



February 26, 2015

OBJECT: URGENT - DRUG RECALL- TYPE II

TO: WHOLESALERS / DISTRIBUTORS / RETAILERS/ PHARMACISTS/ HEALTH CARE PROFESSIONALS

**PRODUCTS: ZENHALE® 50 mcg/ 5mcg
ZENHALE® 100 mcg/ 5mcg
ZENHALE® 200 mcg/ 5 mcg**

**LOT: See attached list
EXP: See attached list
DIN: See attached list**

Be advised that Merck Canada Inc. ("Merck Canada") is recalling lots of **ZENHALE®** (mometasone furoate/formoterol fumarate dihydrate inhalation aerosol) after discussion with Health Canada.

This recall is only for lots and strengths of **ZENHALE®** listed on the attachment.

Merck Canada is initiating this recall due to the possibility of device malfunction of **ZENHALE®** after 24 months shelf-life, resulting in the potential for a patient to receive a lower dose than expected. Health Canada has agreed to the request of Merck Canada to change the shelf life of all **ZENHALE®** products from 36 months to 24 months.

Merck Canada is conducting a **TYPE II** recall to wholesalers, distributors, retailers, pharmacists and healthcare professionals. A **TYPE II** recall is a situation in which the use of, or the exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequence is remote.

This recall is being implemented with the knowledge of, and in consultation with, Health Canada.

PROCEDURE TO FOLLOW:

Please immediately stop all sale and/or distribution and quarantine all lots of these products with lots numbers shown on the attached list.

IF YOU ARE A WHOLESALER OR DISTRIBUTOR, please also advise your direct customers of this recall as they must return product to you from the lots listed in the attached table..

Also, please complete the attached reply card, even if you do not have any units of these mentioned lots and fax it to: 1-877-228-2567 no later than March 6, 2015

If you do have units of these lots, please **RETURN THOSE UNITS** along with the enclosed **REPLY CARD** to the following address:

Merck Canada Inc. – Event ID: 3407
C/O Stericycle ULC Inc.
25 Ironside Crescent.
Toronto, ON
M1X 1G5

Return authorisation #: 3407

Use UPS account number 572105 (postal code L7L 4X6) for your return or call Merck Canada Customer Service Department for other options.

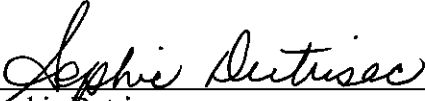
If you have any questions regarding this advisory, please contact the Merck Canada Order Department at 1-800-463-7251

For medical questions, please contact Medical Services at 1-800-567-2594.

Reimbursement for the returned products will be made by credit memorandum.

Please be assured that Merck Canada appreciates your immediate attention and cooperation and sincerely regrets any inconvenience caused by this action.

Thank you for your understanding and collaboration.



Sophie Dutrisac
Director, Quality Operations
Merck Canada Inc.

ATTACHMENT

PRODUCTS: ZENHALE® 50 mcg/ 5 mcg
 ZENHALE® 100 mcg/ 5 mcg
 ZENHALE® 200 mcg/ 5 mcg

DIN	DESCRIPTION	UPC	Reference Code	LOT	EXPIRATION DATE	
02361744	ZENHALE® 50/5mcg 120 doses	067055048166	1008959	1010247	June 2015	
				1014439	June 2015	
02361752	ZENHALE® 100/5mcg 120 doses	067055048173	1008960	932702	February 2015	
				970946	March 2015	
				1011672	June 2015	
				1031209	September 2015	
				1034145	June 2015	
				1052117	September 2015	
				1061619	September 2015	
				1070764	September 2015	
				1073690	September 2015	
	ZENHALE® 100/5mcg 120 doses samples	067055048203	1008991	1011676	June 2015	
				1014427	June 2015	
				1034146	September 2015	
				1052043	August 2015	
				1056057	September 2015	
				1084790	September 2015	
	02361760	ZENHALE® 200/5mcg 120 doses	067055048180	1008961	873905	September 2015
					980452	June 2015
					1011673	September 2015
1011674					December 2015	
1016321					October 2015	
1016660					September 2015	
1023002					February 2016	
1033618					October 2015	
1051407					October 2015	
1057902		February 2016				
ZENHALE® 200/5mcg 120 doses samples		067055048210	1008992	937459	April 2015	
				1014443	September 2015	
				1016320	October 2015	
				1028593	October 2015	
				1031232	December 2015	
					1043770	December 2015

February 26, 2015

CARTE RÉPONSE / REPLY CARD**Urgent: TYPE II RECALL**

Nom du Produit / Product Name : **ZENHALE® 50/5mcg**
ZENHALE® 100/5mcg
ZENHALE® 200/5mcg

DIN	Description du Produit/Product Description	UPC Code	Reference Code/Code de référence	LOT #	UNITÉS EN MAIN / UNITS ON HAND
02361744	ZENHALE® 50/5mcg 120 doses	067055048166	1008959	1010247	
				1014439	
02361752	ZENHALE® 100/5mcg 120 doses	067055048173	1008960	932702	
				970946	
				1011672	
				1031209	
				1034145	
				1052117	
				1061619	
				1070764	
	ZENHALE® 100/5mcg 120 doses samples	067055048203	1008991	1011676	
				1014427	
				1034146	
				1052043	
				1056057	
				1084790	
				1129736	
				02361760	ZENHALE® 200/5mcg 120 doses
980452					
1011673					
1011674					
1016321					
1016660					
1023002					
1033618					
1051407					
1057902					
02361760	ZENHALE® 200/5mcg 120 doses samples	067055048210	1008992	937459	

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				1014443	
				1016320	
				1028593	
				1031232	
				1043770	

Une réponse immédiate à cet avis de rappel est requise. S'il vous plaît compléter et retourner par télécopieur (1 - 877-228-2567) d'ici le 06 mars 2015, et ce, même si vous n'avez pas d'unités de ces lots des produits rappelés en votre possession . **Inclure une copie de cette carte réponse avec les unités retournées.**

Your timely response to this recall notification is required. Please fill out and fax (1- 877-228-2567) this reply card no later than March 06, 2015, even if you don't have any units of the recalled lots in your possession. Please make sure that a copy of this Reply Card is included with the units returned.

Merci / Thank you.

Signature : _____ Titre / Title : _____

Nom / Name : _____ Tél. / Tel. : _____

Compagnie / Company : _____

Numéro de compte / Account Number : _____