URGENT: DRUG RECALL
Alendronate Sodium Tablets USP, 70 mg

February 11, 2016

Dear Trading Partner:

This notice is to inform you of a drug product recall involving:

Drug Product Name: Alendronate Sodium Tablets USP, 70 mg

Manufacturer: Sun Pharmaceutical Industries, Ltd.

NDC Number: 47335-638-68 (Blister of 4 Tablets)

Dosage Form: Tablets

Route of Administration: Oral

Type of Drug Product: Prescription

Intended Use/Indications: Indicated for treatment and prevention of osteoporosis in postmenopausal women.

Package Type and Number of Doses/Sizes: 4 tablets packed in aluminium blister.

Lot Numbers

<table>
<thead>
<tr>
<th>Product name</th>
<th>Batch No.</th>
<th>Mfg. Date</th>
<th>Exp. Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alendronate Sodium Tablets USP, 70 mg</td>
<td>JKP2234A</td>
<td>05/2015</td>
<td>04/2017</td>
</tr>
<tr>
<td></td>
<td>JKP2235A</td>
<td>05/2015</td>
<td>04/2017</td>
</tr>
</tbody>
</table>
**Reason for Recall**

This recall is voluntarily initiated based upon stability results. During the analysis of 3 month long term stability testing, it was noticed that observed levels of highest unknown impurity was exceeding specification limit.

These lots were distributed during September 2015 to November 2015.

Immediately examine your inventory and quarantine subject lots to this recall. Please stop distributing these lots immediately. This recall is being initiated to the retail level. In addition, if you have further distributed this product, please notify your customers at once of this product recall. Your notification may be enhanced by including a copy of this recall letter.

This recall is being made with the knowledge of Food and Drug Administration.

For return of affected product, please email rxrecalls@inmar.com or call 800-967-5952, during Monday to Friday, from 8:00 am to 5:00 pm (EST). Please complete and return the enclosed response form along with your affected customer list as soon as possible.

Affected product should be sent to:
Inmar
4332 Empire Road
South Dock
Fort Worth, TX 76155

Sincerely,

[Signature]

Blynda B. Masters
Director, Customer Service
URGENT: DRUG RECALL - RESPONSE FORM

Please Complete This Form and A Provide Return Invoice and Fax to: 817-868-5362 or Email to: rxrecalls@inmar.com

We do not have any stock☐

Or,

Please enter the quantity you shall be returning.

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number</th>
<th>Pack size</th>
<th>NDC Number</th>
<th>Exp. Date</th>
<th>Quantity to be returned</th>
</tr>
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</tbody>
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Name______________________ DEA #____________________

Company____________________

Address____________________

City______________________ State _____ Zip Code_______

Phone Number____________________

Email Address____________________

Wholesaler____________________ City/State____________________

For return of affected product, please email rxrecalls@inmar.com or call 800-967-5952
*Each tablet contains 3.27 mg Alendronate Sodium, USP
(70 mg free acid equivalent).

**Usual Adult Dosage:** One 70 mg Tablet once weekly
See accompanying insert for complete dosage information.

**Important Information:**
- Please read the enclosed Medication Guide before taking
  Once Weekly Alendronate Sodium Tablets. Keep this and all drug labels out of
  the reach of children.
- Store at 68°F (20°C) excursions permitted between
  15° and 86°F (5° and 30°C) (USP Controlled Room Temperature).

**How to Take Once Weekly Alendronate Sodium Tablets 70 mg:**
- Choose your day of the week that best fits your schedule.
- Every week, take one Alendronate Sodium Tablet on your
  chosen day.

After getting up for the day on your chosen day of the
week, swallow 30 to 45 minutes before your
Alendronate Sodium Tablet with a full glass (10 to 12 fl. oz.)
of plain water on an empty stomach. Do not take Alendronate
Sodium Tablet with or before eating for the day.
- Begin your evening activities... just before dinner
- Drink no more than 1 glass of water.
- After dinner, avoid eating and drinking for at least 30 minutes.
- If you want to be done after 30 minutes, you must not
  drink anything first.
- Remember to take one Alendronate Sodium Tablet once each
  week on the same day for as long as your doctor
  prescribes it.
- If you miss a dose, take only one Alendronate Sodium
  Tablet the next day when you remember.
- Do not take two tablets on the same day.

Choose your day for taking Once Weekly Alendronate Sodium Tablets, USP 70 mg*

<table>
<thead>
<tr>
<th>WEEK 1 Date Taken</th>
<th>WEEK 2 Date Taken</th>
<th>WEEK 3 Date Taken</th>
<th>WEEK 4 Date Taken</th>
</tr>
</thead>
</table>

Once Weekly Alendronate Sodium Tablets, USP

70 mg*

Rx only

4 Tablets

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Halol-Baroda Highway,
Halol-380 350, Gujarat, India.

Distributed by:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512