to as SGOT)
ATG	antithymocyte globulin
AUC	area under the curve
AV	atrioventricular
AZT	azidothymidine
BAL	British anti-Lewisite
BG	blood glucose
BID	two times daily
BLC	blood lead concentration
BMI	body mass index
BMT	bone marrow transplant
BPD	bronchopulmonary dysplasia
BPM	beats per minute
BSA	body surface area
BUN	blood urea nitrogen
CABG	coronary artery bypass graft
CAPD	continuous ambulatory peritoneal dialysis
CBC	complete blood count
CDAD	<i>Clostridium difficile</i> -associated diarrhea
CDC	Centers for Disease Control and Prevention
CDH	congenital diaphragmatic hernia
CDP-1	crystalline degradation product
CF	cystic fibrosis
CGA	calculated gestational age
CGA	comprehensive geriatric assessment
CHD	congenital heart disease
CHF	congestive heart failure
CINV	chemotherapy-induced nausea and vomiting
CLD	chronic lung disease
CML	chronic myelogenous leukemia
CMV	cytomegalovirus
CNS	central nervous system
CPB	cardiopulmonary bypass
CPK	creatine phosphokinase
CPK-MB	creatine phosphokinase MB isoenzyme

CPR	cardiopulmonary resuscitation
CrCl	creatinine clearance
CRRT	continuous renal replacement therapy
CSF	cerebral spinal fluid
CT	computerized tomography
CTCAE	common terminology criteria for adverse events
CVVH	continuous venovenous hemofiltration
CYP	cytochrome P
CYP1A2	cytochrome P450 isoenzyme 1A2
CYP2A4	cytochrome P450 isoenzyme 2A4
CYP2B6	cytochrome P450 isoenzyme 2B6
CYP2C19	cytochrome P450 isoenzyme 2C19
CYP2C9/10	cytochrome P450 isoenzymes 2C9 and 2C10
CYP2E1	cytochrome P450 isoenzyme 2E1
CYP3A3/4	cytochrome P450 isoenzymes 3A3 and 3A4
DAART	dexamethasone: A Randomized Trial
DEHP	diethylhexyl phthalate
DIC	disseminated intravascular coagulation
DKA	diabetic ketoacidosis
DPT	Demerol, Phenergan, Thorazine
DRESS	drug reaction with eosinophilia and systemic symptoms
DVT	deep vein thrombosis
DW	dosing weight
ECG	electrocardiogram
ECMO	extracorporeal membrane oxygenation
ED	emergency department
EDTA	ethylenediaminetetraacetic acid
EEG	electroencephalogram
ELBW	extremely low birth weight
EMIT	enzyme-multiplied immunoassay technique
ESA	erythropoiesis-stimulating agent
ET	endotracheal
EtOH	ethanol
EVA	ethylene vinyl acetate
FAB	digoxin immune Fab
FDA	Food and Drug Administration
FE	fat emulsion
FFP	fresh frozen plasma
FPIA	fluorescence polarization immunoassay
FT4	free thyroxine
GFR	glomerular filtration rate
GI	gastrointestinal
GM-CSF	granulocyte-macrophage colony-stimulating factor

xxii Abbreviations

GVHD	graft versus host disease
H1	histamine-1 receptor antagonist
H2	histamine-2 receptor antagonist
Hb	hemoglobin; also Hgb
Hct	hematocrit
HD	hemodialysis
HHV	human herpes virus
HIB	<i>Haemophilus influenzae</i> type B
HIT	heparin-induced thrombocytopenia
HITTS	heparin-induced thrombocytopenia with thrombosis syndrome
HIV	human immunodeficiency virus
HLA	human leukocyte antigen
HPLC	high-performance liquid chromatography
hr	hour
HSV	herpes simplex virus
HUS	hemolytic uremic syndrome
iNO	inhaled nitric oxide
IBW	ideal body weight
ICP	intracranial pressure
ICU	intensive care unit
IE	infective endocarditis
IgG	immunoglobulin G
IgM	immunoglobulin M
IH	idiopathic hyperphosphatasia
IM	intramuscular
INR	international normalized ratio
IO	intraosseous
IP	intraperitoneal
IQ	intelligence quotient
ISMP	Institute for Safe Medication Practices
IT	intrathecal
ITP	idiopathic thrombocytopenic purpura
IV	intravenous
IVFE	intravenous fat emulsion
IVH	intraventricular hemorrhage
IVIG	intravenous immune globulin; intravenous immunoglobulin
IVR	in vivo recovery
JIA	juvenile idiopathic arthritis
LBM	lean body mass
LD	loading dose
LDH	lactate dehydrogenase
LFT	liver function test
LGS	Lennox–Gastaut syndrome

MAC	<i>Mycobacterium avium</i> complex
MAO	monoamine oxidase
MAOI	monoamine oxidase inhibitor
MAP	mean arterial pressure
MI	myocardial infarction
MIC	minimum inhibitory concentration
min	minute
MMR	measles, mumps, and rubella
mo	month
MRI	magnetic resonance imaging
MRSA	methicillin-resistant <i>Staphylococcus aureus</i>
MTX	methotrexate
NAC	n-acetylcysteine
NAPA	n-acetylprocainamide
NEC	necrotizing enterocolitis
NHL	non-Hodgkin lymphoma
NIH	National Institutes of Health
NMS	neuroleptic malignant syndrome
NMTT	n-methyl-thiotetrazole side chain
NPO	nothing by mouth
NSAID	nonsteroidal anti-inflammatory drug
OI	osteogenesis imperfecta
OTC	over-the-counter
PaO ₂	arterial partial pressure of oxygen
PALS	pediatric advanced life support
PBPC	peripheral blood progenitor cell
PCA	partial-controlled analgesia
PCA	postconceptional age
PCI	percutaneous coronary intervention
PCP	phencyclidine
PDA	patent ductus arteriosus
PE	phenytoin equivalent
PID	pelvic inflammatory disease
PMA	postmenstrual age
PN	parenteral nutrition
PNA	postnatal age
PO	by mouth
PONV	postoperative nausea and vomiting
PPHN	persistent pulmonary hypertension of the newborn
PPI	proton-pump inhibitor
PRN	pro re nata; as needed
PT	prothrombin time

xxiv Abbreviations

PTH	parathyroid hormone
PTT	partial thromboplastin time
PVC	polyvinyl chloride
PVR	pulmonary vascular resistance
q	every
RBC	red blood cell
SA	sinoatrial
SBECD	sulfobutyl ether beta-cyclodextrin sodium
SC	subcutaneous
SCr	serum creatinine
SDC	serum digitalis concentration
sec	second
SIADH	syndrome of inappropriate antidiuretic hormone
SLE	systemic lupus erythematosus
SSRI	selective serotonin reuptake inhibitor
TBW	total body weight
TCA	tricyclic antidepressant
TDD	total digitalizing dose
THC	tetrahydrocannabinol
TID	three times daily
TNA	total nutrient admixture
TNF	tumor necrosis factor
TPA	tissue plasminogen activator
TPN	total parenteral nutrition
TSH	thyroid-stimulating hormone
TTP	thrombotic thrombocytopenic purpura
UGT	uridine diphosphate–glucuronosyltransferase
UOP	urine output
USP	United States Pharmacopeia
UTI	urinary tract infection
VAD	ventricular assist device
VPA	valproic acid
Vitamin B ₁₂	cyanocobalamin
VLBW	very low birth weight
VTE	venous thromboembolism
vWD	von Willebrand disease
VZV	varicella-zoster virus
WBC	white blood cell
wk	week
WGA	weeks gestational age
yr	year

Monographs