



September 5th, 2018

Subject: Important Information on MARVELON® 28 (desogestrel/ethinyl estradiol) Oral Contraceptive Tablets – Absence of Day-of-the-week Label Stickers

Dear Health Care Professionals,

What is the issue?

Merck Canada Inc. would like to inform you that the following lots of MARVELON® 28 (desogestrel/ethinyl estradiol) Oral Contraceptive Tablets distributed in Canada do not contain day-of-the-week label stickers (see picture below).

Product	Lot Number	Expiry Date
MARVELON® 28	R014281	31-MAR-2021
	N032638	31-MAR-2020
	R000269	31-MAR-2020
	R006559	31-MAR-2020
	R000270	31-MAR-2020
	N023314	31-OCT-2019

What is the risk?

Day-of-the-week label stickers may help the patient track the tablet intake. The absence of these stickers may increase the risk of non-adherence to the schedule and taking an incorrect number of tablets. Non-adherence to daily oral contraceptive tablet intake can increase the risk of pregnancy.

Please note that this issue does not impact the efficacy or safety of the tablet itself if taken as prescribed.

Background information

The day-of-the-week label is a sticker that can be applied on the blister pack, indicating the first day of the week when the medication is started. It may help the patient track the tablet intake.

SUN	MON	TUE	WED	THU	FRI	SAT	
MON	TUE	WED	THU	FRI	SAT	SUN	
TUE	WED	THU	FRI	SAT	SUN	MON	
WED	THU	FRI	SAT	SUN	MON	TUE	
THU	FRI	SAT	SUN	MON	TUE	WED	
FRI	SAT	SUN	MON	TUE	WED	THU	
SAT	SUN	MON	TUE	WED	THU	FRI	
DIM	LUN	MAR	MER	JEU	VEN	SAM	
LUN	MAR	MER	JEU	VEN	SAM	DIM	
MAR	MER	JEU	VEN	SAM	DIM	LUN	
MER	JEU	VEN	SAM	DIM	LUN	MAR	
JEU	VEN	SAM	DIM	LUN	MAR	MER	
VEN	SAM	DIM	LUN	MAR	MER	JEU	2221301
SAM	DIM	LUN	MAR	MER	JEU	VEN	56523148

Actions taken by Merck Canada Inc.

We recommend that Health Care Professionals proactively mention the absence of day-of-the-week label stickers to their patients when prescribing or dispensing MARVELON® 28. Furthermore, patients can be counseled to use a calendar to track the tablet intake.

Clinics which received MARVELON® 28 samples:

Starting the week of September 17th, representatives of Merck Canada Inc. will deliver day-of-the-week label stickers to clinics which received MARVELON® 28 samples. Upon reception of the day-of-the-week label stickers, physicians may decide to store them next to MARVELON® 28 boxes they have in stock to provide at the time of dispensing, or insert them in each box. Merck Canada Inc. recommends that the labels be offered to the patients. Patients should be instructed to choose the appropriate day-of-the-week label strip that starts with Day 1 of their menstrual period (for Day 1 starts) or Sunday (for Sunday starts) and to apply on the blister pack above the first row of tablets.

Retail pharmacies:

During the week of September 10th, the distribution of the day-of-the-week label stickers will commence to Canadian retail pharmacies. Upon reception of the day-of-the-week label stickers, pharmacists may decide to store them next to MARVELON® 28 boxes they have in stock to provide at the time of dispensing, or insert them in each box. Merck Canada Inc. recommends that the labels be offered to the patients. Patients should be instructed to choose the appropriate day-of-the-week label strip that starts with Day 1 of their menstrual period (for Day 1 starts) or Sunday (for Sunday starts) and to apply on the blister pack above the first row of tablets.

Additional day-of-the-week label stickers:

If additional day-of-the-week label stickers are required, they can be ordered by calling the following toll-free number 1-800-567-2594 ext. 3 or by e-mail to medinfoCanada@merck.com.

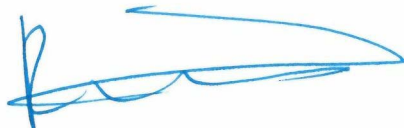
Alternative options:

We understand that generic alternatives to MARVELON® 28 are also available and do contain day-of-the-week label stickers.

Merck Canada Inc. apologizes for this situation and is working on correcting this issue in a timely manner. In the meantime, Merck Canada Inc. is not distributing MARVELON® 28 until the product contains day-of-the-week label stickers. Please note that MARVELON® 21 is not affected by this situation.

Please do not return the MARVELON® 28 products that you currently have, since this issue does not impact the efficacy or safety of the tablet itself if taken as prescribed.

Regards,



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Merck Canada Inc.

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