



July 1, 2009

Steve Pinneke, PharmD
Director of Pharmacy
Bromenn Healthcare
1304 Franklin
Normal, IL 61761

Dear Dr. Pinneke:

Thank you for your inquiry regarding how long Hospira large volume parenteral solutions in LifeCare® flexible containers can be stored out of the overwrap.

Product stability once the overwrap has been removed is dependent on the solution and the type of solution container. Hospira flexible containers are made primarily of two types of materials: polyvinyl chloride (PVC) or nonplasticized thermoplastic copolyester (CR3).

PVC Containers

LifeCare flexible containers are made of PVC, a material which is permeable to moisture vapor. Once the overwrap is removed, moisture escapes from the bag at a faster rate than when the overwrap is in place. Continuous water evaporation causes the content of the bag to become progressively more concentrated. At a certain point enough water loss will occur so that 5% dextrose becomes 5.5% dextrose, at which time the contents of the bag are technically beyond the labeled specification range ($\pm 10\%$).

We recommend that PVC LifeCare containers with fill volumes of greater than 25 mL, out of their overwrap, be used within **thirty (30) days**. LifeCare containers with 25 mL fill volumes should be used within **twenty one (21) days** after removal from the overwrap. The containers should be kept at room temperature, and no additives should be made. Under these conditions the solution remains sterile, nonpyrogenic and within labeled specifications.

This recommendation applies to the following Hospira products:

- 1) **General I.V. Solutions**
- 2) **ADD-Vantage® Partial-Fill and LifeCare Partial-Fill Solutions**
- 3) **LifeCare Premix I.V. Solutions**

	List Numbers
Cimetidine in 0.9% Sodium Chloride Injection	7350 and others
Gentamicin Sulfate in 0.9% Sodium Chloride Injection	7879, 7880, and others
Fluconazole Injection	4684, 4688
Heparin Sodium in 0.45% Sodium Chloride	7650 and 7651
Heparin Sodium in 0.9% Sodium Chloride	7620
Heparin Sodium in 5% Dextrose	7760 and 7761
Hetastarch 6% in 0.9% Sodium Chloride	7248
Hextend®(6% hetastarch in Lactated Electrolyte)	1555

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Lidocaine Hydrochloride in 5% Dextrose Injection	7916, 7931 and 7939
4% and 8% Magnesium Sulfate in Water for Injection	6729 and 6730
Metronidazole Injection in Water for Injection	7811
Theophylline Injection in 5% Dextrose Injection	7662, 7665, and others
Tobramycin Sulfate in 0.9% Sodium Chloride	1984, 3469 and 3470
4) Multiple Electrolyte I.V. Solutions: Normosol-R or Ionosol M in D5W	
5) Premixed Potassium Chloride I.V. Solutions	

CR3 Containers

The other type of material used to make flexible containers is CR3, which is a specially formulated non-plasticized thermoplastic copolyester material offering greater container clarity. Length of stability out of the overwrap varies from product to product.

- Flexible containers of **Dopamine Hydrochloride in 5% Dextrose Injection, USP** are fabricated from CR3. Once these containers are removed from the overwrap, they may be stored for up to **seven (7) days** at room temperature (25°C). We do not recommend that this product be used if it has been out of the overwrap exceeding seven days or if the solution becomes discolored.
- **Nutrimix® Dual Chamber** flexible containers which bear Aminosyn II in the top chamber and dextrose in the bottom chamber may be removed from the overwrap initially. If no additives have been made to the container, it is acceptable to replace it in the overwrap and store it in the **refrigerator for up to fourteen (14) days**. If additives are made to either chamber, then the bag should be used within 24 hours.
- **Dobutamine in 5% Dextrose** in flexible CR3 containers is stable for **fourteen (14) days** after removal of the overwrap. We do not recommend that this product be used if it has been out of the overwrap in excess of 14 days.

Flexible containers of **Heparin in 5% Dextrose** are fabricated from CR3 containers, and are stable for **seven (7) days** after removal of the overwrap. We do not recommend that this product be used if it has been out of the overwrap in excess of 7 days (list numbers 7793 and 7794).

I hope this information is helpful. If you have any further questions, please contact Hospira Medical Information at 1-800-615-0187 or e-mail us at medcom@hospira.com.

Sincerely,

Kate Anderson

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