

## URGENT RECALL-RETAIL LEVEL

**Infants' Simethicone Drops, 30mL bottles**

**NDC 0603-0894-50**

**Lot Numbers L107E10A, L045H10A, L046H10A, L028K10A, L029K10A, and L107J10A**  
**AND**

**Triamcinolone Acetonide Lotion 0.1%, USP, 60mL bottles**

**NDC 0603-7864-49**

**Lot Numbers L002K10A and L004K10A**

June 29, 2011

MEDSPACE, INC  
23610 N 20TH DR STE 10  
PHOENIX AZ 85085-0627

Dear Sir / Madame:

Please be advised that the following product manufactured by Qualitest Pharmaceuticals is being recalled to the **RETAIL LEVEL**. Only the NDC numbers and lots listed below are affected.

PRODUCT DESCRIPTION	NDC NUMBER	LOT #	EXP
Infants' Simethicone Drops, 30mL bottles	0603-0894-50	L107E10A	08/12
Infants' Simethicone Drops, 30mL bottles	0603-0894-50	L045H10A	09/12
Infants' Simethicone Drops, 30mL bottles	0603-0894-50	L046H10A	09/12
Infants' Simethicone Drops, 30mL bottles	0603-0894-50	L028K10A	10/12
Infants' Simethicone Drops, 30mL bottles	0603-0894-50	L029K10A	10/12
Infants' Simethicone Drops, 30mL bottles	0603-0894-50	L107J10A	10/12
Triamcinolone Acetonide Lotion 0.1%, USP, 60mL bottles	0603-7864-49	L002K10A	10/12
Triamcinolone Acetonide Lotion 0.1%, USP, 60mL bottles	0603-7864-49	L004K10A	10/12

**REASON FOR RECALL-** Possible microbial contamination with *Burkholderia cepacia*.

### **RECALL INSTRUCTIONS:**

1. Please examine your stock immediately to determine if you have any product with the NDC numbers as listed, on hand. If so, immediately discontinue distribution and / or dispensing.
2. Wholesale distributors, notify any customers or sub accounts who may have received this product from you to examine their stock, and request they return any affected product directly to CLS MedTurn, an Inmar company.
3. If you are a retail pharmacy, please post the enclosed consumer notice in your pharmacy in order to alert your patients / consumers of this action.
4. We request you immediately complete and return the included "Recall Response Form" to CLS MedTurn, an Inmar company. Upon receipt, a return kit will be sent to you including return authorization label(s) and return instructions.

This recall is being conducted with the knowledge of the U.S. Food & Drug Administration.

We apologize for any inconvenience, and thank you in advance for your cooperation as well as your continued support of Qualitest Pharmaceuticals.

Sincerely,



Larry Kass  
Attachment



CHARACTER. COMMITMENT. COMMUNITY.

PHARMACIST: PLEASE POST

JUNE 29, 2011

QUALITEST PHARMACEUTICALS  
ISSUES VOLUNTARY, NATIONWIDE RETAIL LEVEL RECALL  
OF THE FOLLOWING PRODUCT LOTS

PRODUCT DESCRIPTION	NDC NUMBER	LOT #	EXP
Infants' Simethicone Drops, 30mL bottles	0603-0894-50	L107E10A	08/12
Infants' Simethicone Drops, 30mL bottles	0603-0894-50	L045H10A	09/12
Infants' Simethicone Drops, 30mL bottles	0603-0894-50	L046H10A	09/12
Infants' Simethicone Drops, 30mL bottles	0603-0894-50	L028K10A	10/12
Infants' Simethicone Drops, 30mL bottles	0603-0894-50	L029K10A	10/12
Infants' Simethicone Drops, 30mL bottles	0603-0894-50	L107J10A	10/12
Triamcinolone Acetonide Lotion 0.1%, USP, 60mL bottles	0603-7864-49	L002K10A	10/12
Triamcinolone Acetonide Lotion 0.1%, USP, 60mL bottles	0603-7864-49	L004K10A	10/12

There is possible microbial contamination in a raw material used in the manufacture of these products. While finished product testing of these lots yielded no evidence of this organism, as a conservative approach, the above listed lots are being recalled.

These lots were distributed between September 16, 2010 and April 20, 2011 to wholesale and retail pharmacies nationwide (including Puerto Rico). Lot numbers can be found on the side of the manufacturer's bottle and also on the display carton for Infants' Simethicone Drops.

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

Qualitest is notifying all customers who may have received affected product and arranging for the return of any affected product.

Consumers and patients with questions may contact Qualitest at 1-800-444-4011 for more information. Monday through Friday between the hours of 8AM and 5PM CST.