



URGENT DRUG RECALL
Nimodipine Capsules, 30 mg

September 4, 2012

Dear Trading Partner,

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

Drug Product Name: Nimodipine Capsules 30 mg

Manufacturer: Pharmaceutics International Inc.

Firm Drug Product Code: 135

Dosage Form: Immediate Release Capsules

Route of Administration: Oral

Intended Use/ Indications: Nimodipine Capsules, 30 mg are indicated for the improvement of neurological outcome by reducing the incidence and severity of ischemic deficits in patients with subarachnoid hemorrhage from ruptured intracranial berry aneurysms regardless of their post-ictus neurological condition (i.e. Hunt and Hess I-V).

Package Type and Number of Doses/Sizes: Blister Cards, Unit Dose Blisters of 30 (5x6) and Unit Dose Blisters of 100 (25x4)

NDC Number:

57664-135-64 – Unit Dose Blisters of 30 (5x6)

57664-135-65 - Unit Dose Blisters of 100 (25x4)

UPC Number:

357664135648

357664135655



Reason for the Recall:

The recall is being initiated due to the presence of crystals of Nimodipine within the capsule solution. The crystallization of the nimodipine fill material in the capsule could adversely affect the product's bioavailability. Although clinical health implications are unknown, use of the product when the nimodipine has crystallized in the capsule may be of great clinical significance. The product may no longer be bioequivalent and may potentially affect patients who are being treated for a medical emergency. As a precautionary measure, Sun is recalling the following lot numbers to minimize any potential risk to patients.

Product Name	NDC	Pack Size	Lot Number	Expiration Dates (MM-YY)
Nimodipine Capsules, 30 mg	57664-135-64	30 (5x6)	3305.039B	07/13
	57664-135-65	100 (25x4)	3305.039A	07/13

The lot numbers affected by this recall were shipped between January 19, 2012 and April 24, 2012. Please find enclosed copies of the drug label.

This recall has been indicated as a consumer level recall. Immediately examine your inventory and quarantine product subject to this recall. Please stop distributing the referred lots of this product immediately. In addition, if you have further distributed this product, please identify your customers and 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 is being made with the knowledge of the Food and Drug Administration.

For return of affected product, please call Inmar at 800-967-5952. Representatives are available Monday through Friday, 8 AM to 5 PM EST. Please complete and return the enclosed response form as soon as possible.

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



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

Product Name	NDC	Pack Size	Lot #	Quantity to be Returned
Nimodipine Capsules, 30 mg	57664-135-64	30 (5x6)	3305.039B	
	57664-135-65	100 (25x4)	3305.039A	

Name _____ Title _____

Company _____

Address _____

City _____ State _____ Zip Code _____

Phone Number _____ Email _____

For return of affected product, please call Inmar at 800-967-5952. Representatives are available Monday through Friday, 8 AM to 5 PM EST.

Affected Product must be returned to:

Inmar Inc.
South Dock
4332 Empire Road
Fort Worth, TX 76155

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

Nimodipine Capsules

Nimodipine Capsules

30 mg

**30 Capsules Unit Dose
(5 x 6)**

USUAL ADULT DOSAGE:

For dosage and other prescribing information see accompanying product literature.

STORE at 20° - 25° C (68° - 77° F).
(See USP Controlled Room Temper

Capsules should be protected from light and freezing.

Contents are not packaged child-resistant.

Capsules are individually blister sealed. Do not use if seal is damaged or broken.

EACH CAPSULE CONTAINS:

Nimodipine, USP.....30 mg

Clear yellow solution filled in oblong opaque light yellow softgel capsules, imprinted "135" in black ink.

Distributed by: Caraco Pharmaceutical Laboratories, Ltd.
Detroit, MI 48202
Affiliate of
Sun Pharmaceutical Industries, Inc.



Rx only
FOR INSTITUTIONAL USE ONLY
PACKAGE IS NOT CHILD-RESISTANT
30 Capsules Unit Dose
(5 x 6)

30 mg

Nimodipine Capsules

Lot No.
Exp. Date

NDC 57664-135-64

Nimodipine Capsules

30 mg

Rx only
FOR INSTITUTIONAL USE ONLY

Place Rx label here.

PACKAGE IS NOT CHILD-RESISTANT

**30 Capsules Unit Dose
(5 x 6)**



Nimodipine Capsules

30 mg

Rx only
FOR INSTITUTIONAL USE ONLY
PACKAGE IS NOT CHILD-RESISTANT
30 Capsules Unit Dose
(5 x 6)

Stock No. 5000L01
02/07

Nimodipine Capsules
30 mg
100 Capsules Unit Dose
(25 x 4)
Rx only
FOR INSTITUTIONAL USE ONLY
PACKAGE IS NOT CHILD-RESISTANT

Nimodipine Capsules
30 mg
100 Capsules Unit Dose
(25 x 4)

USUAL ADULT DOSAGE:
For dosage and other prescribing information see accompanying product literature.
STORE at 20° - 25° C (68° - 77° F).
(See USP Controlled Room Temperature).
Capsules should be protected from light and freezing.
Contents are not packaged child-resistant.
Capsules are individually blister sealed. Do not use if seal is damaged or broken.
EACH CAPSULE CONTAINS:
Nimodipine, USP.....30 mg
Clear yellow solution filled in oblong opaque light yellow softgel capsules, imprinted "135" in black ink.

Distributed by: Caraco Pharmaceutical Laboratories, Ltd.
Detroit, MI 48202
Affiliate of
Sun Pharmaceutical Industries, Inc.



Nimodipine Capsules
30 mg
100 Capsules Unit Dose
(25 x 4)
Rx only
FOR INSTITUTIONAL USE ONLY
PACKAGE IS NOT CHILD-RESISTANT

Lot No.
Exp. Date

NDC 57664-135-65
Nimodipine Capsules
30 mg

Rx only
FOR INSTITUTIONAL USE ONLY

Place Rx label here.

PACKAGE IS NOT CHILD-RESISTANT

100 Capsules Unit Dose
(25 x 4)



Nimodipine Capsules
30 mg
100 Capsules Unit Dose
(25 x 4)
Rx only
FOR INSTITUTIONAL USE ONLY
PACKAGE IS NOT CHILD-RESISTANT

Stock No. 5001L01
02/07