STERIMAX

Customer Communication

Mycophenolate Mofetil for Injection USP, 500mg per vial, DIN 02479974

Effective Date: July 23, 2021

Dear Customer:
SteriMax Inc, in consultation with Health Canada, is providing this important Customer Communication for the following lots of Mycophenolate Mofetil for Injection USP, 500mg per vial, DIN 02479974. This communication has been initiated because the affected lots may appear cloudy after reconstitution with diluent below 20°C.

The following lots are affected (see table below).

Product Name & Strength	DIN	UPC Code	Lot #	Expiry	First Date of Sale
Mycophenolate Mofetil for Injection USP, 500mg per vial	02479974	*Carton*: 834324002354 *Vial*: (01)00834324002347	AD915	09-2021	Dec 02 2019
			AD109	03-2023	Jul 26 2021

Information for Healthcare Professionals:

- **Mycophenolate Mofetil for Injection USP is a sterile lyophilized powder and requires reconstitution and dilution to make the infusion solution at concentration of 6 mg/mL in the infusion container as per the PM.**
- **For complete prescribing information, including Dosage and Administration, please refer to the Mycophenolate Mofetil for Injection USP Product Monograph (PM).**
- **As with all parenteral drug products, the diluted solution should be inspected visually for clarity, particulate matter, precipitate, discoloration, and leakage prior to administration whenever solution and container permit.**
- **Solutions that are reconstituted with 5% Dextrose below 20°C may result in a cloudy solution.**
- **Reconstituted vials that appear cloudy can be warmed up to 25°C until the solution becomes clear and administered within 4 hours of reconstitution.**
- **Vials that continue to show haziness, particulate matter, precipitate, discoloration, or leakage should not be used, segregated, and returned to SteriMax as per the attached Response Form.**

Report health or safety concerns

Any serious or unexpected side effects including administration of cloudy solution in patients receiving Mycophenolate Mofetil for Injection should be reported to SteriMax Inc. or Health Canada.
SteriMax Inc.
E-mail: pv@sterimaxinc.com
Telephone: 1-800-881-3550

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting for information on how to report online, by mail or by fax.

For other health product inquiries related to the product and any questions concerning this communication, contact SteriMax at 1-800-881-3550 or email medinfo@sterimaxinc.com.

Thank You,

DocuSigned by:

Narvin Ali | Director, Quality Assurance and Compliance
SteriMax Inc.,
2770 Portland Drive,
Oakville, ON, L6H 6R4

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Health Professional Response Form

Please complete this form and return to medinfo@sterimaxinc.com for product vials with cloudy solution after reconstitution.

Name of Health Professional: _____
Address: _____
City: _____ Province: _____ Postal Code: _____
Phone Number: _____
Email: _____

Complete below table for vials with cloudy solution obtained following reconstitution. SteriMax will provide reimbursement to the reporting site.

Product Name & Strength	DIN	UPC Code	Lot #	Expiry	Number of vials found with cloudy solution
Mycophenolate Mofetil for Injection USP, 500mg per vial	02479974	*Carton*: 834324002354 *Vial*: (01)00834324002347	AD915	09-2021	
			AD109	03-2023	

Shipping address for reimbursement product:

Attention to:

Address with Postal code