



URGENT: RETAIL LEVEL DRUG RECALL

Hindy Schiff, Vice President Regulatory Affairs and Compliance
Ascend Laboratories, LLC
339 Jefferson Road, Suite 101
Parsippany, NJ, 07054

September 20, 2024

Dear Customer:

This is to inform you of a product recall involving Mycophenolic Acid Delayed-Release (DR) Tablets, 360 mg. Please reference lot-specific information included below.

	Product Name	Lot Number	Strength	Expiration Date	Pack Size	NDC	Initial Distribution Date	Quantity Distributed
1	Mycophenolic Acid DR Tablets	22123437	360 mg	September 2024	120 tablets/bottle	67877-427-12	March 6, 2023	4,663
2	Mycophenolic Acid DR Tablets	22123438	360 mg	September 2024	120 tablets/bottle	67877-427-12	March 13, 2023	4,656
3	Mycophenolic Acid DR Tablets	22123535	360 mg	September 2024	120 tablets/bottle	67877-427-12	March 13, 2023	4,628
4	Mycophenolic Acid DR Tablets	22123536	360 mg	October 2024	120 tablets/bottle	67877-427-12	April 17, 2023	4,593
5	Mycophenolic Acid DR Tablets	22123537	360 mg	October 2024	120 tablets/bottle	67877-427-12	April 17, 2023	4,493
6	Mycophenolic Acid DR Tablets	22123538	360 mg	October 2024	120 tablets/bottle	67877-427-12	April 17, 2023	4,511
7	Mycophenolic Acid DR Tablets	22123646	360 mg	October 2024	120 tablets/bottle	67877-427-12	April 17, 2023	4,558
8	Mycophenolic Acid DR Tablets	22123647	360 mg	October 2024	120 tablets/bottle	67877-427-12	May 8, 2023	4,555
9	Mycophenolic Acid DR Tablets	23120529	360 mg	January 2025	120 tablets/bottle	67877-427-12	June 26, 2023	4,392
10	Mycophenolic Acid DR Tablets	23120530	360 mg	January 2025	120 tablets/bottle	67877-427-12	July 7, 2023	4,330
11	Mycophenolic Acid DR Tablets	23120703	360 mg	February 2025	120 tablets/bottle	67877-427-12	July 24, 2023	4,394
12	Mycophenolic Acid DR Tablets	23120705	360 mg	February 2025	120 tablets/bottle	67877-427-12	July 28, 2023	4,434

13	Mycophenolic Acid DR Tablets	23121429	360 mg	April 2025	120 tablets/bottle	67877-427-12	August 14, 2023	4,464
14	Mycophenolic Acid DR Tablets	23121726	360 mg	April 2025	120 tablets/bottle	67877-427-12	September 13, 2023	4,582
15	Mycophenolic Acid DR Tablets	23122049	360 mg	April 2025	120 tablets/bottle	67877-427-12	September 18, 2023	393
16	Mycophenolic Acid DR Tablets	23122097	360 mg	April 2025	120 tablets/bottle	67877-427-12	September 22, 2023	3,958
17	Mycophenolic Acid DR Tablets	23121984	360 mg	May 2025	120 tablets/bottle	67877-427-12	September 25, 2023	4,620
18	Mycophenolic Acid DR Tablets	23121985	360 mg	May 2025	120 tablets/bottle	67877-427-12	September 25, 2023	4,628
19	Mycophenolic Acid DR Tablets	23121986	360 mg	May 2025	120 tablets/bottle	67877-427-12	October 2, 2023	4,428
20	Mycophenolic Acid DR Tablets	23122325	360 mg	June 2026	120 tablets/bottle	67877-427-12	October 27, 2023	4,502
21	Mycophenolic Acid DR Tablets	23122329	360 mg	June 2026	120 tablets/bottle	67877-427-12	November 6, 2023	4,461
22	Mycophenolic Acid DR Tablets	23122330	360 mg	June 2026	120 tablets/bottle	67877-427-12	November 6, 2023	4,392
23	Mycophenolic Acid DR Tablets	23122331	360 mg	June 2026	120 tablets/bottle	67877-427-12	November 15, 2023	4,366
24	Mycophenolic Acid DR Tablets	23122776	360 mg	August 2026	120 tablets/bottle	67877-427-12	December 22, 2023	4,488
25	Mycophenolic Acid DR Tablets	23122852	360 mg	August 2026	120 tablets/bottle	67877-427-12	January 2, 2024	4,452
26	Mycophenolic Acid DR Tablets	23122853	360 mg	August 2026	120 tablets/bottle	67877-427-12	December 22, 2023	1,284
27	Mycophenolic Acid DR Tablets	23123154	360 mg	August 2026	120 tablets/bottle	67877-427-12	January 8, 2024	3,984
28	Mycophenolic Acid DR Tablets	23123155	360 mg	August 2026	120 tablets/bottle	67877-427-12	January 11, 2024	4,284
29	Mycophenolic Acid DR Tablets	23123458	360 mg	September 2026	120 tablets/bottle	67877-427-12	No first date of sale	0
Total Distributed								117,493



See enclosed product label for ease in identifying the product.

This recall has been initiated due to an out of specification (OOS) result in dissolution testing (buffer stage) of Mycophenolic Acid DR Tablets, 360 mg. OOS was initially observed in batch number 22123437. Mycophenolic Acid DR Tablets are an antimetabolite immunosuppressant indicated for prophylaxis of organ rejection in adult patients receiving kidney transplants and in pediatric patients at least 5 years of age and older who are at least 6 months' post operative procedure. Use of affected Mycophenolic Acid Delayed-Release Tablets, 360 mg (detailed in the table above) can result in a slight delay of intended pharmacologic effect. As a precautionary measure, all other live batches--totaling 29 batches—subject to single large lot coating during manufacturing will also be recalled.

Our firm began shipping this product on March 6, 2023. Immediately examine your inventory and quarantine product subject to recall for the lot numbers specified in the table above.

Please perform the following activities:

- a. Immediately examine your inventory and quarantine product subject to recall for the lot numbers specified in the table above. Please follow the directions in the attached recall stock response to return the affected product.
- b. Promptly identify your recall customer(s) who received the recall product and provide them with clear instructions to return the recall product.
- c. Promptly complete the attached recall stock response form even if you have no product to return.
- d. The completed Recall Response Form can be submitted by any of the following methods:

Fax: 817-868-5362 or E-mail: rxrecalls@inmar.com

This recall is being carried out to the RETAIL level. Your assistance is appreciated and necessary to prevent consumer harm.

Your assistance is appreciated and necessary in this voluntary recall. If you have any questions related to customer service, please contact product inquiries—available 24 hours a day, 7 days a week—at 877-272-7901. If you have any questions about the return of the product, please contact Inmar toll free at 877-902-4119—available 9:00 AM to 5:00 PM ET Monday through Friday.

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

Sincerely,

A handwritten signature in black ink that reads "Hindy Schiff". The signature is written in a cursive, flowing style.

Hindy Schiff

Vice President, Regulatory Affairs and Compliance



RECALL STOCK RESPONSE FORM

Recall-Mycophenolic Acid DR Tablets, 360 mg

Lots: 22123427, 22123438, 22123535, 22123536, 22123537, 22123538, 22123646, 22123647, 23120529, 23120530, 23120703, 23120705, 23121429, 23121726, 23122049, 23122097, 23121984, 23121985, 23121986, 23122325, 23122329, 23122330, 23122331, 23122776, 23122852, 23122853, 23123154, 23123155, 23123458

Company Name: _____ DEA #: _____

Please note that DEA # is required. If it is not provided, the processing of your form will be delayed.

Address: _____

City: _____ State: _____ Zip Code: _____

Contact Name (please print): _____ Telephone #: _____

Contact Signature: _____ Date: _____

Wholesaler Information if not directly purchased from Ascend:

Wholesaler Name: _____ Wholesaler DEA#: _____

Wholesaler City: _____ Wholesaler State: _____ Wholesaler Zip: _____

Please check and fill out each section accordingly.

- ☐ I have read and understand the recall instructions provided in the Recall Letter.
- ☐ I have checked my stock for the quarantined inventory indicated in the table below.

	Product Name	Lot Number	Strength	Expiration Date	Pack Size	NDC	Quantity on Hand
1	Mycophenolic Acid DR Tablets	22123437	360 mg	September 2024	120 tablets/bottle	67877-427-12	
2	Mycophenolic Acid DR Tablets	22123438	360 mg	September 2024	120 tablets/bottle	67877-427-12	
3	Mycophenolic Acid DR Tablets	22123535	360 mg	September 2024	120 tablets/bottle	67877-427-12	
4	Mycophenolic Acid DR Tablets	22123536	360 mg	October 2024	120 tablets/bottle	67877-427-12	
5	Mycophenolic Acid DR Tablets	22123537	360 mg	October 2024	120 tablets/bottle	67877-427-12	

6	Mycophenolic Acid DR Tablets	22123538	360 mg	October 2024	120 tablets/bottle	67877-427-12	
7	Mycophenolic Acid DR Tablets	22123646	360 mg	October 2024	120 tablets/bottle	67877-427-12	
8	Mycophenolic Acid DR Tablets	22123647	360 mg	October 2024	120 tablets/bottle	67877-427-12	
9	Mycophenolic Acid DR Tablets	23120529	360 mg	January 2025	120 tablets/bottle	67877-427-12	
10	Mycophenolic Acid DR Tablets	23120530	360 mg	January 2025	120 tablets/bottle	67877-427-12	
11	Mycophenolic Acid DR Tablets	23120703	360 mg	February 2025	120 tablets/bottle	67877-427-12	
12	Mycophenolic Acid DR Tablets	23120705	360 mg	February 2025	120 tablets/bottle	67877-427-12	
13	Mycophenolic Acid DR Tablets	23121429	360 mg	April 2025	120 tablets/bottle	67877-427-12	
14	Mycophenolic Acid DR Tablets	23121726	360 mg	April 2025	120 tablets/bottle	67877-427-12	
15	Mycophenolic Acid DR Tablets	23122049	360 mg	April 2025	120 tablets/bottle	67877-427-12	
16	Mycophenolic Acid DR Tablets	23122097	360 mg	April 2025	120 tablets/bottle	67877-427-12	
17	Mycophenolic Acid DR Tablets	23121984	360 mg	May 2025	120 tablets/bottle	67877-427-12	
18	Mycophenolic Acid DR Tablets	23121985	360 mg	May 2025	120 tablets/bottle	67877-427-12	
19	Mycophenolic Acid DR Tablets	23121986	360 mg	May 2025	120 tablets/bottle	67877-427-12	
20	Mycophenolic Acid DR Tablets	23122325	360 mg	June 2026	120 tablets/bottle	67877-427-12	
21	Mycophenolic Acid DR Tablets	23122329	360 mg	June 2026	120 tablets/bottle	67877-427-12	
22	Mycophenolic Acid DR Tablets	23122330	360 mg	June 2026	120 tablets/bottle	67877-427-12	

23	Mycophenolic Acid DR Tablets	23122331	360 mg	June 2026	120 tablets/bottle	67877-427-12	
24	Mycophenolic Acid DR Tablets	23122776	360 mg	August 2026	120 tablets/bottle	67877-427-12	
25	Mycophenolic Acid DR Tablets	23122852	360 mg	August 2026	120 tablets/bottle	67877-427-12	
26	Mycophenolic Acid DR Tablets	23122853	360 mg	August 2026	120 tablets/bottle	67877-427-12	
27	Mycophenolic Acid DR Tablets	23123154	360 mg	August 2026	120 tablets/bottle	67877-427-12	
28	Mycophenolic Acid DR Tablets	23123155	360 mg	August 2026	120 tablets/bottle	67877-427-12	
29	Mycophenolic Acid DR Tablets	23123458	360 mg	September 2026	120 tablets/bottle	67877-427-12	

☐ Indicate disposition of recall product:

☐ Returned/Held for Return (Yes / No)

- ☐ Quantity: _____
- ☐ Date: _____
- ☐ Method: _____

OR

☐ No recall product on hand (Yes / No)

☐ I have identified and notified my customers that were shipped/received or may have been shipped this product by:

- ☐ Date: _____
- ☐ Method of Notification: _____

Were there any adverse events associated with the recalled product?

- ☐ Yes
- ☐ No

If yes, please explain: _____



If you have any questions regarding this form or product return, please contact Inmar at 1-877-902-4119.
Office Hours: 9:00 AM to 5:00 PM EST Monday through Friday.


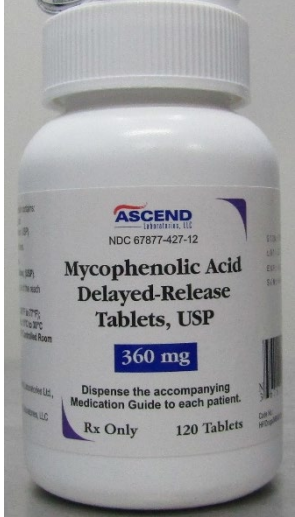
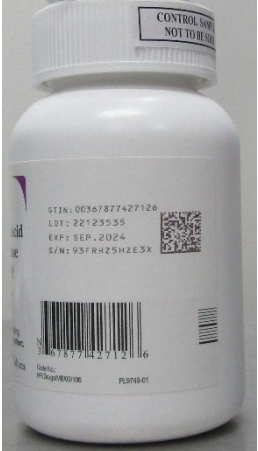

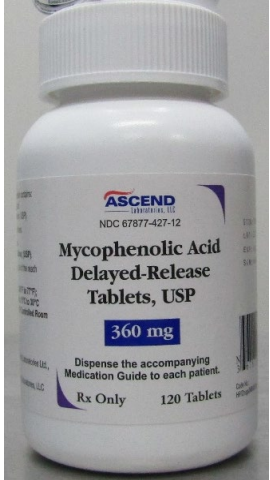
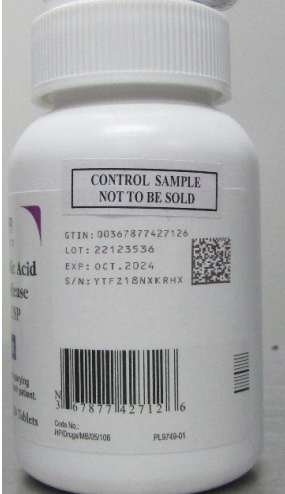
Please return this form by fax to 1-817-868-5362 or E-mail rxrecalls@inmar.com.






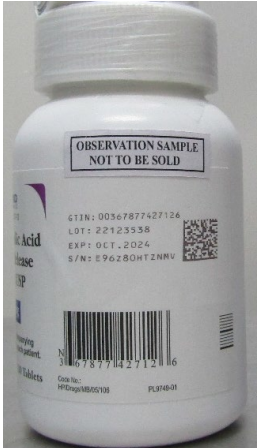
After receipt of this response form, a return kit will be provided for affected product return to:



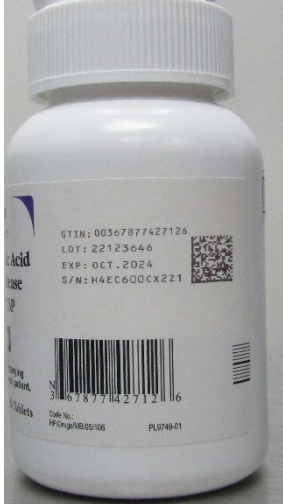


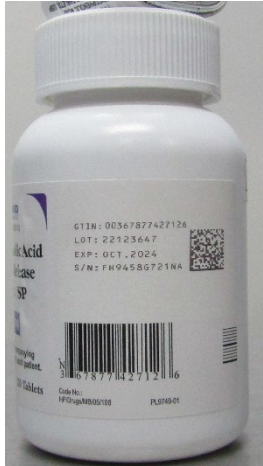
Inmar Rx Solutions
3845 Grand Lakes Way
Grand Prairie, TX, 75050

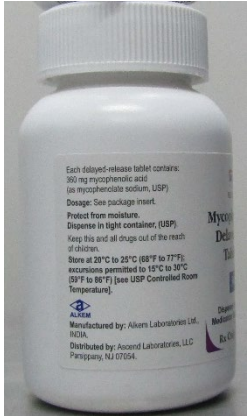

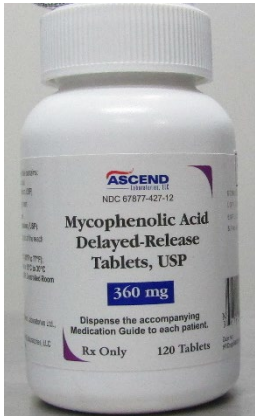
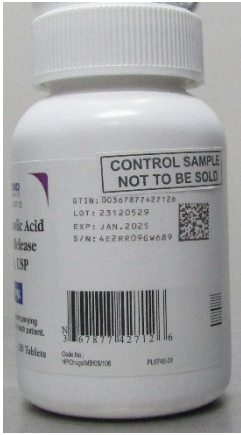

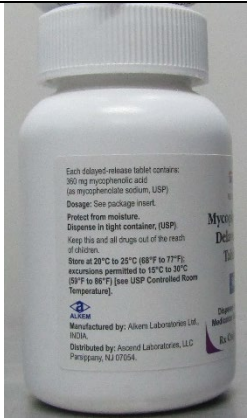

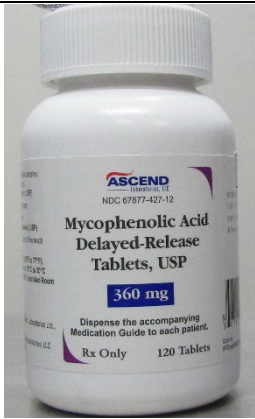
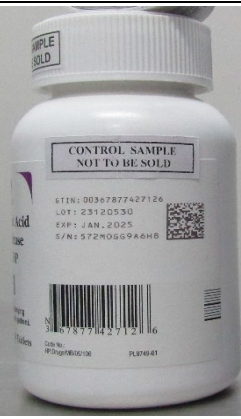

Inmar Recall Event ID: RCL226-24


Batch No.	Label Part I	Label Part II	Label part III
22123437	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ALKEM Manufactured by: Alkem Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>120 Tablets</p> <p>GTIN: 00367877427126 LOT: 22123437 EXP: SEP. 2024 S/N: HKXPDDHGRND4</p> <p>Code No.: HPSDrgs MB05/06 PL9748-01</p>
22123438	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ALKEM Manufactured by: Alkem Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>120 Tablets</p> <p>GTIN: 00367877427126 LOT: 22123438 EXP: SEP. 2024 S/N: 10M5DZRTAKHT</p> <p>Code No.: HPSDrgs MB05/06 PL9748-01</p>



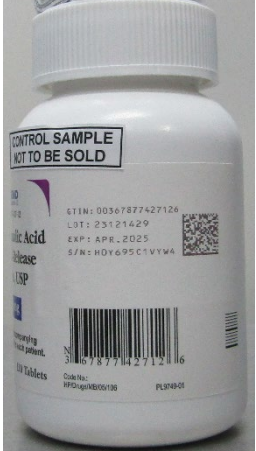

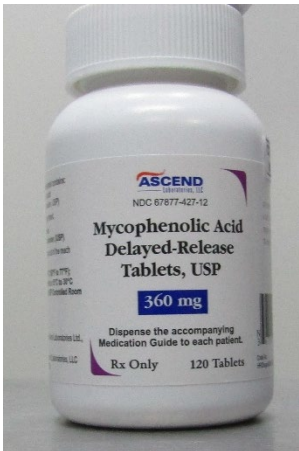
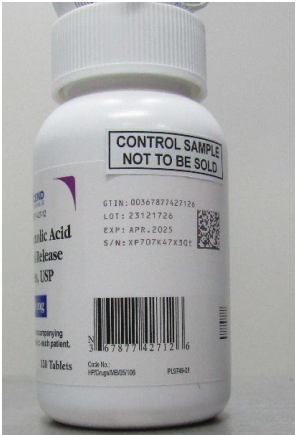
Batch No.	Label Part I	Label Part II	Label part III
22123535	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ALKEM Manufactured by: Alkem Laboratories Ltd., INDIA Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427126 LOT: 22123535 EXP: SEP, 2024 S/N: 93FR425H2E3X</p> <p>3607877427126</p> <p>PL3749-01</p>
22123536	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ALKEM Manufactured by: Alkem Laboratories Ltd., INDIA Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427126 LOT: 22123536 EXP: OCT, 2024 S/N: YTFZ18NXXRHX</p> <p>3607877427126</p> <p>PL3749-01</p>

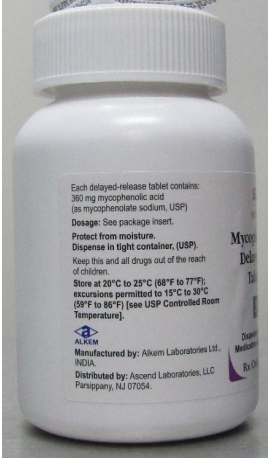
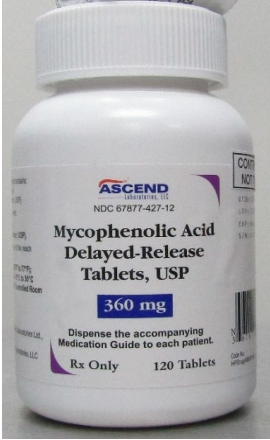



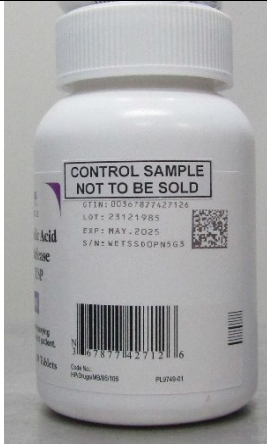
Batch No.	Label Part I	Label Part II	Label part III
22123537	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ALKEM Manufactured by: Alkem Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427126 LOT: 22123537 EXP: OCT. 2024 S/N: CA2ANEC3CV27</p> <p>367877427126</p> <p>Code No.: PFDmg/MS/05/100 PLN/49-01</p>
22123538	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ALKEM Manufactured by: Alkem Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>OBSERVATION SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427126 LOT: 22123538 EXP: OCT. 2024 S/N: E96280HTZNRV</p> <p>367877427126</p> <p>Code No.: PFDmg/MS/05/100 PLN/49-01</p>

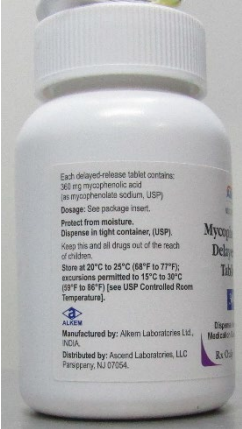
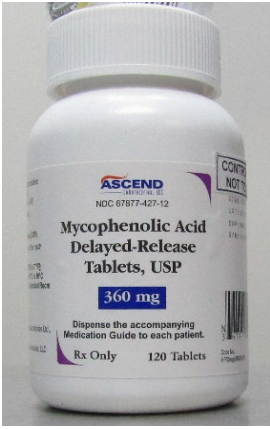

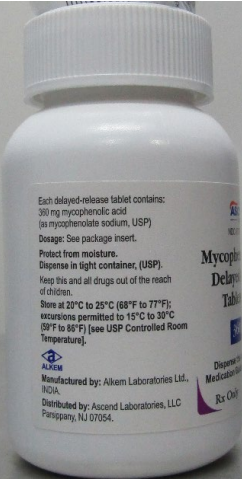
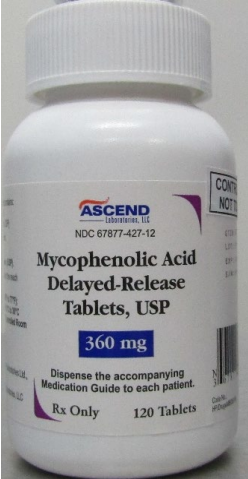

Batch No.	Label Part I	Label Part II	Label part III
22123646	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ALKEM Manufactured by: Alkem Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Paraspary, NJ 07054.</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP 360 mg Rx Only</p>	 <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>GTIN: 00367877427126 LOT: 22123646 EXP: OCT. 2024 S/N: H4EC6Q0CX2Z1</p> <p>360 mg Delayed-Release Tablets, USP 360 mg Rx Only</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>120 Tablets</p> <p>Code No.: HFD-updMB05/06</p> <p>PLS749-01</p>
22123647	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ALKEM Manufactured by: Alkem Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Paraspary, NJ 07054.</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP 360 mg Rx Only</p>	 <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>GTIN: 00367877427126 LOT: 22123647 EXP: OCT. 2024 S/N: FH9458G721NA</p> <p>360 mg Delayed-Release Tablets, USP 360 mg Rx Only</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>120 Tablets</p> <p>Code No.: HFD-updMB02/08</p> <p>PLS749-01</p>



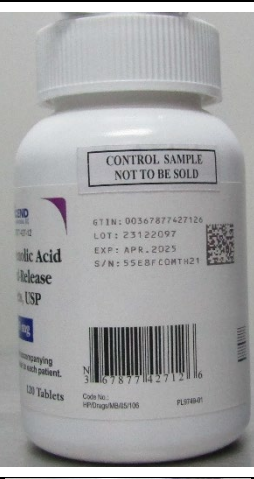

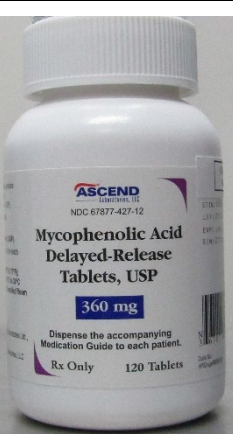
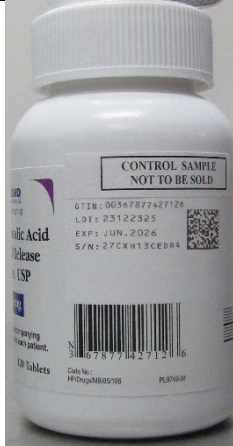
Batch No.	Label Part I	Label Part II	Label part III
23120529	 <p>Each delayed-release tablet contains 360 mg mycophenolic acid (as mycophenolate sodium, USP). Doseage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) (see USP Controlled Room Temperature).  Manufactured by: Alkerm Laboratories Ltd., RMA, Distributed by: Ascend Laboratories, LLC Parippany, NJ 07654.</p>	 <p>ASCEND NDC 67877-427-12 Mycophenolic Acid Delayed-Release Tablets, USP 360 mg Dispense the accompanying Medication Guide to each patient. Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD GTIN: 00367877427126 LOT: 23120529 EXP: JAN. 2025 S/N: 4E2RR096W689  N 00367877427126 Date No. 4P03H0803108 PL3740-01</p>
23120530	 <p>Each delayed-release tablet contains 360 mg mycophenolic acid (as mycophenolate sodium, USP). Doseage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) (see USP Controlled Room Temperature).  Manufactured by: Alkerm Laboratories Ltd., RMA, Distributed by: Ascend Laboratories, LLC Parippany, NJ 07654.</p>	 <p>ASCEND NDC 67877-427-12 Mycophenolic Acid Delayed-Release Tablets, USP 360 mg Dispense the accompanying Medication Guide to each patient. Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD GTIN: 00367877427126 LOT: 23120530 EXP: JAN. 2025 S/N: 572H0G69A6H8  N 00367877427126 Date No. 4P03H0803108 PL3740-01</p>

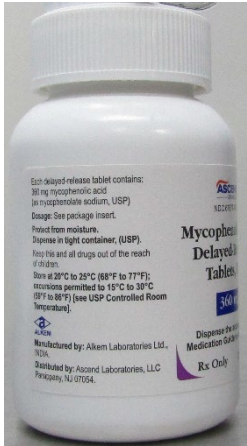
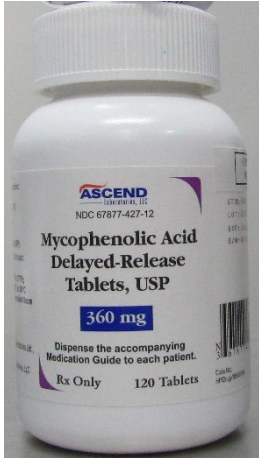




Batch No.	Label Part I	Label Part II	Label part III
23120703	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ALKEM Manufactured by: Alkem Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427126 LOT: 23120703 EXP: FEB. 2025 S/N: RZVD01CAHNR</p> <p>3 67877 42712 6</p> <p>Date No. P02dayM05/08</p> <p>PL3749-01</p>
23120705	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ALKEM Manufactured by: Alkem Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427126 LOT: 23120705 EXP: FEB. 2025 S/N: AFCS06A0DECH</p> <p>3 67877 42712 6</p> <p>Date No. P02dayM05/06</p> <p>PL3749-01</p>


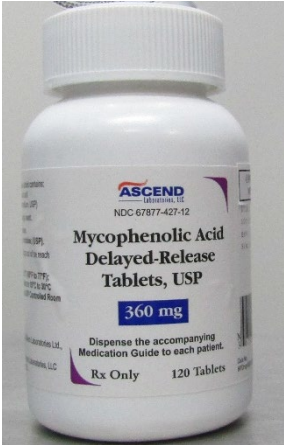

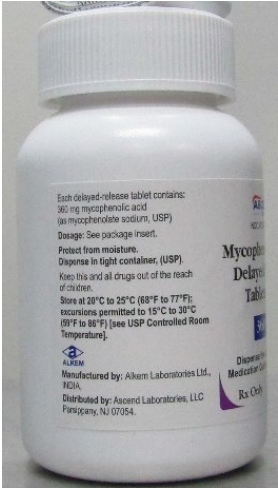


Batch No.	Label Part I	Label Part II	Label part III
23121429	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP)</p> <p>Dosage: See package insert. Protect from moisture. Dispense in light container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only</p> <p>Manufactured by: Akem Laboratories Ltd., KICA Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427126 LOT: 23121429 EXP: APR. 2025 S/N: HDV695C1VYM4</p> <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p> <p>Code No: WPD491805/138 PL3749-01</p>
23121726	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP)</p> <p>Dosage: See package insert. Protect from moisture. Dispense in light container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only</p> <p>Manufactured by: Akem Laboratories Ltd., KICA Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427126 LOT: 23121726 EXP: APR. 2025 S/N: XP707K47X301</p> <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p> <p>Code No: WPD491805/138 PL3749-01</p>

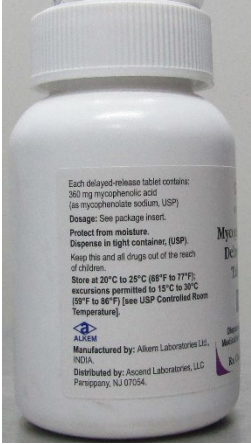
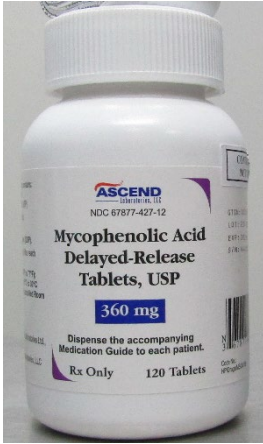

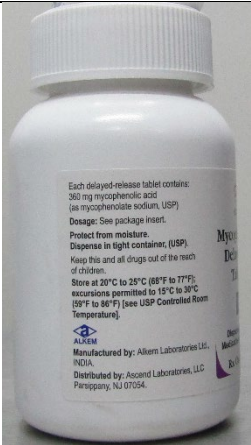


Batch No.	Label Part I	Label Part II	Label part III
23121984	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP)</p> <p>Dosage: See package insert.</p> <p>Protect from moisture. Dispense in light container, (USP).</p> <p>Keep this and all drugs out of the reach of children.</p> <p>Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) (see USP Controlled Room Temperature).</p> <p>AKUM Manufactured by: Akum Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Paripattur, NJ 07054.</p>	 <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427126 LOT: 23121984 EXP: MAY, 2025 S/N: 4CFR0BET5AR6</p> <p>360 mg Delayed-Release Tablets, USP</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p> <p>Code No: HFDUpM050158 PL70401</p>
23121985	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP)</p> <p>Dosage: See package insert.</p> <p>Protect from moisture. Dispense in light container, (USP).</p> <p>Keep this and all drugs out of the reach of children.</p> <p>Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) (see USP Controlled Room Temperature).</p> <p>AKUM Manufactured by: Akum Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Paripattur, NJ 07054.</p>	 <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427126 LOT: 23121985 EXP: MAY, 2025 S/N: NETSS0DPN5G3</p> <p>360 mg Delayed-Release Tablets, USP</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p> <p>Code No: HFDUpM050158 PL70401</p>

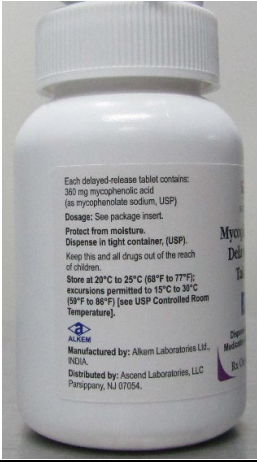
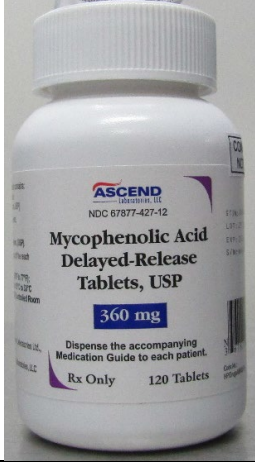

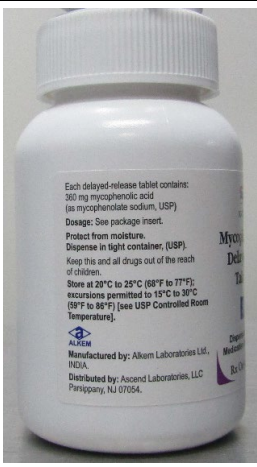
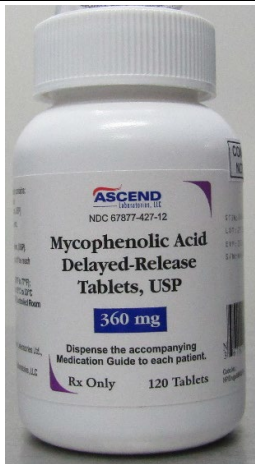
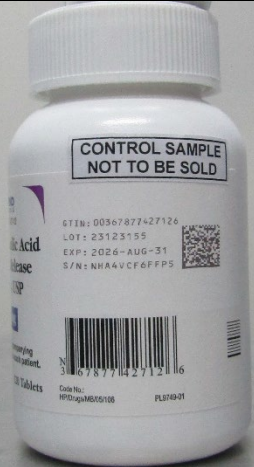
Batch No.	Label Part I	Label Part II	Label part III
23121986	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ASCEND Manufactured by: Alkerm Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427126 LOT: 23121986 EXP: MAY.2025 S/N: GKSAFF7YH287</p>
23122049	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ASCEND Manufactured by: Alkerm Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427126 LOT: 23122049 EXP: APR. 2025 S/N: 6P2A2TVYR020</p>

Batch No.	Label Part I	Label Part II	Label part III
23122097	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ALKERMES Manufactured by: Alkem Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427128 LOT: 23122097 EXP: APR. 2025 S/N: 55E8FCMTN21</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p> <p>Carton No.: PFD03pM655708</p> <p>PL0760-01</p>
23122325	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ALKERMES Manufactured by: Alkem Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427128 LOT: 23122325 EXP: JUN. 2026 S/N: 27CXN13CEDR4</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p> <p>Carton No.: PFD03pM655708</p> <p>PL0760-01</p>

Batch No.	Label Part I	Label Part II	Label part III
23122329	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) (see USP Controlled Room Temperature). Manufactured by: Alkem Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054. Rx Only</p>	 <p>ASCEND LABORATORIES, LLC NDC 67877-427-12 Mycophenolic Acid Delayed-Release Tablets, USP 360 mg Dispense the accompanying Medication Guide to each patient. Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD GTIN: 00367877427126 LOT: 23122329 EXP: JUN. 2026 S/N: GK55HCREESEF 360 mg 120 Tablets PLS 43-01</p>
23122330	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) (see USP Controlled Room Temperature). Manufactured by: Alkem Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054. Rx Only</p>	 <p>ASCEND LABORATORIES, LLC NDC 67877-427-12 Mycophenolic Acid Delayed-Release Tablets, USP 360 mg Dispense the accompanying Medication Guide to each patient. Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD GTIN: 00367877427126 LOT: 23122330 EXP: JUN. 2026 S/N: A4A2RUPFV9X 360 mg 120 Tablets PLS 43-01</p>

Batch No.	Label Part I	Label Part II	Label part III
23122331	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ASCEND Laboratories, LLC Manufactured by: Alkerm Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>ASCEND Laboratories, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427126 LOT: 23122331 EXP: JUN. 2026 S/N: ZEDCYRPS1N</p> <p>Barcode: 00367877427126</p> <p>Code No.: P0104860708 PLR04-01</p>
23122776	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ASCEND Laboratories, LLC Manufactured by: Alkerm Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>ASCEND Laboratories, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427126 LOT: 23122776 EXP: 2026-AUG-31 S/N: C62VG2YKNT86</p> <p>Barcode: 00367877427126</p> <p>Code No.: P0104860708 PLR04-01</p>

Batch No.	Label Part I	Label Part II	Label part III
23122852	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in light container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ALKEN Manufactured by: Alken Laboratories Ltd, INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>ASCEND Laboratories, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427126 LOT: 23122852 EXP: 2026-AUG-31 S/N: 440X2859AKK</p> <p>360 mg Delayed-Release Tablets, USP</p> <p>120 Tablets</p> <p>Code No.: MPC0367877427126 PLR00-01</p>
23122853	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in light container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ALKEN Manufactured by: Alken Laboratories Ltd, INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>ASCEND Laboratories, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427126 LOT: 23122853 EXP: 2026-AUG-31 S/N: 7H1PY45805W9</p> <p>360 mg Delayed-Release Tablets, USP</p> <p>120 Tablets</p> <p>Code No.: MPC0367877427126 PLR00-01</p>

Batch No.	Label Part I	Label Part II	Label part III
23123154	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ALKERM Manufactured by: Alkem Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427126 LOT: 23123154 EXP: 2026-AUG-31 S/N: 8P7Z25GXMOVZ</p> <p>360 mg Delayed-Release Tablets, USP</p> <p>Dispensing Instructions: See patient. 120 Tablets</p> <p>Code No.: HPD-ugM655108</p> <p>PLN749-01</p>
23123155	 <p>Each delayed-release tablet contains: 360 mg mycophenolic acid (as mycophenolate sodium, USP) Dosage: See package insert. Protect from moisture. Dispense in tight container, (USP). Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>ALKERM Manufactured by: Alkem Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054.</p>	 <p>ASCEND LABORATORIES, LLC NDC 67877-427-12</p> <p>Mycophenolic Acid Delayed-Release Tablets, USP</p> <p>360 mg</p> <p>Dispense the accompanying Medication Guide to each patient.</p> <p>Rx Only 120 Tablets</p>	 <p>CONTROL SAMPLE NOT TO BE SOLD</p> <p>GTIN: 00367877427126 LOT: 23123155 EXP: 2026-AUG-31 S/N: NWR4VCF6FFP5</p> <p>360 mg Delayed-Release Tablets, USP</p> <p>Dispensing Instructions: See patient. 120 Tablets</p> <p>Code No.: HPD-ugM655108</p> <p>PLN749-01</p>

Batch No.	Label Part I	Label Part II	Label part III
23123458			