# CONNECTICUT MEDICAL ASSISTANCE PROGRAM
# DEPARTMENT OF SOCIAL SERVICES
# &
# HEALTH INFORMATION DESIGNS, INC.

CONNECTICUT DEPARTMENT OF SOCIAL SERVICES
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HEALTH INFORMATION DESIGNS

## Special Storage and Handling

### Pradaxa ® (dabigatran)

In October 2010, Pradaxa ® was approved by the U.S. Food and Drug Administration (FDA) to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. Pradaxa ® was approved with special storage and handling requirements because capsules will hydrolyze over time when exposed to humidity, reducing the effectiveness of the medication due to breakdown of the active ingredient.

Recently, the FDA issued an alert about the importance of proper storage and handling of Pradaxa ® capsules. The label and Medication Guide clearly explain the storage and handling requirements; however, the FDA is concerned that these requirements are not commonly known and are not being followed by patients and pharmacies.

Many patients use medication boxes or organizers to aid them in taking their medications on the appropriate schedule. However, because of the potential for product breakdown and loss of potency, consumers should not store Pradaxa ® in any container other than the original manufacturer packaging.

Additionally, pharmacies should only dispense Pradaxa ® in the original manufacturer packaging. Pharmacies should never repackage the capsules in standard amber vials; keeping the capsules in original packaging significantly reduces product breakdown from moisture because the caps contains a desiccant.

The original package insert stated that the product should be discarded 60 days after the original bottle is opened. However, new information has been released and the package insert has been updated indicating that the product maintains potency up to 120 days after the bottle is opened, as long as it is stored in the original bottle and the handling requirements are met. These include closing the cap tightly after each use and keeping the bottle away from excessive moisture, heat, and cold.

**Patient Counseling Information for Storage and Handling:**

Keep Pradaxa ® capsules in the original bottle to protect the product from moisture.

Open only one bottle of Pradaxa ® at a time. Once a bottle is opened, it must be used within 120 days.

Remove only one capsule from the bottle at the time of use and immediately close the bottle tightly.

Date the bottle to expire 120 days after opening.

Do not store Pradaxa ® capsules in medication boxes or organizers.

### Xarelto ® (rivaroxaban)

In November 2011, Xarelto ® was approved by the U.S. Food and Drug Administration (FDA) to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. Additionally, Xarelto is also indicated for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing knee or hip replacement surgery.

### Xarelto ® (cont.)

Xarelto ® does not carry the same storage and handling instructions as Pradaxa ® and can be dispensed in the original manufacturing packaging, standard amber vials, or be placed in medication boxes or organizers. Dosing is an additional difference between the two drugs. Xarelto ® is dosed once a day with the evening meal , whereas Pradaxa ® is dosed twice a day. Dyspepsia can be a troublesome side effect in patients receiving Pradaxa, but the drug was noted to be slightly more efficacious than warfarin in preventing strokes.[3]

Both Xarelto ® and Pradaxa ® have similar bleeding risks and costs associated.


References

1. Food and Drug Administration. Pradaxa (dabigatran etexilate mesylate) capsules: Special Storage and Handling Requirements. March 30, 2011. Retrieved from http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm249005.htm

2. PL Detail-Document, Extended Storage Time for Pradaxa (Dabigatran). Pharmacist's Letter/Prescriber's Letter. May 2011.

3. PL Detail-Document, Anticoagulants. Pharmacist's Letter. December 2011.

4. Pradaxa [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Corp; 2011.

5. Xarelto [package insert]. Titusville, NJ: Janssen Pharmaceuticals Corp; 2011.

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## Proper Storage of Reconstituted and Liquid Antibiotics

Proper storage and administration of medications is a serious issue, especially with antibiotics that can vary greatly from one agent to another. The following table summarizes some of the most common antibiotic suspensions and how to store and administer them:

| Brand Name | Generic Name | Type of Antibiotic | Expiration | Storage (Refrigeration or Room Temperature) | Administration Instructions & Other Cautions |
|---|---|---|---|---|---|
| Amoxil® | Amoxicillin | Penicillin | 14 Days | Either[1] | May be taken with or without food. |
| Augmentin® | Amoxicillin/ Clavulanate | Penicillin | 10 Days | Refrigerate | Take with food. Storage at room temperature for 4 hours or more may decrease potency. |
| Biaxin® | Clarithromycin | Macrolide | 14 Days | Room Temperature[2] | May be taken without regards to meals. Follow each dose with water or food to rinse mouth. May become bitter tasting if stored in the refrigerator. |
| Cipro® | Ciprofloxacin | Fluroquinolone | 14 Days | Either[1] | Preferred dosing is 2 hours after a meal. Drinking extra fluids is recommended. Avoid $Mg^{2+}$, $Al^{3+}$, $Ca^{2+}$, $Zn^{2+}$, or $Fe^{2+}$ 2 hours before or after dose. |
| Cleocin® | Clindamycin | Lincomycin | 14 Days | Room Temperature[2] | Take with food. |
| Diflucan® | Fluconazole | Azole Antifungal | 14 Days | Either[1] | May be taken with or without food. |
| E.E.S.® | Erythromycin | Macrolide | 10 Days[3] | Room Temperature[2,3] | May be taken with or without food. |
| Keflex® | Cephalexin | Cephalosporin | 14 Days | Refrigerate | May be taken with or without food. Medication expires after 1 day if stored at room temperature. |
| Levaquin® | Levofloxacin | Quinolone | N/A[3] | Room Temperature[2] | Take on an empty stomach. Drinking extra fluids is recommended. Avoid $Mg^{2+}$, $Al^{3+}$, $Ca^{2+}$, $Zn^{2+}$, or $Fe^{2+}$ 2 hours before or after dose. |
| Omnicef® | Cefdinir | Cephalosporin | 10 Days | Room Temperature[2] | May be taken with or without food. Avoid $Al^{3+}$ and $Mg^{2+}$ within 1 hour before or 2 hours after dose. |
| Pen VK® | Penicillin | Penicillin | 14 Days | Refrigerate | Take on an empty stomach. No specific data for storage at room temperature, may be good for up to 5 days. |
| Septra® | Sulfamethoxazole/ Trimethoprim | Sulfonamide | N/A[3] | Room Temperature[2] | May be taken with or without food. Take with a full glass of water and increase water intake. |
| Vibramycin® | Doxycycline | Tetracycline | 14 days | Room Temperature[2] | May be taken with or without food. Take with a full glass of water. Do not lie down for 30 minutes after dose. Do not take $Al^{3+}$, $Ca^{2+}$, $Mg^{2+}$, $Fe^{2+}$, bismuth subsalicylate, or sucralfate within 1-2 hours before or 2-3 hours after dose. |
| Zithromax® | Azithromycin | Macrolide | 10 Days | Room Temperature[2] | May be taken with or without food. Do not take 1 hour before or 2 hours after taking $Mg^{2+}$ or $Al^{3+}$. |
| Zyvox® | Linezolid | Oxazolidinone | 21 Days | Room Temperature[2] | May be taken with or without food. |

[1]*Placing medication in refrigerator may improve palatability.*
[2]*Storage in refrigerator may thicken the medication and make it difficult to pour an accurate dose.*
[3]*Consult the package insert for specific product details.*