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October 2008 ~ Volume 24 ~ Number 241001

Stability of Refrigerated and Frozen Drugs

-Chart modified November 2008-

(Based on U.S. product labeling and relevant studies)

Failure to follow storage recommendations of pharmaceutical products can result in subpotent products and potentially, therapeutic failure.¹⁻³ In addition, hundreds of thousand of medications are discarded each year because of improper storage conditions resulting in millions of dollars wasted.^{1.2} This can occur for a variety of reasons including improper shipping, failure to refrigerate or freeze a product upon receipt or after use, and in the event of a power failure. It is important to recognize when pharmaceutical products have not been stored according to the manufacturer's specifications and take appropriate action. Depending on the product, lot number and expiration date, time of exposure to temperatures outside of the recommended range and actual temperature of exposure, some medications may be deemed suitable for administration while others should be discarded. The following chart provides general guidelines for the room temperature stability of common medications and vaccines which are stored in the refrigerator or freezer. However, if a pharmaceutical product has not been stored according to the recommended conditions, it is important to contact the manufacturer and provide the specifics (lot number, expiration date, exposure temperature, length of time) to determine if the product is viable. Continue to the end of this chart for helpful tips on what to do during a power failure or when there is a potential for flooding.

• For a listing of Anti-infective Suspensions and their stability after reconstitution, see *Detail-Document* #231107

Generic name (Brand Name)*	Recommended Storage**	Stability at Room Temperature** FOR SPECIFIC INFORMATION, CONTACT MANUFACTURER	Manufacturer Contact Information (Quality Control)
Adalimumab (<i>Humira</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	Abbott Laboratories 800-633-9110
Alprostadil injection (Caverject solution)	Refrigerate 40 mcg strength at 36° to 46° F (2° to 8°C) until dispensed. (Store the 5, 10, and 20 mcg strengths at or below 77°F [25°C]).	After dispensing 40 mcg strength: Three months at or below 25°C (77°F).	Pfizer 800-438-1935
Alprostadil urethral suppository (<i>Muse</i>)	Refrigerate at 36° to 46° F (2° to 8°C).	14 days.	Vivus, Inc. 650-934-5200

• For a listing of Insulin Products and their storage/stability information, see *Detail-Document* #220910

Generic name (Brand Name)*	Recommended Storage**	Stability at Room Temperature** FOR SPECIFIC INFORMATION, CONTACT MANUFACTURER	Manufacturer Contact Information (Quality Control)
Amphotericin B (<i>Amphocin</i> , others)	Refrigerate at 36° to 46°F (2° to 8°C) before reconstitution (lyophilized powder) After reconstitution, refrigerated solution (5 mg/mL concentration, diluted with Sterile Water for Injection) stable for one week.	24 hours (reconstituted solution at concentration of 5 mg/mL, diluted with Sterile Water for Injection).	Pfizer 800-438-1935
Azithromycin ophthalmic (<i>Azasite</i>)	Refrigerate at 36° to 46° F (2° to 8°C).	Once the bottle is opened, store at 2° to 25°C (36° to 77°F) for up to 14 days. Discard after 14 days.	Inspire Pharmaceuticals 888-881-4696
Becaplermin (<i>Regranex</i>)	Refrigerate at 36° to 46°F (2° to 8°C). Do not freeze.	Contact manufacturer.*** Off-label [§] information indicates that unopened bottles left out of refrigerator are stable (up to 86°F or 30°C) for up to six days or less, one time only. ¹⁴	Johnson and Johnson Wound Management 888-REGRANEX
Benzoyl peroxide/clindamycin (Duac)	Refrigerate at 36° to 46°F (2° to 8°C). Do not freeze.	60 days.	Stiefel Labs 888-500-3376
Calcitonin nasal (Fortical)	Refrigerate unopened bottle at 36° to 46° F (2° to 8°C).	After opening, store bottle in use in an upright position for up to 30 days at 68° to 77°F (20° to 25°C). Excursions permitted to 59°F to 86°F (15° to 30°C). Off-label [§] information indicates that unopened bottles left out of refrigerator (up to 77°F or 25°C) in the pharmacy for seven days or less can be safely dispensed to the patient. ⁴ Contact manufacturer.***	Upsher-Smith Laboratories 763-315-2000





Generic name (Brand Name)*	Recommended Storage**	Stability at Room Temperature** FOR SPECIFIC INFORMATION, CONTACT MANUFACTURER	Manufacturer Contact Information (Quality Control)
Calcitonin injectable (<i>Miacalcin</i>)	Refrigerate unopened bottle at 36° to 46° F (2° to 8°C).	Contact manufacturer.***	Novartis 888-669-6682
Calcitonin nasal (<i>Miacalcin</i>)	Refrigerate unopened bottle at 36° to 46° F (2° to 8°C).	Opened bottle may be stored at 59°F to 86°F (15° to 30°C) in upright position for 35 days.	Novartis 888-669-6682
Chlorambucil (Leukeran)	Refrigerate at 36° to 46° F (2° to 8°C).	Contact manufacturer.*** Off-label [§] information indicates stable when maintained at up to 86°F (30°C) for up to one week. ⁵	GlaxoSmithKline 866-475-8222
Darbepoetin alfa (Aranesp)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	Amgen 800-772-6436
Desmopressin (DDAVP Rhinal Tube)	Refrigerate at 36° to 46° F (2° to 8°C).	Up to three weeks.	Sanofi Aventis 908-243-6000
Dinoprostone cervical gel (<i>Prepidil</i>)	Refrigerate at 36° to 46° F (2° to 8°C).	Contact manufacturer.*** Off-label [§] information indicates stable when maintained for 24 hours. ⁶	Pfizer 800-438-1935
Dornase alfa (<i>Pulmozyme</i>)	Refrigerate at 36° to 46° F (2° to 8°C).	Up to 24 hours. Contact manufacturer.*** Off-label [§] information indicates stable when maintained for up to 48 cumulative hours at a temperature up to 86°F (30°C). ⁷	Genentech 650-225-1000





Generic name (Brand Name)*	Recommended Storage**	Stability at Room Temperature** FOR SPECIFIC INFORMATION, CONTACT MANUFACTURER	Manufacturer Contact Information (Quality Control)
Dronabinol (Marinol)	Refrigerate at 36° to 46° F (2° to 8°C) or store in a cool environment between 46°F to 59°F (8°C to 15°C).	Contact manufacturer.*** Off-label [§] information indicates stable when maintained at room temperature 77°F (25°C) for 24 months. ⁸	Solvay Pharmaceuticals 770-578-9000
Epoetin alfa (Epogen)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	Amgen 800-772-6436
Epoetin alfa (<i>Procrit</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.*** Off-label [§] information indicates the following stability data when maintained at room temperature up to 86°F (30°C): Single-dose vial – 14 days. ¹⁵ Unopened multi-dose vial – seven days. ¹⁵	Ortho Biotech 888-227-5624
Estradiol/norethindrone acetate transdermal system (<i>CombiPatch</i>)	Prior to dispensing, refrigerate at 36° to 46°F (2° to 8°C).	After dispensing, store at room temperature below 77°F (25°C) for up to six months.	Novartis 888-669-6682
Etonogestrel/ethinyl estradiol vaginal ring (NuvaRing)	Refrigerate at 36° to 46°F (2° to 8°C).	After dispensing, store at 77°F (25°C) for up to four months; excursions permitted to 59° to 86°F (15° to 30°C).	Organon 877-688-2746
Estramustine (<i>Emcyt</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	Pfizer 800-438-1935
Etanercept injection (<i>Enbrel</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.*** However, one reference suggests: ¹ Vial – seven days. ¹ Prefilled syringe – four days. ^{1,16}	Immunex Corporation 888-436-2735
Etoposide capsules (VePesid)	Prior to dispensing, refrigerate at 36° to 46° F (2° to 8°C).	Contact manufacturer.***	Bristol-Myers Squibb 609-897-2000





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Generic name (Brand Name)*	Recommended Storage**	Stability at Room Temperature** FOR SPECIFIC INFORMATION, CONTACT MANUFACTURER	Manufacturer Contact Information (Quality Control)
Exenatide (<i>Byetta</i>)	Prior to first use, refrigerate at 36° to 46° F (2° to 8°C). Do not freeze.	After first use, store at a room temperature not to exceed 77°F (25°C). Discard after 30 days.	Amylin Pharmaceuticals 800-349-8919
Filgrastim (Neupogen)	Refrigerate at 36° to 46° F (2° to 8°C).	Stable at room temperature for up to 24 hours.	Amgen 800-772-6436
Formoterol (Foradil)	Prior to dispensing, refrigerate at 36° to 46° F (2° to 8°C).	Store at room temperature 68° to $77^{\circ}F$ (20° to 25°C). Off-label [§] information indicates stable when maintained at room temperature for up to 6 months. ⁹	Schering Corporation 800-222-7579
Gabapentin oral suspension (<i>Neurontin</i>)	Refrigerate at 36° to 46° F (2° to 8°C).	Contact manufacturer.*** Off-label [§] information indicates oral solution stable for seven days at temps up to 86°F (30°C). ⁶	Pfizer 800-438-1935
Glatiramer acetate injection (<i>Copaxone</i>)	Refrigerate at 36° to 46° F (2° to 8°C).	One month at room temperature of 59° to 86° F (15° to 30° C).	Teva Neuroscience 888-838-2872
Interferon alfacon-1 (<i>Infergen</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	Three Rivers Pharm. 724-778-6100
Interferon beta-1a (Avonex)	Refrigerate unreconstituted vial of lyophilized powder at 36° to 46°F (2° to 8°C).	Lyophilized powder vial – 30 days. Prefilled syringes – seven days.	Biogen Idec 800-456-2255
Interferon beta-1a (Rebif)	Refrigerate at 36° to 46° F (2° to 8°C).	30 days.	Pfizer 800-438-1935



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Generic name (Brand Name)*	Recommended Storage**	Stability at Room Temperature** FOR SPECIFIC INFORMATION, CONTACT MANUFACTURER	Manufacturer Contact Information (Quality Control)
Interferon gamma-1b (<i>Actimmune</i>)	Refrigerate at 36° to 46°F (2° to 8°C) immediately upon receipt to ensure optimal retention of physical and biochemical integrity. Do not freeze.	Unopened vial should not be left at room temperature for a total time exceeding 12 hours prior to use. Vials stored at room temperature should not be returned to the refrigerator.	InterMune, Inc. 888-486-6411
Latanoprost (<i>Xalatan</i>)	Prior to dispensing and opening, store unopened bottles in refrigerator at 36°F to 46°F (2°C to 8°C).	During shipment, unopened bottle stable at up to 104°F (40°C) for no more than eight days. After first use, store at a room temperature not to exceed 77°F (25°C) for up to 6 weeks. Off-label [§] information indicates unopened bottle stable when maintained at continuous room temperature 77°F (25°C) for 12 months. ⁶ Contact manufacturer.***	Pfizer 800-438-1935
Liotrix (Thyrolar)	Refrigerate at 36° to 46° F (2° to 8°C).	Contact manufacturer.***	Forest Pharmaceuticals 1-800-678-1605, ext. 66297
Lopinavir/ritonavir solution (<i>Kaletra</i>)	Refrigerate at 36° to 46°F (2° to 8°C) until dispensed. Stable until expiration date if stored in refrigerator.	Two months.	Abbott Laboratories 800-633-9110
Lorazepam intensol oral concentrate	Refrigerate at 36° to 46° F (2° to 8°C).	Contact manufacturer.*** Off-label [§] information indicates stable when maintained at continuous room temperature 77°F (25°C) for 30 days. ¹⁰	Roxane Laboratories 614-276-4000





Generic name (Brand Name)*	Recommended Storage**	Stability at Room Temperature** FOR SPECIFIC INFORMATION, CONTACT MANUFACTURER	Manufacturer Contact Information (Quality Control)
Melphalan tablets (<i>Alkeran</i>)	Refrigerate at 36° to 46° F (2° to 8°C).	Contact manufacturer.***	GlaxoSmithKline 888-825-5249
Octreotide (Sandostatin)	Refrigerate at 36° to 46° F (2° to 8°C).	At room temperature (70°F to 86°F, 20°C to 30°C), stable for 14 days, when protected from light.	Novartis 888-669-6682
Octreotide injectable suspension (Sandostatin LAR)	Refrigerate at 36° to 46° F (2° to 8°C).	Drug kit can remain at room temperature for 30 to 60 minutes prior to preparation. However, must be used immediately after preparation.	Novartis 888-669-6682
Papain/urea topical (<i>Ethezyme</i>) PRODUCT DISCONTINUED BY MANUFACTURER	Refrigerate at 36° to 46°F (2° to 8°C) or in cool (46° to 59°F) place (8° to 15°C).	Contact manufacturer.*** Off-label [§] information indicates stable when maintained up to 77°F (25°C) for three months. ¹¹	Ethex 800-321-1705
Peginterferon alfa-2a (<i>Pegasys</i>)	Refrigerate at 36° to 46° F (2° to 8°C).	24 hours.	Roche Laboratories 800-526-0625
Peginterferon alfa-2b (<i>PegIntron</i>)	PegIntron vials - Store at roomtemperature (77°F [25°C]; excursionpermitted to 59°F to 86°F [15°C to 30°C]).After reconstitution, the solution shouldbe used immediately, but may be storedup to 24 hours at 36° to 46°F (2° to 8°C).PegIntron Redipen - Refrigerate at 36° to46° F (2° to 8°C). After reconstitution, thesolution should be used immediately, butmay be stored up to 24 hours at 36° to46° F (2° to 8°C).	Contact manufacturer.*** Off-label [§] information indicates the <i>PegIntron Redipen</i> (unreconstituted lyophilized powder) is stable when maintained up to 86°F (30°C) for one day. However, there is no data to address the re-refrigeration of the product after maintained in an un- refrigerated state. ⁹	Schering Corporation 800-222-7579



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Generic name (Brand Name)*	Recommended Storage**	Stability at Room Temperature** FOR SPECIFIC INFORMATION, CONTACT MANUFACTURER	Manufacturer Contact Information (Quality Control)
Pramlintide injection (Symlin)	Refrigerate at 36° to 46°F (2° to 8°C).	30 days.	Amylin Pharmaceuticals 800-349-8919
Promethazine suppositories (<i>Promethegan</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	G & W Laboratories 908-753-2000
Proparacaine ophthalmic solution	Refrigerate at 36° to 46° F (2° to 8°C).	Contact manufacturer.***	Akorn 847-279-6100
Ritonavir capsules (Norvir)	Refrigerate at 36° to 46°F (2° to 8°C) until dispensed. Stable until expiration date if stored in refrigerator.	30 days.	Abbott Laboratories 800-633-9110
Sinecatechins (Veregen)	Prior to dispensing to the patient, refrigerate at 36° to 46°F (2° to 8°C).	After dispensing, can be stored at room temperature.	Doak Dermatologics 800-929-9300
Sirolimus solution (<i>Rapamune</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Up to 15 days.	Wyeth Pharmaceuticals 800-395-9938
Teriparatide (Forteo)	Refrigerate at 36° to 46° F (2° to 8°C). Minimize time out of refrigerator during use.	Contact manufacturer.***	Eli Lilly 800-545-5979
Tobramycin for oral inhalation (<i>Tobi</i>)	Refrigerate at 36° to 46° F (2° to 8°C).	Opened or unopened pouches may be stored at room temperature (up to 77°F or 25°C) for up to 28 days.	Novartis 888-669-6682
Trifluridine (Viroptic)	Refrigerate at 36° to 46° F (2° to 8°C).	Contact manufacturer.*** Off-label [§] information indicates stable when maintained up to 77°F (25°C) for two weeks. However, due to slight changes in pH (no change in potency), ocular stinging or discomfort may occur. ¹⁷	King Pharmaceuticals 800-776-3637



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Generic name (Brand Name)*	Recommended Storage**	Stability at Room Temperature** FOR SPECIFIC INFORMATION, CONTACT MANUFACTURER	Manufacturer Contact Information (Quality Control)
Vaccines			
Diphtheria, tetanus toxoids (DT) (pediatric)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	Sanofi Pasteur 800-822-2463
Tetanus, diphtheria toxoids (Td) (adult) (<i>Decavac</i>)			
Diphtheria, tetanus toxoids, acellular pertussis vaccine (DTaP) (pediatric) <i>(Tripedia, Daptacel</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	Sanofi Pasteur 800-822-2463
Diphtheria, tetanus toxoids, acellular pertussis vaccine (DTaP) (pediatric) (<i>Infanrix</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.*** Off-label [§] information indicates stable when maintained above 46°F to 77°F (above 8°C to 25°C) for 72 hours (<i>Infanrix</i>). ¹²	GlaxoSmithKline 866-475-8222
Diphtheria, tetanus toxoids, acellular pertussis vaccine, hepatitis B vaccine, inactivated polio vaccine (DTaP/HepB/IPV) (pediatric) (<i>Pediarix</i>)		Contact manufacturer.*** Off-label [§] information indicates stable when maintained above 46°F to 77°F (above 8°C to 25°C) for 72 hours (<i>Pediarix</i>). ¹²	
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Generic name (Brand Name)*	Recommended Storage**	Stability at Room Temperature** FOR SPECIFIC INFORMATION, CONTACT MANUFACTURER	Manufacturer Contact Information (Quality Control)
Tetanus toxoid, reduced, diphtheria toxoids, acellular pertussis vaccine (Tdap) (adult) (<i>Boostrix</i>)	Refrigerate at 36° to 46°F (2° to 8°C)	Contact manufacturer.*** Off-label [§] information indicates stable when maintained above 46°F to 77°F (above 8°C to 25°C) for 72 hours (<i>Boostrix</i>). ¹²	GlaxoSmithKline 866-475-8222
Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine (pediatric) (<i>Pentacel</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	Sanofi Pasteur 800-822-2463
Haemophilus influenzae type B conjugate vaccine (Hib) (PedvaxHIB)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	Merck 800-637-2590
Haemophilus influenzae type B conjugate vaccine (Hib) (ActHIB)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	Sanofi Pasteur 800-822-2463
Haemophilus influenzae type B conjugate (Hib) and hepatitis B vaccines (Comvax)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	Merck 800-637-2590
Hepatitis A vaccine (<i>Havrix</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.*** Off-label [§] information indicates stable when maintained above 46°F to 77°F (above 8°C to 25°C) for 72 hours. ¹²	GlaxoSmithKline 866-475-8222



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Generic name (<i>Brand</i> <i>Name</i>)*	Recommended Storage**	Stability at Room Temperature** FOR SPECIFIC INFORMATION, CONTACT MANUFACTURER	Manufacturer Contact Information (Quality Control)
Hepatitis A vaccine (Vaqta)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	Merck 800-637-2590
Hepatitis A and Hepatitis B vaccine (<i>Twinrix</i>)	Refrigerate at 36° to 46° F (2° to 8°C).	Contact manufacturer.*** Off-label information indicates stable when maintained above 46°F to 77°F (above 8°C to 25°C) for 72 hours (<i>Twinrix</i>). ¹²	GlaxoSmithKline 866-475-8222
Hepatitis B vaccine (<i>Engerix-B</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.*** Off-label [§] information indicates stable when maintained above 46°F to 77°F (above 8°C to 25°C) for 72 hours. ¹²	GlaxoSmithKline 866-475-8222
Hepatitis B vaccine (<i>Recombivax HB</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	Merck 800-637-2590
Human papillomavirus (Types 6, 11, 16, 18) vaccine (<i>Gardasil</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	Merck 800-637-2590
Inactivated polio vaccine (IPV) (<i>IPOL</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	Sanofi Pasteur 800-822-2463
Influenza virus vaccine, types A and B (<i>Afluria</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	CSL Limited 888-4FLU-OFF



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Generic name (Brand Name)*	Recommended Storage**	Stability at Room Temperature** FOR SPECIFIC INFORMATION, CONTACT MANUFACTURER	Manufacturer Contact Information (Quality Control)
Influenza virus vaccine, types A and B (<i>FluLaval</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	GlaxoSmithKline 866-475-8222
Influenza virus vaccine, types A and B (<i>Fluarix</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	GlaxoSmithKline 866-475-8222
Influenza virus vaccine, types A and B (<i>Fluvirin</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	Novartis 800-244-7668
Influenza virus vaccine, types A and B (<i>Fluzone</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	Sanofi Pasteur 800-822-2463
Influenza attenuated influenza vaccine, live (LAIV) (<i>FluMist</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.*** Off-label [§] information indicates stable when maintained above 46°F to 77°F (above 8°C to 25°C) for 8 hours. ¹³	MedImmune 800-949-3789
Measles, mumps. rubella vaccine (MMR) (<i>M-M-R</i> II)	Refrigerate at 36° to 46° F (2° to 8°C). Diluent may be stored in the refrigerator or at room temperature. Do not freeze diluent.	Contact manufacturer.***	Merck 800-637-2590





Generic name (Brand Name)*	Recommended Storage**	Stability at Room Temperature** FOR SPECIFIC INFORMATION, CONTACT MANUFACTURER	Manufacturer Contact Information (Quality Control)
Measles, mumps. rubella (MMR) and varicella vaccines (<i>ProQuad</i>)	Store in freezer at an average temperature of 5°F (-15°C) or colder for up to 18 months. Can be stored in a refrigerator at 36° to 46°F (2° to 8°C) for up to 72 hours before reconstitution. Diluent may be stored in the refrigerator or at room temperature. Do not freeze diluent.	Contact manufacturer.***	Merck 800-637-2590
Meningococcal conjugate, groups A, C, Y and W-135 vaccine (MCV) (<i>Menactra</i> [also contains diphtheria toxoid], <i>Menomune</i>)	Refrigerate at 35° to 46°F (2° to 8°C). (<i>Menomune</i> single-dose vial should be used within 30 minutes of reconstitution)	Contact manufacturer.***	Sanofi Pasteur 800-822-2463
Pneumococcal conjugate vaccine (<i>Prevnar</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	Wyeth 800-999-9384
Pneumococcal polysaccharide vaccine (<i>Pneumovax 23</i>)	Refrigerate at 36° to 46°F (2° to 8°C).	Contact manufacturer.***	Merck 800-637-2590
Rotavirus vaccine (Rotarix)	Refrigerate at 36° to 46°F (2° to 8°C). Diluent may be stored at room temperature.	After reconstitution, can be stored at room temperature up to 77°F (25°C) for 24 hours.	GlaxoSmithKline 866-475-8222
Rotavirus vaccine (<i>RotaTeq</i>)	Refrigerate at 36° to 46°F (2° to 8°C). Administer as soon as possible after removal from refrigerator.	Contact manufacturer.***	Merck 800-637-2590



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Generic name (Brand Name)*	Recommended Storage**	Stability at Room Temperature** FOR SPECIFIC INFORMATION, CONTACT MANUFACTURER	Manufacturer Contact Information (Quality Control)
Varicella (chickenpox) vaccine (<i>Varivax</i>)	Store in freezer at 5° F (-15° C) or colder. Diluent may be stored in the refrigerator or at room temperature. Do not freeze diluent.	May be stored at refrigerator temperatures, 36° to 46° F (2° to 8°C) for up to 72 hours prior to reconstitution. Vaccine stored in refrigerator must be used within 72 hours of removal from freezer. Other storage conditions are determined on a case-by-case basis. Contact manufacturer.***	Merck 800-9-VARIVAX
Typhoid vaccine, live oral (<i>Vivotif</i>)	Refrigerate at 36° to 46° F (2° to 8°C).	Contact manufacturer.***	Berna Biotech, Ltd. 305-443-2900
Zoster (shingles) vaccine (Zostavax)	Store in freezer at 5° F (-15° C) or colder. Diluent may be stored in the refrigerator or at room temperature. Do not freeze diluent.	Contact manufacturer.***	Merck 800-9-VARIVAX

* This table includes commonly used medications and vaccines. For those products not listed, consult the product information or pharmaceutical manufacturer for stability information at room temperature.

** Data based on information provided by prescribing information, unless otherwise indicated. The following PIs were used for this chart: *Humira* (January 2003), *Caverject* (October 2003), *Muse* (August 2003), *Amphocin* (October 2006), *Azasite* (December 2007), *Regranex* (May 2008), *Duac* (August 2002), *Fortical* (February 2004), *Miacalcin* injection (November 2002), *Miacalcin* nasal spray (June 2006), *Leukeran* (November 2006), *Aranesp* (August 2008), *DDAVP Rhinal Tube* (October 2007), *Prepidil* (July 2008), *Pulmozyme* (2008), *Marinol* (March 2008), *Epogen* (August 2008), *Procrit* (August 2008), *CombiPatch* (January 2005), *NuvaRing* (December 2007), *Emcyt* (June 2007), *Enbrel* (June 2008), *VePesid* (July 2006), *Byetta* (June 2008), *Neupogen* (September 2007), *Foradil* (June 2006), *Neurontin* oral solution (January 2007), *Copaxone* (November 2007), *Infergen* (July 2006), *Avonex* (November 2006), *Rebif* (April 2008), *Actimmune* (January 2007), *Xalatan* (November 2006), *Thyrolar* (April 2005), *Kaletra* (November 2007), Lorazepam *Intensol* oral concentrate (June 2007), *Alkeran* (November 2004), *Sandostatin* (September 2005), *Sandostatin LAR* (March 2008), *Ethezyme* (March 2006), *Pegasys* (January 2008), *PegIntron* (April 2008), *Symlin* (July 2008), *Promethegan* suppositories (June 2000), Proparacaine ophthalmic solution (July 2005), *Norvir* capsules (August 2008), *Veregen* (December 2007), *Rapamune*





(January 2008), Forteo (February 2008), Tobi (December 2007), Viroptic (October 2001), Diphtheria and Tetanus Toxoids, adsorbed (December 2005), Decavac (March 2004), Tripedia (March 2001), Daptacel (March 2008), Pentacel (June 2008), Infanrix (July 2003), Pediarix (March 2007), Boostrix (December 2005), PedvaxHIB (January 2001), ActHib (December 2005), Comvax (September 1996), Havrix (March 2008), Vaqta (May 2007), Twinrix (March 2007), Engerix-B (January 2007), Recombivax (May 2007), Gardasil (September 2008), IPOL (December 2005), Afluria (July 2008), FluLaval (July 2008), Fluarix (August 2008), Fluvirin (August 2008), Fluzone (August 2008), FluMist (July 2008), M-M-R II (May 2008), ProQuad (February 2008), Menactra (October 2007), Menomune (December 2005), Prevnar (December 2007), Pneumovax 23 (August 2008), RotaTeq (April 2008), Rotarix (April 2008), Varivax (November 2006), Vivotif (August 2006), Zostavax (July 2007).

*** Room temperature stability determined on a case-by-case basis. Contact manufacturer and provide lot number and expiration date, length of time exposed to room temperature, maximum exposure temperature.

§ Off-label information is not reviewed or approved by the FDA.

Users of this document are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical judgments based on the content of this document. Our editors have researched the information with input from experts, government agencies, and national organizations. Information and Internet links in this article were current as of the date of publication.





Safeguarding Pharmaceutical Products During Power Outages or Flooding

In the event of a **power outage**, there are a number of steps to take to minimize damage to pharmaceutical products. If the power goes out, the time of the power outage should be noted. During the power outage, refrigerator and freezer doors should not be opened. For products which are stored in the freezer, if the power outage continues for more than 24 hours, the products should be removed from the freezer and packed in dry ice.

When the power is restored, the temperature in the refrigerator and freezer should be recorded, and monitored until the temperature has returned to the desired temperature. This allows the calculation of the duration of time the product was stored at a temperature outside of the product labeling and may enable calculations to be made by the product manufacturer, in consultation with FDA as necessary, about the continued potency of the involved products.³

When a **flood** is anticipated, if possible, pharmaceutical products should be moved out of areas which could accumulate flood water. If possible, elevate products stored on warehouse floors off the ground (e.g., on pallets). For those items on shelves, securely anchor the shelves to keep products dry. For refrigerated products, raise refrigerators onto platforms, if possible.³

If flooding occurs, any product which was not sealed in airtight, waterproof bags should be considered contaminated and should be discarded.³

Users of this document are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical judgments based on the content of this document. Our editors have researched the information with input from experts, government agencies, and national organizations. Information and Internet links in this article were current as of the date of publication.

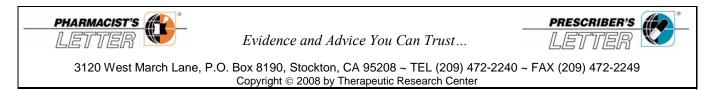
Project Leader in preparation of this Detail-Document: Neeta Bahal O'Mara, Pharm.D., BCPS

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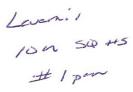
Subscribers to *Pharmacist's Letter* and *Prescriber's Letter* can get *Detail-Documents*, like this one, on any topic covered in any issue by going to **www.pharmacistsletter.com** or **www.prescribersletter.com**

Technician Training Tutorial: Handling Refrigerated Drugs and Vaccines

Several medications and vaccines require refrigeration while stored in the pharmacy and/or after being dispensed to the patient. Inadvertent storage of refrigerated medications at room temperature causes accelerated drug or chemical breakdown resulting in reduced shelf-life or total loss of effectiveness. Rarely, the degraded medication or vaccine may cause an adverse reaction. Other medications lose their physical integrity and become useless (e.g., suppositories melt).

Some refrigerated medications cost hundreds or thousands of dollars. Improper product storage may lead to financial loss for the pharmacy. Of course, the most important consequence of improper storage is treatment failure and harm to the patient. Technicians can help prevent problems by appropriately storing, handling, and labeling refrigerated products. Products that may require refrigeration include vaccines, other injectables, suppositories, oral liquids, powders for reconstitution, and even capsules and eye medications. You should become familiar with the specific products your pharmacy carries that require refrigeration.

Mr. Johnson, a 64 year-old male, drops off a prescription that reads as follows:



Prescription Interpretation:

This prescription is written for *Levemir* 10 units to be injected subcutaneously once daily at bedtime. One pen is to be dispensed. Notice that *Levemir* is a "look-alike, sound-alike" medication that can be confused with "*Lantus*," another insulin product available in pen form. The prescriber has also used abbreviations considered to be error-prone by many experts. The abbreviation "u" for units can be misread as "0," "4," etc. The abbreviation "SQ" can be misinterpreted as "sublingual" or "5 every," and the abbreviation "HS" misread as "half-strength." See more examples of sig or medication abbreviations that should be avoided in our *Dangerous Abbreviations* chart.

How is this medication stored in the pharmacy?

Levemir (insulin detemir) is a long-acting insulin used to treat diabetes. Product labeling specifies that unused *Levemir* must be stored refrigerated (2°C to 8°C [36°F to 46°F]). The refrigerator setting should be 5°C (41°F) to allow for the highest safety margin.

What do you need to consider when filling this prescription?

<u>Product selection</u>. The 3 mL *Levemir* pen contains 300 units of insulin (100 units/mL). Mr. Johnson will need one *Levemir* pen, which will last thirty days. In the U.S., *Levemir* also comes in a 10 mL vial. Take care to choose the correct product from the refrigerator, and in the computer.

<u>Product labeling and verification</u>. When labeling refrigerated items, take care not to cover refrigeration requirements, expiration date, NDC code (DIN in Canada), or other pertinent storage information that may be included on the outside of the package. Consider any delays between prescription preparation and verification for refrigerated items. For example, the product may need to





be stored in the refrigerator while awaiting verification if there is a significant delay in the pharmacy workflow between prescription entry, preparation, and verification.

<u>Auxiliary labeling</u>. Although *Levemir* pen requires refrigeration while stored in the pharmacy, after the first dose, per U.S. labeling it should be kept at room temperature below 30°C (86°F) for up to 42 days. The pharmacist will counsel the patient regarding correct storage. However, a "Refrigerate" auxiliary label will remind the patient to store the medication in the refrigerator if they will not be using it right away. Many pharmacists and technicians also place a "Refrigerate" auxiliary label on the outside of the Rx bag that is placed in the pick-up bin. This extra "Refrigerate" label on the prescription bag serves as a reminder to pharmacy personnel that the medication needs to be taken out of the refrigerator when the patient returns to pick it up (see next section for more on workflow considerations in storing refrigerated prescriptions).

<u>Storage</u>. Once the prescription is verified, it should be stored in the refrigerator until picked up by the patient. Workflow for storage and retrieval of refrigerated prescriptions varies among pharmacies. Many pharmacies place an empty bag, label, and receipt in an alphabetized bin near the cash register, but store medication in a "patient pickup" bin in the refrigerator. With this method, prescription bags are easily located in the normal pharmacy storage area, while meds are safely stored in the fridge. Make sure to use a "Refrigerate" sticker or another reminder notation on the receipt and bag with this method to ensure that the medication is retrieved from the refrigerator when the patient pays for the prescription. Other pharmacies using barcode systems may have a separate storage area in the refrigerator for labeled and bagged prescriptions that are ready to be picked up. Whatever method is used, always store meds requiring refrigeration or freezing appropriately until they are picked up by patients.

What other storage steps should be taken to ensure patient safety and stability of refrigerated or frozen medications and vaccines?

- Frozen medications or vaccines should be stored at $-15^{\circ}C(5^{\circ}F)$ or colder.
- Refrigerated medications should be stored at temperatures between 2°C and 8°C (36°F to 46°F). Refrigerator settings should be mid-range at +5°C (41°F) to allow the highest safety margin.
- Never store medications or vaccines in the refrigerator or freezer unless they are meant to be stored this way.
- Store refrigerated medications and vaccines in their original packaging. This helps protect them from light and keeps them visually distinct to avoid mix-ups. For medications or vaccines with similar names or packaging (e.g., insulins; adult and pediatric vaccines), use shelf tags or store in different locations within the refrigerator.
- Don't crowd medications in the refrigerator. For consistent temperatures, allow air circulation between items.
- Store products in the middle of the refrigerator, not in bins or door compartments, away from the floor, coils, walls, and vents. This helps ensure stable temperatures.
- Do not store food and beverages in the same refrigerator as medications and vaccines. There may even be regulations against this practice in your area.
- Examine arriving orders for refrigerated packaging, and unpack them immediately.
- Follow your pharmacy's policy for checking and logging the refrigerator temperature.

Canadian readers can get more information in our document, *Vaccine Storage and Handling Guidelines*. This document summarizes the 2007 guidelines from the Public Health Agency of Canada.





Mr. Johnson returns to the pharmacy to pick up his prescription. While he is paying for the medication, he reports that he still has a few more errands to run. He asks you if it is okay to leave the medicine in the car for a few hours or if he needs to go home first and drop it off in the fridge. He's a little worried since it's mid-July and it's been really hot lately.

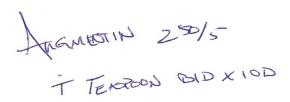
Where can you find information about storage requirements for specific medications?

Product storage guidelines are usually found in the prescribing information, or product monograph in Canada, for each drug. In the U.S., this is also called a "package insert" since it is most often available as a leaflet inserted into the box or glued to the prescription bottle. Storage recommendations are usually found near the end of the prescribing information leaflet. Specific instructions for patients regarding storage that are written in easy-to-understand wording may also be included in the "patient information" section of the prescribing information. Alert the pharmacist about questions regarding storage requirements or concerns about products that may be stored outside their recommended guidelines. Improper storage can result in loss of drug potency and may have harmful consequences to the patient. For example, a loss of potency of Mr. Johnson's insulin could lead to poor blood sugar control in his diabetes.

What can you tell Mr. Johnson about his medication?

According to the prescribing information, *Levemir* can be stored at less than 30°C (86°F) for up to 42 days. However, the temperature inside a vehicle on a hot summer day can exceed this within a few minutes. It is best not to leave any medication inside a vehicle in the summertime for more than a few minutes. Freezing of liquid medications and injectables is a concern in the winter months. Always check package labeling instructions for information about storing any medication outside of recommended guidelines (in the car, during travel, etc) and alert the pharmacist if needed.

Mr. Johnson decides to run his errands, then come back to pick up his insulin. When *Mr.* Johnson returns to the pharmacy to pick up his insulin, he also presents the following prescription for his grandson, whom he says weighs 9 kg (20 lbs):



Prescription Interpretation:

The prescription is written for Augmentin 250 mg/5 mL, one teaspoon twice daily for 10 days.

What do you need to consider when filling this prescription?

<u>Reconstitution</u>: This medication needs to be reconstituted. Per U.S. prescribing information, it is only stable for ten days once reconstituted. To ensure stability through the prescribed course of treatment, do not reconstitute it until Mr. Johnson is available to pick it up.

<u>Auxiliary Labeling</u>: *Augmentin* requires refrigeration once reconstituted. It will require a "Refrigerate" auxiliary label.

Not all antibiotic suspensions require refrigeration. However, for some, refrigeration improves taste (e.g., amoxicillin). For others, refrigeration may make them taste worse and/or hard to pour (e.g.,





clarithromycin [*Biaxin*]). For more information on storage and stability of reconstituted medications see our chart, *Pediatric Oral Antibiotic and Antifungal Suspensions and Liquids (Detail-Documents* #231107 [U.S. subscribers] and #231122 [Canadian subscribers]) and our *Technician Training Tutorial, Dispensing Pediatric Antibiotic Suspensions*.

The next day, Mr. Johnson's daughter calls, concerned because she left her child's Augmentin at room temperature overnight (from 10 PM until 7 AM). What should be done?

Surprisingly, many antibiotic suspensions retain potency even when left at room temperature for an extended period of time. However, it's important to always double check storage requirements after drug reconstitution to avoid loss of drug potency. Also alert the pharmacist to this and similar questions in case additional information is needed from the patient before answering their question.

Room temperature stability of some refrigerated medications is provided in our *Pediatric Oral Antibiotic and Antifungal Suspensions and Liquids* (see links above) and our *Stability of Refrigerated and Frozen Drugs* chart (#241001 [U.S. subscribers] and #241014 [Canadian subscribers]). For some medications or situations, the manufacturer may need to be called for advice. The manufacturer will need to know how long the medication or vaccine has been out of the refrigerator, and might ask for the lot number of the product.

A severe storm had knocked out power in your area. It may not be restored for several days.

What should be done about the products in the pharmacy refrigerator?

You should become familiar with your pharmacy's action plan for handling this situation. It is a good idea to have an agreement in advance with a local facility with a backup generator (e.g., hospital, clinic, wholesaler) for product storage in the event of a prolonged outage to avoid loss of products.

In the event of a power outage, do not open the refrigerator or freezer until absolutely necessary, such as when you are ready to transport the products.

If the temperature in the storage unit exceeds the product's recommended storage temperature, the product may need to be discarded and replaced. Or, it may still be usable, but its shelf-life may be reduced. In this case, the new expiration date should be noted on the product. The manufacturer can assist with these determinations.

What advice should patients be given regarding their refrigerated medications in the event of a power outage?

Refrigerated medications may remain potent for several days if extreme heat is avoided. For example, most insulin vials can be used for at least 28 days if kept at temperatures less than 30°C (86°F). Advise patients to keep the medication as cool as possible but avoid freezing if ice is used. They should also keep the medication out of direct sunlight. Discussion with the pharmacist and perhaps the manufacturer will be needed to determine if and when the medication needs to be replaced.



