URGENT DRUG RECALL
OXCARBAZEPINE TABLETS 300 MG

February 11, 2014

Dear Trading Partner,

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

Drug Product Name: Oxcarbazepine Tablets 300 mg

Manufacturer: Sun Pharmaceutical Industries, Ltd

Firm Drug Product Code: 184

Dosage Form: Immediate Release Tablets

Route of Administration: Oral

Package Type and Size: 100 tablets in a bottle

NDC Number:
62756-184-88

Lot Number:
JKM7075A

Reason for the Recall:
This recall is voluntarily initiated after investigation into complaints found the potential for lot # JKM7075A of Oxcarbazepine Tablets 300 mg to contain broken tablets.

Please Consider: If broken tablets are consumed the patient may not get the recommended dose for the underlying seizure disorder and a sudden decrease in dose may increase the risk of seizure frequency in patients due to which there is also a possibility of aggravation of the existing clinical condition.

Product Name	NDC	Pack Size	Lot Number	Expiry Date
Oxcarbazepine 300 mg 100 ct	62756-184-88	100	JKM7075A	10/2015

1150 Elijah McCoy Drive Detroit, Michigan 48202 Tel: 313-871-8400 Fax: 313-871-8314

Intended Use/ Indications:
For use as monotherapy or adjunctive therapy in treatment of partial seizures (ps) in adults and as monotherapy in the treatment of ps in children aged 4 years and above with epilepsy, and as adjunctive therapy in children aged 2 years and above with partial seizures.

The affected lot JKM7075A was shipped between January 8, 2014 and January 9, 2014. Please find enclosed copies of the drug label.

Immediately examine your inventory and quarantine product lot subject to this recall. Please stop distributing lot number JKM7075A immediately. In addition, if you may have further distributed this product, please provide your sub-account contact information (address, phone number) and /or notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

This recall has been classified as a Retail level recall (Class II).

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 817-868-5389. Please complete and return the enclosed response form as soon as possible.

Affected product should be sent to:

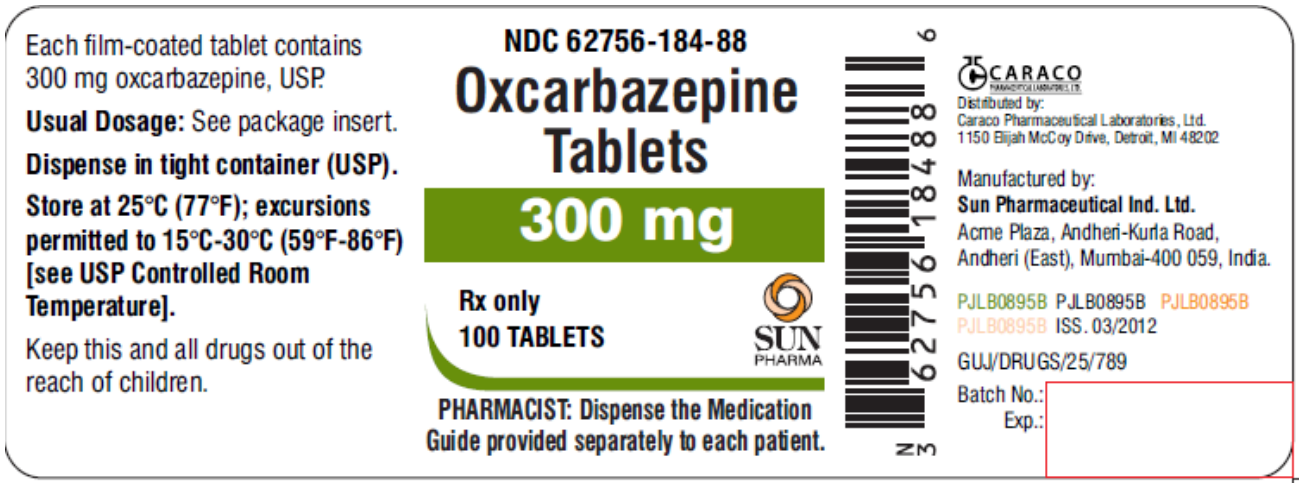
Inmar
4332 Empire Road
South Dock
Fort Worth, TX 76155

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

Sincerely,

Robert Kurkiewicz
Sr. Vice President, Regulatory

Container Label - Oxcarbazepine Tablets, 300 mg



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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 Caraco:

Product Name	NDC	Pack Size	Lot Number	Qty to be Returned
Oxcarbazepine 300 mg 100 ct	62756-184-88	100	JKM7075A	

Name_____ Title_____

Company_____

Address_____

City _____State _____ Zip Code_____

Phone Number_____ Email_____

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