



URGENT VOLUNTARY RECALL: Pharmacy Level, October 10, 2024

Cinacalcet Tablets 30 mg, 60 mg and 90 mg

Accord Healthcare, Inc. (“Accord Healthcare”) is voluntarily recalling **multiple batches of Cinacalcet Tablets 30 mg, 60 mg and 90 mg, at the Pharmacy Level.**

This recall is being initiated due to the presence of a nitrosamine impurity, N-nitroso-cinacalcet, at or above the acceptable daily intake (ADI) limits established by regulatory authorities. During testing, the presence of **N-nitroso-cinacalcet** above ADI limits was detected, a type of nitrosamine impurity in certain batches of Cinacalcet Tablets. Nitrosamines are classified as probable human carcinogens based on laboratory studies and long-term exposure above the ADI may increase the risk of cancer. As patient safety is its highest priority, Accord Healthcare is taking immediate action to recall the affected product batches. To date, Accord Healthcare has not received any reports of adverse events related to the presence of a nitrosamine impurity in the medicine.

Please examine your inventory of Accord Healthcare’s Cinacalcet Tablets 30 mg, 60 mg and 90 mg for the below listed batch numbers carefully.

The product label for recalled products should have the following details, please refer to the enclosed product labels included with this recall letter.

| Cinacalcet Tablets | | | | |
|--------------------|------------------|--------------|-----------|-------------|
| Strength | Bottle Pack size | Product NDC | Batch No. | Expiry Date |
| 30MG | 30 Tablets | 16729-440-10 | M2118190 | 11/2024 |
| 30MG | 30 Tablets | 16729-440-10 | M2201091 | 11/2024 |
| 30MG | 30 Tablets | 16729-440-10 | M2206241 | 11/2024 |
| 30MG | 30 Tablets | 16729-440-10 | M2206451 | 04/2025 |
| 30MG | 30 Tablets | 16729-440-10 | M2208674 | 06/2025 |
| 30MG | 30 Tablets | 16729-440-10 | M2213850 | 08/2025 |
| 30MG | 30 Tablets | 16729-440-10 | M2215221 | 09/2025 |
| 30MG | 30 Tablets | 16729-440-10 | M2216236 | 11/2025 |
| 30MG | 30 Tablets | 16729-440-10 | M2217098 | 11/2025 |
| 30MG | 30 Tablets | 16729-440-10 | M2300664 | 11/2025 |
| 30MG | 90 Tablets | 16729-440-15 | M2210808 | 06/2025 |
| 30MG | 90 Tablets | 16729-440-15 | M2212212 | 08/2025 |
| 30MG | 90 Tablets | 16729-440-15 | M2214435 | 09/2025 |
| 30MG | 90 Tablets | 16729-440-15 | M2217097 | 11/2025 |
| 30MG | 90 Tablets | 16729-440-15 | M2301921 | 01/2026 |
| 60MG | 30 Tablets | 16729-441-10 | M2204481 | 02/2025 |
| 60MG | 30 Tablets | 16729-441-10 | M2212389 | 08/2025 |

Contd..



| Cinacalcet Tablets | | | | |
|--------------------|------------------|--------------|-----------|-------------|
| Strength | Bottle Pack size | Product NDC | Batch No. | Expiry Date |
| 60MG | 30 Tablets | 16729-441-10 | M2214271 | 09/2025 |
| 60MG | 30 Tablets | 16729-441-10 | M2215970 | 10/2025 |
| 60MG | 30 Tablets | 16729-441-10 | M2216458 | 10/2025 |
| 60MG | 90 Tablets | 16729-441-15 | M2212869 | 08/2025 |
| 60MG | 90 Tablets | 16729-441-15 | M2216362 | 09/2025 |
| 60MG | 90 Tablets | 16729-441-15 | M2215969 | 10/2025 |
| 90MG | 30 Tablets | 16729-442-10 | M2303264 | 01/2026 |
| 90MG | 90 Tablets | 16729-442-15 | M2306979 | 04/2026 |

Pharmacy - Please perform the following activities:

- Examine your inventory immediately for listed batch numbers of Cinacalcet Tablets 30 mg, 60 mg and 90 mg.
- Immediately discontinue distribution of the recalled batch numbers of Accord Healthcare's Cinacalcet Tablets 30 mg, 60 mg and 90 mg.
- Promptly complete the attached recall stock response form and reply even if you have **NO** Product to return.
- If you do have product to return, complete the attached recall stock response form, quarantine the stock and follow the instructions given on recall stock response form.
- If you have further distributed these batch numbers to other retailers, please immediately contact your customers and advise them of the recall and have them return their outstanding recalled stock to you. Return this stock as per the instructions on the attached Product Recall Response Form.

Your assistance is appreciated and necessary to prevent any potential health risk to the consumer.

Accord is working with Inmar Inc. to complete this recall. This recall is being made with the knowledge of the Food & Drug Administration. Your cooperation and prompt response to this notice is much appreciated.

Please complete and return the enclosed "PRODUCT RECALL RESPONSE FORM" as soon as possible, but no later than five business days from receipt of this letter.

Completed Product Recall Response form should be emailed, or sent via FAX to INMAR,
Attn: Inmar Rx Solutions, 3845 Grand Lakes Way, Grand Prairie, TX 75050.
INMAR Email: rxrecalls@inmar.com. FAX: 1-817-868-5362.

If you have any questions about the logistics for returning affected batch numbers or other issues, please call Recall Services at 1-877-902-4127, Monday – Friday (excluding holidays), 9am to 5 pm EST.





INMAR will send you a Return Goods Authorization and shipping label. Appropriate credit for the returned product plus handling and shipping expenses will be issued to you upon receipt of the recalled product with the completed Return Goods Authorization. All recalled products returned without a Return Goods Authorization may delay the issuance of your credit.

We appreciate your assistance in this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Sabita Nair", written over a horizontal line.

Sabita Nair, RAC, ASQ-CPGP
Vice President – Regulatory Affairs
Accord Healthcare, Inc.
8041 Arco Corporate Drive, Suite 200
Raleigh, NC 27617
USA



Each film coated tablet contains cinacalcet 30 mg (equivalent to 33 mg of cinacalcet hydrochloride).
Dosage: See Package Insert.
Store at 25°C (77°F); excursions permitted from 15°C to 30°C (59°F to 86°F). [See USP controlled room temperature].
Dispense in tight, light-resistant container per USP.
Manufactured for:
Accord Healthcare, Inc.,
Durham, NC 27703.
Manufactured by:
Intas Pharmaceuticals Limited,
Ahmedabad - 382 210, INDIA.

NDC 16729-440-10

Cinacalcet Tablets

30 mg

Rx Only

30 Tablets

 accord

10 3205 2 6014562 INL088 Mfg. Lk. No.: GZ571339



3 16729 440101 3

Keep area blank & varnish free for
overcoding Lot and EXP & Data matrix
45 X 22 mm



Each film coated tablet contains cinacalcet 30 mg (equivalent to 33 mg of cinacalcet hydrochloride).

Dosage: See Package Insert.
Store at 25°C (77°F); excursions permitted from 15°C to 30°C (59°F to 86°F). [See USP controlled room temperature].

Dispense in tight, light-resistant container per USP.

Manufactured for:
Accord Healthcare, Inc.,
Durham, NC 27703.

Manufactured by:
Intas Pharmaceuticals Limited,
Ahmedabad - 382 210, INDIA.

NDC 16729-440-15

Cinacalcet Tablets

30 mg

Rx Only
90 Tablets
accord

10 3206 2 6014563 INL088 Mg. Lb. No.: GZ571339



Keep area blank & varnish free for
overcoding Lot and EXP & Data matrix
45 X 22 mm



Each film coated tablet contains cinacalcet 60 mg (equivalent to 66 mg of cinacalcet hydrochloride).

Dosage: See Package Insert.
Store at 25°C (77°F); excursions permitted from 15°C to 30°C (59°F to 86°F). [See USP controlled room temperature].

Dispense in tight, light-resistant container per USP.

Manufactured for:
Accord Healthcare, Inc.,
Durham, NC 27703.

Manufactured by:
Intas Pharmaceuticals Limited,
Ahmedabad - 382 210, INDIA.

NDC 16729-441-10

Cinacalcet Tablets

60 mg

Rx Only

30 Tablets

accord



Keep area blank & varnish free for
overcoding Lot and EXP & Data matrix
45 X 22 mm



10 3208 2 6014564 INL088 Mfg. Lc. No.: GZ57139

Each film coated tablet contains cinacalcet 60 mg (equivalent to 66 mg of cinacalcet hydrochloride).

Dosage: See Package Insert.
Store at 25°C (77°F); excursions permitted from 15°C to 30°C (59°F to 86°F). [See USP controlled room temperature].

Dispense in tight, light-resistant container per USP.

Manufactured for:
Accord Healthcare, Inc.,
Durham, NC 27703.

Manufactured by:
Intas Pharmaceuticals Limited,
Ahmedabad - 382 210, INDIA.


NDC 16729-441-15

Cinacalcet Tablets

60 mg

Rx Only

90 Tablets

 accord



N
3 1 6 7 2 9 4 4 1 1 5 5

Keep area blank & varnish free for
overcoding Lot and EXP & Data matrix
45 X 22 mm



10 3208 2 6014565 INL088 Mg., Lb. No.: GZ57139

Each film coated tablet contains cinacalcet 90 mg (equivalent to 99 mg of cinacalcet hydrochloride).

Dosage: See Package Insert.
Store at 25°C (77°F); excursions permitted from 15°C to 30°C (59°F to 86°F). [See USP controlled room temperature].

Dispense in tight, light-resistant container per USP.

Manufactured for:
Accord Healthcare, Inc.,
Durham, NC 27703.

Manufactured by:
Intas Pharmaceuticals Limited,
Ahmedabad - 382 210, INDIA.

NDC 16729-442-10

Cinacalcet Tablets

90 mg

Rx Only

30 Tablets

accord



Keep area blank & varnish free for
overcoding Lot and EXP & Data matrix
45 X 22 mm



10 3215 2 6014566 INL088 Mfg. L.L. No.: G251139

Each film coated tablet contains cinacalcet 90 mg (equivalent to 99 mg of cinacalcet hydrochloride).

Dosage: See Package Insert.
Store at 25°C (77°F); excursions permitted from 15°C to 30°C (59°F to 86°F). [See USP controlled room temperature].

Dispense in light, light-resistant container per USP.

Manufactured for:
Accord Healthcare, Inc.,
Durham, NC 27703.

Manufactured by:
Intas Pharmaceuticals Limited,
Ahmedabad - 382 210, INDIA.

NDC 16729-442-15

Cinacalcet Tablets

90 mg

Rx Only

90 Tablets

accord



Keep area blank & varnish free for
overcoding Lot and EXP & Data matrix
50 X 25 mm



10 3216 2 601467 INL092 Mfg. Lic. No.: GZ571339

PRODUCT RECALL RESPONSE FORM

Product Recall Date: October 10, 2024

Voluntary Recall: Pharmacy Level

| Cinacalcet Tablets | | | | | |
|---------------------------|-------------------------|--------------------|------------------|--------------------|--|
| Strength | Bottle Pack size | Product NDC | Batch No. | Expiry Date | Quantity Returning (In Bottles/units) |
| 30MG | 30 Tablets | 16729-440-10 | M2118190 | 11/2024 | |
| 30MG | 30 Tablets | 16729-440-10 | M2201091 | 11/2024 | |
| 30MG | 30 Tablets | 16729-440-10 | M2206241 | 11/2024 | |
| 30MG | 30 Tablets | 16729-440-10 | M2206451 | 04/2025 | |
| 30MG | 30 Tablets | 16729-440-10 | M2208674 | 06/2025 | |
| 30MG | 30 Tablets | 16729-440-10 | M2213850 | 08/2025 | |
| 30MG | 30 Tablets | 16729-440-10 | M2215221 | 09/2025 | |
| 30MG | 30 Tablets | 16729-440-10 | M2216236 | 11/2025 | |
| 30MG | 30 Tablets | 16729-440-10 | M2217098 | 11/2025 | |
| 30MG | 30 Tablets | 16729-440-10 | M2300664 | 11/2025 | |
| 30MG | 90 Tablets | 16729-440-15 | M2210808 | 06/2025 | |
| 30MG | 90 Tablets | 16729-440-15 | M2212212 | 08/2025 | |
| 30MG | 90 Tablets | 16729-440-15 | M2214435 | 09/2025 | |
| 30MG | 90 Tablets | 16729-440-15 | M2217097 | 11/2025 | |
| 30MG | 90 Tablets | 16729-440-15 | M2301921 | 01/2026 | |
| 60MG | 30 Tablets | 16729-441-10 | M2204481 | 02/2025 | |
| 60MG | 30 Tablets | 16729-441-10 | M2212389 | 08/2025 | |
| 60MG | 30 Tablets | 16729-441-10 | M2214271 | 09/2025 | |
| 60MG | 30 Tablets | 16729-441-10 | M2215970 | 10/2025 | |
| 60MG | 30 Tablets | 16729-441-10 | M2216458 | 10/2025 | |
| 60MG | 90 Tablets | 16729-441-15 | M2212869 | 08/2025 | |
| 60MG | 90 Tablets | 16729-441-15 | M2216362 | 09/2025 | |
| 60MG | 90 Tablets | 16729-441-15 | M2215969 | 10/2025 | |
| 90MG | 30 Tablets | 16729-442-10 | M2303264 | 01/2026 | |
| 90MG | 90 Tablets | 16729-442-15 | M2306979 | 04/2026 | |



Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the recall instructions and have taken the appropriate action.

Customer Name _____ DEA # _____

**DEA # is required, if not provided the processing of your form will be delayed.*

Address _____

City _____ State _____

Zip _____

Contact Name (please print) _____ Telephone # _____

Contact Signature _____ Date _____

If you did not purchase the product directly from the Manufacturer, please complete the following section.

Purchased from: Name _____ DEA # _____

Address _____

City _____ State _____

Zip _____

Please check all appropriate boxes:

- I have read and understand the recall instructions provided in the letter.
- I have checked my stock and have quarantined inventory consisting of _____ bottles/units.

Any adverse events associated with recalled product?

Yes NO If yes, please explain: _____

Please describe your business: _____

I have checked my stock and:

_____ Do not have any stock of recalled **items**.

OR

_____ Have quarantined and listed in the box above the quantity of bottles/units of **Cinacalcet Tablets 30 mg, 60 mg and 90 mg** and will be returning them to Inmar, as soon as possible.

Upon receipt of this Response Form, Inmar will issue return authorization label(s).

Please indicate the number of box labels needed: _____

Please fax this form to 1-817-868-5362 or E-mail at: rxrecalls@inmar.com. Questions - 1-877-902-4127.

