PEDIATRIC DRUG DIRECTORY

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PEDIATRIC DRUG DIRECTORY

8th Edition

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Foreword

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Pediatric Drug Directory

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Everybody striving to contribute to child health and welfare for a brighter future globally

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Foreword

I feel much honored in critically reviewing the drafts of the eighth edition of the *Pediatric Drug Directory* by the India's well-known pediatric educationist and author, Professor Suraj Gupte, and his young, enterprising daughter, Dr Novy Gupte. Dr Rita Smith who had coauthored the first seven editions has opted for the role as an Advisor Emeritus.

This book provides a plethora of handy information eagerly sought by all those involved in the pharmacotherapy of sick children including neonates and adolescents. Salient clinical pharmacological features of such new molecules as fifth generation cephalosporins (ceftarolin, ceftobiprole), non-penicillin non-cephalosporin beta-lactams (aztreonam, imipenem-cilastatin, meropenem), tigecycline, dalbavancin, oritavancin, etc. find a due incorporation in the text. Addition of a fine, brief and to-the-point chapter on pediatric emergencies in the new edition is a wise step. This may well be further expanded in the future edition.

Over and above the excellent contents, the presentation is simple, lucid and to-the-point. Rational division of the contents in sections, chapters and listing of the drugs of various groups in alphabetic order are of great help to the reader. Additionally, a comprehensive index facilitates easy and speedy access to and retrieval of the requisite information.

In my considered opinion, Drs Suraj Gupte and Novy Gupte's *Pediatric Drug Directory* is a strongly recommended treatise for the undergraduates, pediatric postgraduates/scholars, and practitioners of child health and disease not only in India but elsewhere also, on account of the wealth of information it provides on different aspects of pediatric drug therapy.

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Preface to the Eighth Edition

The eighth edition of the *Pediatric Drug Directory* has been extensively revised, updated and enlarged in keeping with the changing concepts and advances in the field as also to meet the growing needs of the readers who include not only the medical students, residents and pediatricians but also general practitioners and family physicians having a pediatric clientage.

- *Section 1* deals with an overview of the basics of pediatric drug therapy, including principles, pharmacodynamics and pharmacokinetics, drug monitoring, etc.
- *Section 2* specifically provides salient information about general medications, beginning with analgesics and antipyretics through antihypertensives to miscellaneous drugs.
- *Section 3* embarks on antimicrobials including antibiotics, antiviral, antifungal and antiparasitic drugs.
- *Section 4* is a spotlight on drugs employed in neonatology.
- *Section 5* gives guidelines on standard therapeutic approach to neonatal and pediatric emergencies.
- *Section 6* provides useful information related to pediatric drug therapy, including India's national and IAP immunization schedules.

A plethora of appendices provide the useful information related to pediatric drug therapy and India's National Immunization Schedule and Indian Academy of Pediatrics (IAP) Immunization Time Table/Schedule are incorporated.

Additionally, a glossary of abbreviations and index have been incorporated.

Over and above the essential details of the drugs, adverse drug reactions (ADRs), precautions, drug interactions and contraindications have been particularly included, as and when warranted, in the interest of safety for the sick child.

Here's wishing you all a fruitful reading and referencing in the larger interest of the child patients needing drug therapy.

Suraj Gupte
Novy Gupte

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Preface to the First Edition

Drugs, says Professor Harry C Shirkey, are our fine servants and awful masters. This holds nowhere as good as in pediatric practice. Their injudicious use in infants and children can indeed prove disastrous.

Yet, the most troublesome to the freshers in the field of pediatrics, as also to the general practitioners who care for children as well, is the pediatric drug therapy. Which drug to give to a particular patient? The brand name? How available? How much to give? Side effects? The young doctors—many not-so-young also—sure feel puzzled.

Pediatric Drug Directory aims to be the answer. It provides the much-needed information as pointed out above plus much more. Section 1—the largest—deals with the brand names, availability, dosage and side effect of the important drugs. As a rule, drugs are arranged alphabetically according to the generic names. Section 2 deals with drugs excreted into the breast milk, Section 3 with drugs that discolor the stools and Section 4 with drugs that discolor the urine. Drugs likely to cause hemolysis in G6PD deficient individuals are listed in Section 5. Sections 6 and 7 deal with the WHOs urban and rural immunization schedules. The important patent formulary and surface area chart are the other highlights.

Dr (Mrs) VV Gujral has been gracious enough to advance highly useful criticism and to write the Foreword to the book.

While thanking all those who helped us in compiling this directory, we sincerely look forward to constructive criticism and suggestions from the readers. That will be a vital contribution to the subsequent editions.

Suraj Gupte
Rita Smith

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- *Goodman and Gillman's Pharmacologic Basis of Therapeutics* for using some state-of-the-art material.
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- The management and administration of Mamata Medical College and Hospitals, Khammam, Andhra Pradesh, India, especially Mr Ajay Kumar, Chairman, and Mr K Sreedhar, Director (Estt), and the Dean/Principal, Dr K Koteshwer Rao, for providing motivation and moral support for completing this project.
- Dr Gagan Hans, Psychiatrist, Lady Hardinge Medical College (LHMC) and Hospitals, New Delhi, India, for voluntary help at various stages of development of this book, including inputs concerning neuropsychiatric drugs.
- Dr Rita Smith, who actively shared the editorship from the inception through the eighth edition of the book, for graciously agreeing to be the Advisor Emeritus in spite of her overwhelming commitments in other academic endeavors, including pharmacovigilance initiative globally.
- The Executive Editor, Manu Gupte, for excellent coordination in handling the project.
- The publisher, M/s Jaypee Brothers Medical Publishers (P) Ltd, New Delhi, India, and their staff for admirable and skillful production qualities of the book.

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Contents

SECTION 1 Basics of Pharmacotherapy in Neonates, Infants and Children

1. Principles 1
2. Rational Drug Therapy 11
3. Therapeutic Drug Monitoring 14
4. Certain Golden Rules in Pediatric Drug Therapy 17

SECTION 2 General Medications

5. Analgesics/Antipyretics/Nonsteroid Anti-inflammatory Drugs (NSAIDs) 18
6. Antiasthma Drugs/Bronchodilators 25
7. Antihistamines 31
8. Nasal Decongestants 39
9. Antitussives 41
10. Gastrointestinal Tract Drugs 42
11. Central Nervous System Drugs 53
12. Anticonvulsants 56
13. Cardiovascular Drugs (Cardiotonics) 68
14. Diuretics 77
15. Anticoagulants 81

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16. Drugs for Endocrinal Disorders/Hormones/Enzymes 84

17. Antihypertensive Drugs 94

18. Immunoglobulins 100

19. Hematinics 106

20. Vitamins 110

21. Trace Elements 114

22. Anticancer Drugs 117

23. Antitoxins 124

24. Miscellaneous 126

SECTION 3 Drugs for Infections and Infestations

25. Antibacterial Drugs 132

26. Antimycobacterial Drugs 184

27. Antiviral Drugs 198

28. Antifungal Drugs 210

29. Antimalarial Drugs 215

30. Antiparasitic (Intestinal) Drugs 223

31. Antiparasitic (Extraintestinal) Drugs 233

SECTION 4 Drug Therapy in Neonates

32. Emergency Drugs in Neonates 237

33. Drug Dosage in Neonates 239

Jaypee Brothers

SECTION 5 Pharmacotherapy in Emergencies

34. Important Emergency Drugs 253

35. Pharmacotherapy of Common Emergencies 254

SECTION 6 Vaccines

36. Conventional and New Vaccines for Routine Use 271

37. Combination Vaccines 297

APPENDICES Useful Information Related to Pediatric Drug Therapy

Appendix 1: Specific Antidotes 301
Appendix 2: Various Solutions Used in the Treatment of Dehydration and Dyselectrolytemia 303
Appendix 3: Drugs Likely to Have Adverse Effects on the Fetus When Consumed During Pregnancy 305
Appendix 4: Drugs in Treatment/Prevention of Fetal Disease 307
Appendix 5: Therapeutic Range of Some Drugs 308
Appendix 6: Drugs Excreted into Breast Milk 310
Appendix 7: Drugs that Discolor the Stools 313
Appendix 8: Drugs that Discolor the Urine 314
Appendix 9: Drugs Likely to Cause Hemolysis in G6PD Deficiency 316
Appendix 10: Drugs that may Cause Specific Side Effects 317
Appendix 11: ADRs Specific to Certain Drugs 318
Appendix 12: Nomogram for Estimation of Surface Area 340

Jaypee Brothers

Appendix 13: Drug Groups with Adverse Effects on Vitamin Status 341
Appendix 14: Potential Drug Interaction with Chemotherapy 342
Appendix 15: Banned Single Dose Drug Combinations (in India) 344
Appendix 16: Banned Fixed Dose Drug Combinations with Other Agents (in India) 346
Appendix 17: Immunization Schedules 347
Appendix 18: Indian Academy of Pediatrics (IAP) Immunization Recommendations 348
Appendix 19: Adverse Events Following Immunization 357

Glossary of Abbreviations 359
Index 361

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Chapter

18

Immunoglobulins

Globulin, Anti-Rh D Immune Globulin

Brand Names: Imogam, Mastergam P

- *Indications:* Rh negative mother, immediately after delivery, chronic idiopathic thrombocytopenic purpura (ITP).
- *Available as:* Intramuscular injection 100, 125 and 350 mcg.
- *Dose:* Given to the Rh negative mother 2 hours after delivery or abortion/MTP or latest 72 hours postpartum:
  - Without testing: optimal standard dose 350 mcg
  - With testing (up to 10 mL of fetal blood has entered the maternal circulation): 250 mcg
  - For abortion and MTP cases (up to 10 weeks of conception): 100 mcg.
- *ARDs:* Local reaction over the injection site, sensitization due to repeated injection.
- *Contraindications:*
  - Rh (D) negative patient who has inadvertently received Rh (D) positive blood transfusion within three months before delivery
  - Patient earlier immunized to the Rh (D) blood factor.
- *Precaution:* Protection given at delivery of first baby does not protect the mother from exposure to antigen received at a later time. Hence, the agent requires to be given immediately following each pregnancy.

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Human Normal Immunoglobulin

Brand Names: Bharglob, Gamafine, Gammalin, Globunal, Sii Gamma Globulin

- *Indications:* Prophylaxis/treatment of primary immune deficiency disorders, viral infections (measles, hepatitis, HIV/AIDS), bacterial infections, burns, etc.
- *Available as:* 10, 16.5 percent 1 mL vials
- *Dose:* Immunodeficiency disorders: In order to maintain the serum IgG level > 500 mg/dL, dose needs to be 300 to 400 mg/kg (IM) every 3 to 4 weeks.
  - *Attenuation of measles in close contacts:* 0.3 mL/kg of 10 percent sol (IM) within 5 to 6 days of exposure
  - *Attenuation of Hep A (Pre-exposure prophylaxis):* 0.02 to 0.04 mL/kg of 10 percent sol (IM) within 14 days of likely exposure (prexposure prophylaxis for travelers from nonendemic areas)
  - *Attenuation of Hep A (postexposure prophylaxis):* 0.02 mL/kg of 10 percent sol plus hepatitis A virus (HAV) vaccine.

Human Tetanus Specific Immunoglobulin

Brand Names: Equirab, ERIG, Carig, Tetagam-p, Tetaglobulin, Tetglob, Tetanus Immunoglobulin, Immunotetan

- *Indications:* Both prophylaxis and treatment of tetanus.
- *Dose:* Prophylaxis: 250 to 500 units/kg (IM), high dose is for heavily contaminated wounds, presentation of wounded subject after a lapse of > 24 hr.
- *Treatment:*
  - 30 to 300 units/kg (IV)
  - 250 units (intrathecal).

Human Rabies Specific Immunoglobulin

Brand Names: Berirab, Imogam Rabies, Imorab

- *Indications:* Category 3 bites.
- *Available as:* 300, 750, 1000 unit vials.

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- *Dose:*
  - *Human rabies immunoglobulin (HRIG):* 20 units/kg to be infiltrated into the wound and neighborhood. This is the preferred choice.
  - *Equine rabies immunoglobulin (ERIG):* 40 units/kg to be infiltrated into the wound and neighborhood.
- *ADRs:* Rarely, anaphylaxis with ERIG.
- *Precautions:* Test hypersensitivity before administering the agent.

Varicella Zoster Immunoglobulin (VZIG)

VZIG provided passive immunity against varicella.

Brand Name: Varitect

- *Indications:* All susceptible individuals (Box 18.1)
  - Prophylaxis of varicella in neonates whose mothers suffer from varicella 5 days before delivery and up to 2 days following delivery.
  - Postexposure prophylaxis in immunocompromised children and pregnant women.
- *Available as:* Inj 125 units/5 mL ampl.
- *Dose:*
  - *Infants*
    i. < 10 kg 125 units (IM). For subsequent each 10 kg weight, dose is enhanced by 125 units.

Box 18.1: Susceptible individuals needing VZIG	
1.	All unvaccinated children who do not have a clinical history of varicella in the past
2.	All unvaccinated adults who are seronegative for anti-varicella IgG. Bone marrow transplant recipients are considered susceptible even if they had disease or received vaccinations prior to transplantation. A significant contact is defined as any face-to-face contact or stay within the same room for a period greater than 1 hour with a patient with infectious varicella (defined as 1–2 days before the rash till all lesions have crusted) or disseminated herpes zoster.

Contd...

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Contd...

The following groups meeting these two criteria and who are at high-risk of developing severe disease merit prophylaxis with VZIG.
• Neonates born to mothers who develop varicella 5 days before or 2 days after delivery. The risk of varicella related death in these infants as per older estimates is likely to be 30% but may be lower. Other full term healthy newborns are not at increased risk for complications and do not merit prophylaxis if exposed to varicella.
• All neonates born at less than 28 weeks of gestation/with birth weight less than 1000 gm, exposed in the neonatal period.
• All preterm neonates born at more than 28 weeks of gestation and exposed to varicella only if their mothers are negative for anti-varicella IgG, exposed to varicella.
• Pregnant women exposed to varicella.
• All immunocompromised children especially neoplastic disease, congenital or acquired immunodeficiency or those receiving immunosuppressive therapies.
Patients who received IVIG @ 400 mg/kg in the past 3 weeks are deemed protected.

- *Children*
  i. 10 to 20 kg 250 units (IM)
  ii. 20 to 30 kg 375 units (IM)
  iii. 30 to 40 kg 500 units (IM)
  iv. 40 kg 625 units (IM)

- *ADRs:* Allergic reactions and anaphylaxis.
- *Precautions:*
  - Best given within 48 hours and never after 96 hours of postexposure.
  - Max of 2.5 mL should be injected at one site
  - Do not give in mothers actually suffering from herpes zoster.
- *Special remarks:* The cost of VZIG is prohibitive. If non affordable/ not available, other options with uncertain efficacy include IVIG @ 200 mg/kg or oral acyclovir @ 80 mg/kg/day beginning from the 7th day of exposure and given for 7 to 10 days.

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Human Hepatitis B Specific Globulin/Hepatitis B Immunoglobulin (HBIG)

Brand Names: Gamma protect Hepatitis, Hepabig, Hepaglob

- *Indications:* Neonates of HbsAg positive mothers; accidental mucocutaneous exposure to Hep B-infected blood/blood products or accidental needle exposure.
- *Available as:* 0.5, 1.0, 3.0, 5.0 mL ampoules.
- *Dose:*
  - *Neonates of HbsAg positive mothers:* 0.5 to 1.0 mL (100–200 units) IM within 72 hr (within 12 hr is the best) of birth along with first dose of Hep B vaccine IM at a different site for active immunization.
  - *Accidental exposure:* 0.06 to 0.1 mL/kg (40 units/kg) IM within 24 hr (within 6 hr is the best) of exposure along with first dose of Hep B vaccine IM at a different site for active immunization.
- *ADRs:* Anaphylactic reactions.
- *Contraindication:* Allergy or intolerance to human immunoglobulins.
- *Precautions:* Avoid giving immunoglobulin and vaccine at the same site.

Respiratory Syncytial Virus Intravenous Immunoglobulin (RSV-IVIG)

Brand Name: Raspi Gam

- *Indications:* Prevention of serious RSV infection (bronchiolitis, pneumonia) in high-risk children (prematurity, bronchopulmonary dysplasia).
- *Available as:* Injection 50 mg/mL
- *Dose:* 750 mg/kg (IV) once a month. The course should begin a month before and be ongoing during RSV season. For exact recommendations, (Box 18.2).
- *ADRs:* Anaphylaxis, fever, headache, backache, arthralgia, skin reactions, hypertension.
- *Contraindication:* Congenital heart disease (right-to-left shunt).

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Box 18.2: Recommendation for RSV-IVIG

Starting dose: 1.5 mL/kg/hr for 15 min
Then, increase the rate to 3 mL/kg/hr for 15 min
If well tolerated, increase the rate to a maximum of 6 mL/kg/hr until a total of 750 mL/kg is administered.

IV Immunoglobulin (IVIG)

Brand Names: Gamma IV, Globomin IV, Isiven IV, Pentaglobulin, Sandoglubulin, Venimunn, ZY-IVGG

- *Indications:* Immunodeficiency states, chronic ITP, Rh isoimmunization, Kawasaki disease, Guillain-Barré syndrome (GBS), hemolytic-uremic syndrome (HUS), sepsis.
- *Available as:* 0.5,1.0, 2.5, 5.0 g vials.
- *Dose:*
  - *Immunodeficiency state:* 100 to 400 mg/kg/dose (IV) every 2 to 4 wk
  - *Kawasaki disease:* 2.0 g/kg IV infusion over 10 to 12 hr as a single dose.
    Or
    400 mg/kg/day (IV) for 4 days
  - *ITP:* 800 to 1000 mg/kg/dose (IV) for induction of response. Thereafter 400 to 800 mg/kg/dose (IV) once every 4 to 6 wk
- *ADRs:* Anaphylaxis, hypersensitivity reactions, fever, chills, hypotension, transient tachycardia.
- *Contraindication:* IgA deficiency.
- *Precautions:* If ADR occurs, discontinue the infusion until the reaction is controlled. Resume at a slower rate in keeping with tolerance.

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