CARACO
PHARMACEUTICAL LABORATORIES, LTD.

URGENT DRUG RECALL
VENLAFAXINE HCl ER 150 MG TABLETS

June 12, 2014

Dear Trading Partner,

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

Drug Product Name: Venlafaxine Hydrochloride Extended-Release Tablets, 150 mg

Manufacturer: Sun Pharmaceutical Industries, Ltd

NDC Number: 41616-758-83 (30 CRC) and 41616-758-81 (90 CRC).

Dosage Form: Extended Release Tablet

Route of Administration: Oral

Type of Drug Product: Prescription

Intended Use/ Indications: Indicated for the treatment of major depressive disorder.

Package Type and Number of Doses/Sizes: 30 tablets packed in HDPE bottles closed with Child Resistant Caps (CRC) and 90 tablets packed in HDPE bottles closed with Child Resistant Caps (CRC).

Batch Numbers:

Product name	Pack Size	Batch No.	Mfg. Date	Exp. Date
Venlafaxine Hydrochloride Extended-Release Tablets, 150 mg	30 count CRC pack	JKL5054A	09/2012	08/2014
	90 count CRC pack	JKL5054B	09/2012	08/2014
	30 count CRC pack	JKM2305A	04/2013	03/2015
	90 count CRC pack	JKM2305B	04/2013	03/2015

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Reason for Recall
This recall is voluntarily initiated based upon stability results. The product may not meet the drug release specification throughout it expiry period. As a precaution, Caraco is voluntarily recalling these batches ((Venlafaxine Hydrochloride Extended-Release Tablets, 150 mg; batch # JKL5054A, JKL5054B, JKM2305A and JKM2305B).

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 you customers may be enhanced by including a copy of this recall letter.

These batches were shipped between October 29, 2012 and August 28, 2013.

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,

Robert Kurkiewicz

Robert Kurkiewicz
Sr. Vice President, Regulatory

100mm

Black
PANTONE 272 C
CF 1511
30% of CF 1511

Size: 100x40mm
[CRC]
Unvarnish area: 21.5 x 8 mm

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Protect from moisture and humidity.

CARACO

Distributed by:
Caraco Pharmaceutical Laboratories, Ltd.
1150 Elijah McCoy Drive, Detroit, MI 48202

Manufactured at:
Sun Pharmaceutical Ind. Ltd.
Halol-Baroda Highway,
Halol-389 350, Gujarat, India.

NDC 41616-758-81

Venlafaxine Hydrochloride Extended-Release Tablets

150 mg*

Rx only
90 TABLETS

SUN PHARMACEUTICAL INDUSTRIES LTD.

PHARMACIST: PLEASE DISPENSE WITH MEDICATION GUIDE PROVIDED SEPARATELY

*Each extended-release tablet contains venlafaxine hydrochloride equivalent to 150 mg of venlafaxine.

Usual Dosage: Once daily.
See accompanying information.

PJLB1259 PJLB1259
ISS. 07/2009

GUJ/DRUGS/25/789

Batch No.:

Exp.:

N 3 41616 75881 8

50.8mm

152.4mm

Black
PANTONE 272 C
CF 1511
30% of CF 1511

Size: 152.4x50.8mm
[CRC]
Unvarnish area: 33 x 13.5 mm

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use venlafaxine hydrochloride extended-release tablets safely and effectively. See full prescribing information for venlafaxine hydrochloride extended-release tablets.

Venlafaxine Hydrochloride Extended-Release Tablets, for oral use

Initial U.S. Approval: 1993

WARNING: Suicidality and Antidepressants

See full prescribing information for complete boxed warning.

Increased risk of suicidal thinking and behavior in children, adolescents and young adults taking antidepressants for major depressive disorder (MDD) and other psychiatric disorders. Venlafaxine hydrochloride extended-release tablets are not approved for use in pediatric patients. (5.1)

----------INDICATIONS AND USAGE----------

Venlafaxine hydrochloride extended-release tablets are a selective serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for:

- Major Depressive Disorder (MDD) (1.1)

----------DOSAGE AND ADMINISTRATION----------

- Initial Treatment (2.1)

Indication	Starting Dose	Dose Increase	Maximum Dose
Major Depressive Disorder	75 mg/day (in some patients, 37.5 mg/day for 4 to 7 days)	75 mg/day increments at intervals of 4 days or longer	225 mg/day

- Venlafaxine hydrochloride extended-release tablets should be taken as a single daily dose with food in either the morning or evening at the same time each day. (2)
- Discontinuation: Gradual; individualized as necessary. (2.4)

----------DOSAGE FORMS AND STRENGTHS----------

- 37.5 mg, 75 mg, and 150 mg tablets (3)

----------CONTRAINDICATIONS----------

- Concomitant use of monoamine oxidase inhibitors (4)

----------WARNINGS AND PRECAUTIONS----------

- Suicidality: Monitor for clinical worsening and suicide risk. (5.1)
- Monoamine Oxidase Inhibitors (MAOIs): Serious interactions possible. Concomitant use contraindicated. Avoidance of MAOIs recommended for at least 14 days before starting venlafaxine. A MAOI should not be started within 7 days after stopping venlafaxine. (5.2)
- Serotonin syndrome, or Neuroleptic Malignant Syndrome (NMS)-like reactions: Serotonin syndrome or NMS-like reactions have been reported with SSRIs. Discontinue venlafaxine hydrochloride extended-release tablets and initiate supportive treatment. (5.3)
- Sustained hypertension may occur. Blood pressure monitoring recommended. (5.4)
- Mydriasis may occur. Patients with raised intraocular pressure or those at risk of acute narrow-angle glaucoma should be monitored. (5.5)
- Abrupt discontinuation or dose reduction: Discontinuation symptoms may occur (generally self-limiting; serious symptoms possible). Dose reduction recommended to be gradual. (5.6)
- Activation of Mania/Hypomania has occurred. (5.11)
- Symptomatic hyponatremia may occur. (5.12)
- Seizures have been reported. Use with caution in patients with seizure history. (5.13)
- Abnormal bleeding (most commonly ecchymosis) has been reported. (5.14)
- Serum cholesterol: Clinically relevant cholesterol increases may occur. Cholesterol measurements should be considered during long-term therapy. (5.15)
- Interstitial lung disease and eosinophilic pneumonia have been reported. (5.16)

----------ADVERSE REACTIONS----------

Major Depressive Disorder - Adverse events in short-term studies that occurred in at least 5% of the patients receiving venlafaxine extended-release capsules and at a rate at least twice that of the placebo group were abnormal ejaculation, gastrointestinal complaints (nausea, dry mouth, and anorexia), CNS complaints (dizziness, somnolence, and abnormal dreams), and sweating.

To report SUSPECTED ADVERSE REACTIONS, contact CARACO Pharmaceutical Laboratories Ltd. at 1-800-818-4555 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

----------DRUG INTERACTIONS----------

- MAOI's: concomitant use contraindicated (4). Avoid MAOI's 14 days before starting venlafaxine and 7 days after stopping venlafaxine (5.2).
- Cimetidine: Caution in patients with preexisting hypertension, in elderly patients and patients with hepatic dysfunction. (7.2)
- Haloperidol: Increase in Haloperidol AUC and C_{max}. (7.4)
- Ketoconazole: Increase in venlafaxine and O-desmethylvenlafaxine AUC and C_{max}. Caution when using venlafaxine with substances that inhibit both CYP2D6 and CYP3A4. (7.7)
- Metoprolol: Possibly reduced blood-pressure lowering effect despite increased metoprolol plasma levels. Caution should be exercised with coadministration of venlafaxine and metoprolol. (7.8)
- CNS-active drugs: Caution when using venlafaxine with such drugs. (7.10)
- Serotonergic drugs (e.g., triptans, SSRIs, other SNRIs, linezolid, lithium, tramadol, or St. John's Wort): Potential for serotonin syndrome. Careful patient observation advised. (7.10)
- Tryptophan supplements: Concomitant use not recommended. (7.10)

----------USE IN SPECIFIC POPULATIONS----------

- Pregnancy: Use during pregnancy only if clearly needed. Neonates exposed to venlafaxine in the third trimester have developed complications requiring prolonged hospitalization, respiratory support, and tube feeding. Benefits and risk of venlafaxine use in the third trimester should be carefully considered. (2.3; 8.1)
- Nursing: Potential for serious adverse reactions in the infant. Discontinue nursing or drug, considering the importance of the drug to the mother. (8.3)
- Pediatric use: Not approved for use in pediatric patients. When considering use in a child or adolescent, balance potential risks with clinical need. (8.4)
- Hepatic impairment: Reduction of total daily dose by 50% recommended in patients with mild to moderate impairment. In patients with cirrhosis, further reduction may be necessary and dosing individualization may be desirable. (2.3; 8.6)
- Renal impairment: Reduction of daily dose by 25 to 50% recommended. Dosing individualization may be necessary. (2.3; 8.7)
- Hemodialysis: Reduction of daily dose by 50%. (2.3; 8.7)

See 17 for PATIENT COUNSELING INFORMATION and the FDA-approved Medication Guide

Revised: 05/2012

FULL PRESCRIBING INFORMATION: CONTENTS*

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