URGENT: VOLUNTARY DRUG RECALL 08/12/2019

VIVITROL DS 380MG SUSPENSION KIT
NDC# 65757-0300-01 | Besse# 34066

<table>
<thead>
<tr>
<th>LotNbr</th>
<th>Exp.Date</th>
</tr>
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<tbody>
<tr>
<td>2018-3010T</td>
<td>08/31/2021</td>
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Manufactured by Alkermes

Dear Valued Customer,

Alkermes has issued an Urgent Voluntary Drug Recall for a specific lot of the product listed above. Your account purchased the affected lot from Besse Medical between 07/08/2019 and 07/18/2019.

Please see the included letter from Alkermes for additional information and the reason for this recall. Carefully examine your inventory. If you have an affected lot, please quarantine immediately and contact Stericycle at 866-324-3739 or Alkermes2730@Stericycle for a recall response form to begin the pickup process.

If you have any questions related to the reason for this recall, please contact Stericycle at 866-324-3739. For medical inquiries, contact Alkermes at 888-235-8008 or USMedInfo@Alkermes.com. And of course, if you have any questions for us, please call Besse at 800-543-2111.

We appreciate your cooperation as we work with Alkermes to resolve this issue.

Sincerely,

Besse Medical
August 8, 2019

Re:  URGENT DRUG RECALL for VIVITROL® (naltrexone for extended-release injectable suspension, 380 mg/vial) Kit No. 2018-3010T.

Dear Customer:

Alkermes, Inc. is voluntarily recalling VIVITROL® Kit No. 2018-3010T. Please see the attached Recall Letter notice for product identification information, required actions, contact information, and the Business Reply Form.

The Recall concerns incorrect needle packaging in the VIVITROL kit. Administration and preparation needles included in the VIVITROL kit are provided in cardboard sleeves labeled with the needle use and length. In a portion of this lot, 1 inch preparation needles were included in the cardboard sleeve labeled with 1 ½ inch administration needles. As a result, these kits did not contain the 1 ½ inch administration needles. The primary packaging of the needle is labeled with the correct needle length. The drug product vial is not impacted.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. Your assistance in quickly responding to this notice and completing the attached Business Reply Form is appreciated.

Sincerely,

[Signature]

Ann Kurowski
VP, Regulatory Affairs
Alkermes, Inc.
# URGENT – DRUG RECALL

**Alkermes plc**
Corporate Headquarters
Connaught House
1 Burlington Road
Dublin 4, Ireland

**Alkermes, Inc.**
Manufacturing Site
265 Olinger Circle
Wilmington, OH 45177

## PRODUCT

<table>
<thead>
<tr>
<th>Product:</th>
<th>VIVITROL® (naltrexone for extended-release injectable suspension)</th>
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<tbody>
<tr>
<td>NDC:</td>
<td>65757-300-01 kit (outside carton)</td>
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<tr>
<td>Strength:</td>
<td>380 mg</td>
</tr>
<tr>
<td>Package Size:</td>
<td>Single dose kit</td>
</tr>
<tr>
<td>Lot Number(s):</td>
<td>Kit (Packaging) 2018-3010T Exp: 31AUG2021</td>
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<tr>
<td>Manufactured:</td>
<td>Alkermes, Inc.</td>
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<td>Wilmington, OH</td>
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## REASON

One lot of VIVITROL® product is the subject of a voluntary recall by Alkermes, Inc. VIVITROL® Lot 2018-3010T, due to 1 inch needles being placed in the 1 1/2 inch needle cardboard sleeve. Note the primary packaging of all needles is correct. The drug product vial is not impacted.

The probability of an incorrect length needle being used to administer VIVITROL® was assessed as low because the primary needle packaging correctly identifies needle length, and injections are required to be administered by a healthcare provider. Subcutaneous administration of VIVITROL® may be associated with increased risk of injection site reactions.

## ACTION

Please examine your inventory of VIVITROL® immediately and follow the appropriate course of action described below with respect to VIVITROL® (Kit No. 2018-3010T).

1. Stop dispensing/distributing product and quarantine this lot.
2. Please carry out a physical count and record the quantity you are returning on the Business Reply Form and Packing Slip included with this letter.
3. Fax or email the Business Reply Form, even if you do not have any of the affected product lot.
4. Return the recalled product lot and the Packing Slip using the pre-paid UPS Return Service shipping label to:

   Stericycle, Inc.
   2670 Executive Drive, Suite A
   Indianapolis, IN 46241
   Attn: Event 2730

5. To the extent you have distributed or dispensed product subject to this recall, please notify the persons to whom you have shipped product in accordance with your recall protocol and contact Stericycle to provide them with a separate notification package.

## OTHER INFORMATION

This recall is being carried out to the wholesaler, pharmacy and health care provider level and is only for the specific lot number listed above. Notifications of this recall are being sent to direct purchasing accounts that received the affected product lot. For wholesalers that redistribute this product to other entities, please notify entities to which this lot was sold in accordance with your recall protocol contact Stericycle to provide them with a separate notification package. Alkermes began shipping this product on 06/18/19. No other lots, packages or formulations are being recalled. For medical questions contact Alkermes, Inc. 1-888-235-8008 USMedInfo@alkermes.com. For shipping assistance or questions about the recall process please contact Stericycle 1-866-324-3739.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.