eco-med PHARMACEUTICAL

Manufacturers of quality Ultrasound gels, lotions and medical products

URGENT MEDICAL DEVICE RECALL
August 4, 2021

EcoGel 200/MediChoice Ultrasound Gel

Attention: Clinical Departments

Action required:

Eco-Med Pharmaceutical is conducting a voluntary medical device recall for certain lots of EcoGel/MediChoice/Mac Medical ultrasound gel.

Eco-Med has confirmed bacterial contamination from yet unidentified sources in certain lot numbers of these non-sterile, multi-use gel products.

Please take the following action:

a. Immediately return or destroy the products listed below with the affected lot numbers in this chart:

Product	Lot Numbers	Initial Distribution Date
Eco Gel 200 MediChoice M500812	B029	March 26, 2021
	B030	March 30, 2021
	B031	April 5, 2021
	B032	April 7, 2021
	B040	April 26, 2021
	B041	April 26, 2021
	B048	May 7, 2021
	B055	May 26, 2021

b. Immediately stop use of **ALL** ultrasound gels labeled under the following names (regardless of lot):

- EcoGel 200, by Eco-Med (Canada)
- MediChoice Ultrasound Gel, by Owens & Minor (United States)
- MediChoice Ultrasound Gel, by Mac Medical Supply Co Inc. (United States)
- EcoGel 200, by Active Crystal Inc (Canada)
- EcoGel 200, by Agencia Matamoros (Honduras)
- EcoGel 200, by Cardinal Health Canada
- EcoGel 200, by CMCC Supply Centre and Bookstore (Canada)
- EcoGel 200 Blue, by Christie Innomed Inc. (Canada)
- EcoGel 200, by Dectro International (Canada)
- EcoGel 200, by Medline Canada
- EcoGel 200, by Dunbar Medical (Canada)
- EcoGel 200, by Eastern Medical Supply Ltd (Canada)

- EcoGel 200, by Global Medical Solution (NZ) LTD (New Zealand)
- EcoGel 200, by Good-link Electronics Ltd. (Hong Kong)
- EcoGel 200, by Henry Schein Arcona (Canada)
- EcoGel 200, by Maranda Lauzon Inc (Canada)
- EcoGel 200, by Medi's Part Ltd. (Thailand)
- EcoGel 200 Blue, by MJM Distributing (Canada)
- EcoGel 200, by Ortho Canada (Canada)
- EcoGel 200, by So medico SDN BHD (Malaysia)
- EcoGel 200 and EcoGel 200 Blue, by STAT Healthcare Corporation (Canada)
- EcoGel 200 and EcoGel 200 Blue, by The Stevens Company Limited (Canada)
- EcoGel 200, by Strathroy Middlesex General Hospital (Canada)
- EcoGel 200, by Trimedic Supply Network Ltd. (Canada)
- EcoGel 200, by Vitality Depot (Canada)
- Chattanooga Conductor USA, by DJO Global (United States)
- Conductor Australia, by DJO Australia
- DJO Conductor, by DJO Global (United States)
- Liquasonic, by Athena Medical Products Inc. (United States)
- Medico, by Medico Inc. (Canada)
- Medline, by Medline Industries Inc. (United States)
- NDC Eco-Gel 200 Ultrasound Gel, by NDC Inc. (United States)
- Omni, by Accelerated Care Plus Leasing Inc. (United States)
- Red Medical Ultrasound Gel Blue, by Red Medical Supplies Ltd. (Canada)
- Smart 200, by Smart Technology and Product Co., Ltd (Thailand)

Please visit https://eco-med.com/recall/ and complete the form indicating the product and the lots/batch numbers you have identified, and actions taken in the comment section.

In addition, if you have further distributed this product, please identify your customers, and notify them at once of this product recall by sharing this recall notification letter.

Description of the problem and health hazard:

This recall is being initiated due to the bacterial contamination of ultrasound gel with Burkholderia cepacia complex (Bcc). The source(s) of the bacterial contamination is currently unknown. Eco-Gel is conducting a comprehensive investigation to determine the root cause of this contamination and take all necessary corrective action.

Unopened bottles from four lots of EcoGel 200 Blue, otherwise titled as the MediChoice M500812 (lot numbers B031, B040, B048, B055), were found to be contaminated with bacteria, Burkholderia stabilis, a member of the Burkholderia cepacia complex (Bcc). Lot numbers B029, B030, B032 and B041 are suspected of contamination. The lot numbers are identifiable on all labels on the cases and bottles.

The effects of Bcc infection on people vary widely, ranging from no symptoms at all to serious consequences. Bcc bloodstream infections may result in sepsis and in certain cases possible death. Use of ultrasound gels manufactured by Eco-Med have been associated with at least 15 infections to date, including bloodstream infections. Additional infections have been identified that may also be associated with the use of this ultrasound gel and investigation is ongoing. Potential routes of transmission leading to bloodstream infections associated with a contaminated nonsterile gel may have included the use of the gel for visualization prior to, in preparation for, or during an invasive procedure or application of the gel inside the sterile ultrasound probe sleeve during an invasive procedure using ultrasound guidance.

Contact Information:

Distributors must contact Eco-Med Pharmaceuticals to confirm receipt of this notice and that they are proceeding with the recall via email info@eco-med.com.

To contact Eco-Med directly with questions call 905-405-1050 and ask for “regulatory department.”

Sub-recalls must take place where the distributor has further shipped the product to consignees. Please visit https://eco-med.com/recall/ and complete the form indicating the product and the lots/batch numbers you have identified, and actions taken in the comment section.

Your assistance is appreciated and necessary to prevent any consumer illness or patient harm.

Health professionals, consumers and patients can voluntarily report observed or suspected adverse events for human medical products to FDA via the following link: https://www.accessdata.fda.gov/scripts/medwatch/index.cfm

Please complete and return the enclosed response form as soon as possible. If you have any questions, please email the Regulatory department info@eco-med.com

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

Enclosures:
Name: (Print)

_____

Signature:

_____

Title:

_____

Recall Return Response Form

EcoGel 200 Blue – LOTS: B029, B030, B031, B032, B040, B041, B048 and B055

Please check ALL appropriate boxes.

☐ I have read and understand the recall instructions provided in the [date of] letter.

☐ I have checked my stock and have quarantined inventory consisting of [ ] units or cases.

Indicate disposition of recalled product:

☐ returned (specify quantity, date and method)/held for return;

☐ destroyed (specify quantity, date and method);

☐ quarantined pending return

Attached is a list of customers who received/ may have received this product. Please notify my customers.

Any adverse events associated with recalled/failed product? ☐ Yes ☐ No

If yes, please explain:_____

I have checked my stock and have performed the appropriate method of disposition to the inventory consisting of_____[units, cases, etc.].

Please check the appropriate box(es) to describe the nature of your business:

☐ Wholesaler/distributor
☐ Medical laboratory
☐ Repacker
☐ Pharmacy-retail
☐ Hospital pharmacies
☐ Retailer
☐ Other: _____

☐ Hospital/Medical facility
☐ Manufacturer

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Name/Title	
Telephone	
Email address	

Firm Name	
Address	
City/State	

PLEASE COMPLETE THIS FORM AND SEND IT TO info@eco-med.com