The IV Therapy Shortages Update is your way to keep up-to-date on the latest IV shortage and allocation information. If you have a question regarding something you don’t see covered, please post it in the PremierConnect IV Therapy Community.

Recent IV news:
Baxter reopens channels for INTRALIPID | Baxter and FDA collaborate on temporary imports | Fresenius and Premier, Inc. amend current agreement to include limited time imports

**New** Baxter reopens wholesaler/distributor channels for INTRALIPID IV Fat Emulsion products

In a letter dated April 25, 2014, Baxter Healthcare Corporation (PP-IV-133) announced that effective May 15, 2014 INTRALIPID 20% and INTRALIPID 30% Intravenous Fat Emulsion products will again be available for purchase through distributors and wholesalers. Baxter reports a robust supply of INTRALIPID that can support a change of dosing protocols back to pre-shortage levels.

If a facility would like to order through their wholesaler again, they will need to contact them to submit a request and provide usage to their wholesaler. It will take several weeks from when the wholesaler/distributor orders from Baxter to when it will be available at their locations.

The FDA and Baxter collaborate for a temporary import of 0.9% Sodium Chloride

To address the ongoing shortage, on April 28, 2014 the FDA announced that they have coordinated with Baxter Healthcare Corporation to initiate a temporary importation of Sodium Chloride 0.9% manufactured at Baxter’s Spain facility. According to the FDA, quantities will be available starting in May through direct order. A letter from Baxter is available on their website. If there are any questions, please refer to the letter or contact Baxter’s Medical Information Service at 1.800.933.0303. Premier has requested additional information from Baxter regarding pricing, timing, and availability.

Premier adds limited Fresenius national drug codes (NDCs) to expire in concert with FDA collaboration

In an amendment to generic pharmaceuticals agreement #PPPH15APP01, the products in the below table have been added. Products will continue on agreement until such time as the Fresenius import collaboration with the FDA expires. Premier agreement pricing is available to all members. When ordering product, ensure you communicate that you are a Premier member.

<table>
<thead>
<tr>
<th>NDC</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Form</th>
<th>Str</th>
<th>Pkg Size</th>
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</thead>
<tbody>
<tr>
<td>63323062350</td>
<td>Sodium Chloride</td>
<td>Freeflex</td>
<td>0.90%</td>
<td>50mL</td>
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<tr>
<td>63323062359</td>
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Note: The FDA has extended Fresenius collaboration through end of 2014.

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Product information and Premier member pricing

Note: Quantities are limited. If product isn't readily available Fresenius will do their best to estimate availability, but cannot guarantee when the back-order will ship.
As shortages continue: please consider the following recommended steps to ensure product availability for your patients:

1. Continue conservation efforts. See attachments for recently released conservation strategies.
2. Work with your suppliers/distributors to discuss stock requirements and reach out to them first when you have an emergent need.
3. In critical situations, take advantage of the FDA collaboration with Fresenius.

**Placing orders with Fresenius**

For those who already order direct with Fresenius:
- Contact 888.386.1300.
- Indicate you would like to place an order.
- Provide Fresenius-Kabi account number and purchase order information.
- Provide product and quantity you are interested in ordering.

For those **without** established direct accounts:
- Go to Fresenius-Kabi USA website: [www.fresenius-kabi.us](http://www.fresenius-kabi.us)
- Click on 'Order Information' (left column of home page)
- Scroll down to section “Establishing a New Account.” You will find an electronic credit application, general terms and conditions, and contact information (email and phone number)

Learn more: [Fresenius Sodium Chloride 0.9% availability](#) | [Fresenius English label Sodium Chloride 0.9%](#) | [Fresenius Scandinavian label with English translation Sodium Chloride 0.9%](#) | [Fresenius reference chart Sodium Chloride 0.9%](#) | [Fresenius package insert Sodium Chloride 0.9%](#)

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**Shortage updates by Supplier**

The FDA continues to monitor shortages across suppliers. Learn more: [B. Braun](#) | [Baxter](#) | [Hospira](#)

**B. Braun**

The following codes are in a rolling backorder situation. B. Braun is working to get all committed members at 100% of their allocation:
- Sodium Chloride 0.9%, 250 mL bag, PVC/DEHP-free (NDC 00264-7800-20)
- Sodium Chloride 0.9%, 500 mL bag, PVC/DEHP-free (NDC 00264-7800-10)
- Sodium Chloride 0.9%, 1000 mL bag, PVC/DEHP-free (NDC 00264-7800-00)

Customer letter from Braun included a complete list of product codes: [December 27, 2013](#)
B. Braun clinical and technical support: 1.800.854.6851 [http://www.bbraunusa.com/contact-us.html](http://www.bbraunusa.com/contact-us.html)
Baxter

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If a facility would like to order through their wholesaler again, they will need to contact them to submit a request and provide usage to their wholesaler. It will take several weeks from when the wholesaler/distributor orders from Baxter to when it will be available at their locations.

In a letter dated March 3, 2014, Baxter announced removal of allocation on INTRALIPID 20% and INTRALIPID 30% Intravenous Fat Emulsion products. Please see the letter regarding indications and important risk information for INTRALIPID Injections.

**Related news:**

FDA approves Clinolipid for intravenous nutrition -- October 3, 2013 FDA Press Announcement

Baxter has not yet announced a product release date. Once launched, Baxter will manufacture both formulations, INTRALIPID and Clinolipid.

To speak to a clinician, call Baxter medical affairs at 800.933.0303.

For questions about a specific order, call Baxter’s center for service at 888.229.0001

For questions on allocations or general product availability, please contact your Baxter sales representative

**Baxter receives 510(k) clearance for next-generation SIGMA Spectrum infusion pump with master drug library**

On May 8, 2014, Baxter announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its next-generation SIGMA Spectrum Infusion Pump with Master Drug Library. Enhancements to the infusion pump include increased capacity of the master drug library and new asset-tracking capabilities.

Baxter plans to launch the next-generation SIGMA Spectrum with select healthcare facilities beginning in the summer of 2014.

**SIGMA Urgent Device Correction**

In a letter dated February 7, 2014, Baxter Healthcare Corporation initiated an Urgent Device Correction for Error Code 322 on the Sigma Spectrum Infusion System Pumps models 35700BAX and 35700ABB. Infusion therapy will be interrupted if a System Error 322 occurs. Please see letter link above for more information.

Affected products were manufactured from July 1, 2005 through January 15, 2014 and distributed from February 20, 2013 through January 15, 2014.

Visit the FDA website for additional information.

**Baxter to increase allocations for evacuated glass containers**

The inventory levels for the single-indication, fluid-collection-only version of our 1000 mL Evacuated Glass Container 1A8504 as well as the dual-indication 500 mL Evacuated Glass Container 1A8503 and 250 mL Evacuated Glass Container 1A8502 are high enough to increase product allocations for committed Baxter customers with ordering history to 120% for each code.

For the time being, Baxter will not accept additional direct orders from non-committed customers. Please see the customer letter dated May 6 for specific product codes.
Baxter Healthcare Corporation implements measures to help manage supply of key IV solution codes

In a letter dated March 12, 2014, Baxter Healthcare Corporation announced new measures to help manage supply of key IV solution codes. These changes will enable Baxter to continue to meet demand and customers to receive product in a more timely manner.

Please see the March 12, 2014 letter for more information including:
- Allocations will transition from a monthly to a weekly ordering cadence. There is no change in allocation amounts.
- List of affected product codes.
- Clean-up process for existing backorders. A cancelled backorder does not mean you will not get your full allocation. This step is required as part of the new process.

Action steps:
- Work with your local Baxter field representative and customer service to understand weekly allocation amounts specific to your facility for each of the select product codes.
- Continue to order through the same channels, either direct from Baxter, dealer, distributor, or wholesaler.

Previous Baxter communications on IV solutions allocations: November 12, 2013 | January 17, 2014

Baxter allocation update on Nitroglycerin in 5% Dextrose Injection products

Effective immediately, Nitroglycerin allocation has been increased to 60%. Baxter anticipates 100% allocation by April 18th. There is still a potential for backorders as warehouses are replenished. The allocation was directly related to qualification of components with the medical grade glass supplier.

25 mg Nitroglycerin in 5% Dextrose Injection; code 1A0692 (0338-1047-02)
50 mg Nitroglycerin in 5% Dextrose Injection; code 1A0694 (0338-1049-02)
100 mg Nitroglycerin in 5% Dextrose Injection; code 1A0696 (0338-1051-02)

On January 4, 2014 Baxter announced a 40% allocation of Nitroglycerin in 5% Dextrose Injection products.

On March 6, 2014, Nitroglycerin allocation was reduced from 40% to 20%.

ASHP Nitroglycerin Injection bulletin | Medpage article on IV nitroglycerin alternatives

Baxter Nitroglycerin Bottle labels were changed per an FDA request

Attached is a copy of the new labels. Baxter’s Cleveland, MS manufacturing plant will be implementing the new labels during the week of March 24, 2014. Customers will potentially receive product with the new labels at the end of the week of March 31, 2014.

Baxter communicates storage recommendations for Nitroglycerin in 5% Dextrose Injection

Attached is a copy of Baxter’s communication regarding storage recommendations to ensure protection from light to maintain product potency.

Hospira

Due to the high number of hospitals reporting that supply is not available from other sources, Hospira is updating their allocation procedures to align with customers’ contractual commitments.

In order to implement these new procedures Hospira has placed some key large volume I.V. solutions products on market reserve. Our field sales team will shortly communicate new allocation levels to their customers that reflect contractual commitments. New allocation levels will be made effective 30 days after customers are notified.

New | Hospira Supply Status 05-20-14
IV Therapy Shortages Update

IV suppliers: direct order process

*Having challenges ordering fluids directly from a supplier? Suppliers ask that you do the following:* Note: organizations should continue with their current ordering process, unless there is severe issue with getting their “allocation” from the distributor, and direct may be their only option.

1. Contact their supplier representative and inform them of the need to order direct.
2. Work with the supplier representative to determine “Allocation” or “PAR” levels for their hospital.
   **Note:** Each hospital has allocation set at their distributor. The distributor is not able to add additional “Allocation” unless the facility demonstrates the increase in supply demand. If the supply demand is increased, (new hospital, increase census, etc), the “Allocation will be increased” via the supplier representative.
3. Work with your supplier representative to assure all documentation is complete for ordering direct and the supplier customer service has established a facility account number you may order direct from the supplier.
4. Place direct order.
   **Note:** Allocation levels go with the member and will not double if you are ordering via both distribution and direct.

**B. Braun position on ordering:** During the allocation period, customers need to stay with their normal means of receiving product. This action is to avoid additional product shortages and insure that committed customers receive their allocations. Braun is concerned that customers will try to “double-dip” by receiving product through distribution and direct.