URGENT DRUG RECALL
Cetirizine Hydrochloride Chewable Tablets, 5 mg and 10 mg

April 09, 2014

Dear Trading Partner,

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

Drug Product Name: Cetirizine Hydrochloride Chewable Tablets, 5 mg and 10 mg

Manufacturer: Sun Pharmaceutical Industries, Ltd

NDC Number: For 5 mg: 47335-343-83 (30 CRC)
For 10 mg: 47335-344-83 (30 CRC) and 68016-353-30 (30 CRC).

Dosage Form: Chewable Tablet

Route of Administration: Oral

Type of Drug Product: Over-The-Counter

Intended Use/Indications: Indicated For the relief of symptoms associated with seasonal allergic rhinitis, perennial allergic rhinitis and also for the treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria.

Package Type and Number of Doses/Sizes: 30 tablets packed in HDPE bottles closed with Child Resistant Caps (CRC).

Affected Lot numbers

<table>
<thead>
<tr>
<th>Product name</th>
<th>Pack Size</th>
<th>Lot Number</th>
<th>Exp. Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cetirizine Hydrochloride Chewable Tablets, 5 mg</td>
<td>30 count CRC pack</td>
<td>JKM2067A</td>
<td>07/2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JKM2068A</td>
<td>10/2014</td>
</tr>
<tr>
<td></td>
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<td>JKM2069A</td>
<td>01/2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JKM6399A</td>
<td>04/2015</td>
</tr>
<tr>
<td>Cetirizine Hydrochloride Chewable Tablets, 10 mg</td>
<td>30 count CRC pack</td>
<td>JKM2070A</td>
<td>07/2014</td>
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<tr>
<td></td>
<td></td>
<td>JKM2071A</td>
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<td></td>
<td>JKM2072A</td>
<td>01/2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JKM2072B</td>
<td>01/2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JKM6400A</td>
<td>04/2015</td>
</tr>
</tbody>
</table>
Reason for Recall:
This recall is voluntarily initiated based upon stability results. The product may not meet the drug release specification throughout its expiry period. As a precaution, Caraco is voluntarily recalling these lots. Cetirizine Hydrochloride Chewable Tablets, 5 mg; Batch # JKM2067A, JKM2068A, JKM2069A, JKM6399A and Cetirizine Hydrochloride Chewable Tablets, 10 mg; Batch # JKM2070A, JKM2071A, JKM2072A, JKM2072B and JKM6400A.

These lots were shipped between September 3, 2013 and March 13, 2014.

Immediately examine your inventory and quarantine lot subject to this recall. Please stop distributing these lots immediately. This recall has been classified as a retail level recall (Class II). In addition, if you have further distributed this product, please notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall letter.

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

For return of affected product, please email recallnotice@inmar.com or call 800-967-5952. Please complete and return the enclosed response form as soon as possible.

Affected product should be sent to:

Inmar
4332 Empire Road
South Dock
Fort Worth, TX 76155

If there are any further questions, please feel free to contact me at 800-818-4555 x 4105,

Sincerely,

[Signature]
Robert Kurkiewicz
Sr. Vice President, Regulatory
URGENT: DRUG RECALL – RESPONSE FORM

Please Complete Form and Fax to: 817-868-5362

Or Email to: recallnotice@inmar.com

We do not have any stock  

Or,

Please enter the quantity you shall be returning to Inmar

<table>
<thead>
<tr>
<th>Product name</th>
<th>Lot Number</th>
<th>Batch No.</th>
<th>Exp. Date</th>
<th>Quantity Being Returned to Inmar</th>
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<tbody>
<tr>
<td>Cetirizine Hydrochloride Chewable Tablets, 5 mg</td>
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<td>JKM6400A</td>
<td>04/2015</td>
<td></td>
</tr>
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</table>

Name________________________________ DEA#_____________________________________

Company______________________________________________________________

Address_________________________________________________________________

City________________________State_______Zip Code_______________________

Phone Number________________________Email_________________________________

Wholesaler________________________________ City/State_____________________

For return of affected product, please email recallnotice@inmar.com or call 800-967-5952
<table>
<thead>
<tr>
<th>Proof Version</th>
<th>Job</th>
<th>Proofs On</th>
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<tbody>
<tr>
<td>5</td>
<td>400302</td>
<td>12/08/2013</td>
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**Item**: PJLB1515C (12/2013) (2456204-254) Front of Ply 2

**Size & Shape**: 1.1811 x 4.1339 ROUND CORNER

**Description**: CETIRIZINE HYDROCHLORIDE 5 MG / 30 TABLETS RE-SEAL 3 47335 34383 0

**Proofed On**: 12/09/2013

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The colors indicated are a representation. Press will match spot colors to the appropriate color guide. Process images will be matched to a color controlled proof.

To avoid delays, please approve this proof by end of day Tuesday December 10, 2013.

Return proof to If approving this item by fax, please send this page only

- Approved As Is
- Submit New Proof

<table>
<thead>
<tr>
<th>CSR</th>
<th>Jennifer Reese</th>
<th>Phone</th>
<th>714-253-0517</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email</td>
<td><a href="mailto:jreese@wspackaging.com">jreese@wspackaging.com</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax</td>
<td>+1 714-894-6543</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Drug Facts

Active Ingredient
(in each chewable tablet)

Cetirizine hydrochloride, USP 5 mg.............Antihistamine

Uses

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

To avoid delays, please approve this proof by end of day Tuesday December 10, 2013.
The colors indicated are a representation. Press will match spot colors to the appropriate color guide. Process images will be matched to a color controlled proof.

To avoid delays, please approve this proof by end of day Tuesday December 10, 2013.
Proof Version 3
Job 401396
Proofed On 12/09/2013

Item: PJLB1515C (12/2013) (2456204-257) Panel 1

Size & Shape: 2.0625 x 5.0
Description: ONSET CETIRIZINE HYDRCHL 3 UP 5 MG / 30 TABLETS

Proofed On: 12/09/2013

The colors indicated are a representation. Press will match spot colors to the appropriate color guide. Process images will be matched to a color controlled proof.

To avoid delays, please approve this proof by end of day Tuesday December 10, 2013.

Approved As Is
Submit New Proof

Signature
Date
Insert 1 Back
1/8" from die edges
Finished Book Size
5 0/8" x 2 0/8

Drug Facts (continued)
kidney disease. Your doctor should determine if
you need a different dose.
Ask a doctor or pharmacist before use if you are
taking tranquilizers or sedatives.

When using this product
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may
increase drowsiness

Drug Facts (continued)
kidney disease. Your doctor should determine if
you need a different dose.
Ask a doctor or pharmacist before use if you are
taking tranquilizers or sedatives.

When using this product
• drowsiness may occur • avoid alcoholic drinks
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increase drowsiness

The colors indicated are a representation. Press will match spot colors to the appropriate color guide. Process images will be matched to a color controlled proof.

To avoid delays, please approve this proof by end of day Tuesday December 10, 2013.
Insert 2 Top

1/8” from die edges

Finished Book Size

5 0" W x 7 0" H
The colors indicated are a representation. Press will match spot colors to the appropriate color guide. Process images will be matched to a color controlled proof.

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To avoid delays, please approve this proof by end of day Tuesday December 10, 2013.
Drug Facts

Active ingredient (in each chewable tablet)

Cetirizine hydrochloride 10 mg .........................................Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

• runny nose
• sneezing
• itchy, watery eyes
• itchy throat or nose

Warnings

Do not use if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

When using this product:

• drowsiness may occur
• avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

If pregnant or breast-feeding:

• if breast-feeding: not recommended
• if pregnant: ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Drug Facts

Directions

• may be taken with or without water

adults and children 6 years and over

adults 65 years and over

children under 6 years of age

consumers with liver or kidney disease

Other information

Inactive ingredients

acesulfame potassium, colloidal silicon dioxide, compressible sugar, crospovidone, FD & C Blue No # 2 Aluminum Lake, FD & C Red No # 40 Aluminum Lake, guar gum, magnesium oxide light powder, mannitol, microcrystalline cellulose, pregelatinized starch, prosweet N & A flavor powder, talc, tutti frutti flavor

Questions?

Call toll free 1-800-818-4555 weekdays

This proof is for color break only.
Please refer to The Pantone® Matching System swatches for accurate color. This color WILL NOT MATCH your final printed labels.
<table>
<thead>
<tr>
<th>Drug Facts</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Active Ingredient</strong></td>
<td>Cetirizine Hydrochloride 10 mg/tablet</td>
</tr>
<tr>
<td><strong>Use</strong></td>
<td>Cetirizine Hydrochloride 10 mg/tablet</td>
</tr>
</tbody>
</table>

**Indications**: For the relief of symptoms of types I and II allergies, including runny nose, sneezing, itching, and rash associated with allergic rhinitis and conjunctivitis.

**Dosage**:
- **Children 6 to 11 years**: Not recommended.
- **Children 12 years or older**: Use as directed by a physician.
- **Adults**: Take one tablet every 12 hours as needed.

**Precautions**:
- **Allergic Reactions**: In case of an allergic reaction, discontinue use and contact a physician immediately.
- **Gastrointestinal Symptoms**: In case of gastrointestinal symptoms, discontinue use and consult a physician.
- **Renal Impairment**: In case of renal impairment, use with caution and consult a physician.

**Warnings**:
- Use in patients with severe renal impairment (creatinine clearance <10 mL/min).
- Use in patients with concurrent medications that may affect renal function.

**Contraindications**:
- Hypersensitivity to cetirizine or any component of the formulation.

**Adverse Reactions**:
- **Common**: Drowsiness, dry mouth, constipation.
- **Rare**: Nausea, vomiting, diarrhea, headache.

**Usage**:
- Take with or without food.

**Storage**:
- Store at room temperature (15°C to 30°C) in a cool, dry place.

**Manufacture**:
- Premier Value Pharmaceutical Corporation

**Questions**:
- Please consult your healthcare provider for further information.