

**Health Canada Endorsed Important Safety Information on
DURAGESIC® MAT (fentanyl transdermal system)**



July 28, 2014

Dear Healthcare Professional:

Subject: DURAGESIC® MAT (fentanyl transdermal system) –Introduction of a Single Ink Colour (Dark Green) on all Strengths of Patches

Janssen Inc., in consultation with Health Canada, would like to inform you of the potential for dosing errors with changes to ink printing on the patches of DURAGESIC® MAT. Currently, different colours of ink in combination with the text on the patch are used to identify the different strengths of DURAGESIC® MAT (12, 25, 50, 75, and 100 mcg/h). Current users should be aware that one shade of dark green ink, intended to enhance visibility of the patch, will now be used on all strengths. The product carton and pouch will retain the use of the multi-colour system to aid in further differentiating the various patch strengths.

- **There is a potential for dosing errors (overdose or underdose) with a change from the existing use of different ink colours to identify individual strengths of DURAGESIC® MAT patches to a single ink colour (dark green) across all strengths;**
- **Healthcare professionals should emphasize the following points when counselling patients or caregivers on the use of DURAGESIC® MAT:**
 - **The colour of the ink printed on the DURAGESIC® MAT patches will change to a dark green ink regardless of patch strength;**
 - **Ink colour printed on the patch should not be used to identify patch strength upon application and removal;**
 - **If using multiple patches, check the strength on each patch before application and removal given the change to a single ink colour for all strengths and the similarity of some actual patch sizes;**
 - **Instructions on safe storage, handling, use and disposal to reduce the risk of accidental exposure.**
- **Current users of DURAGESIC® MAT patches should be made aware that both the original and revised patches will overlap in the market place for a transitional period.**

Graphics displaying the changes to the new dark green ink for the various patch strengths are provided below for your reference.

The first lots of DURAGESIC® MAT with one colour ink for all strengths will begin to be shipped to wholesalers in late July.

Health Canada is working with Janssen Inc., the Market Authorization Holder for DURAGESIC® MAT, on revisions to the outer packaging to highlight the change to darker green ink printing on all strengths of the patch.

DURAGESIC[®] MAT is indicated in the management of persistent, moderate to severe chronic pain that cannot be managed by other means such as opioid combination products or immediate-release opioids.

Signs of Overdose

- Fentanyl overdosage can lead to serious or life-threatening respiratory depression.
- Patients and caregivers should be made aware of the signs and symptoms of overdose.
- Patients should be advised to remove the patch and seek medical attention immediately with any signs and symptoms of overdose.

Signs of Underdose

- Underdosage can result in inadequate analgesia and the potential for withdrawal symptoms such as nausea, vomiting, diarrhea, anxiety and shivering.

Accidental exposure

Accidental exposure can occur by unintentional patch transfer to a non-patch wearer while hugging, sharing a bed or moving a patient. Accidental ingestion or use of patches can also occur from patches that have either fallen off or been inappropriately stored or discarded.

To reduce the risk of accidental exposure, information on the safe storage, handling, use and disposal of fentanyl patches is available at <http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2013/36239a-eng.php>.

A patient information sheet is included in the package of DURAGESIC[®] MAT patches dispensed to the patient. Please refer to the DURAGESIC[®] MAT Product Monograph for full prescribing information. The current DURAGESIC[®] MAT Product Monograph can be found at the Janssen Canada Web site (<http://www.janssen.ca>) and Health Canada's Web page (<http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp>).

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of dosing errors or other serious or unexpected adverse reactions in patients receiving DURAGESIC[®] MAT should be reported to Janssen Inc. or Health Canada. Medication errors can also be reported to the Institute for Safe Medication Practices (ISMP) Canada through the [Canadian Medication Incident Reporting and Prevention System](#).

Drug Safety Department
Janssen Inc.
19 Green Belt Drive
Toronto, Ontario
M3C 1L9
Or call toll free at 1-866-825-7122
Or email to dsscan@jocica.jnj.com
Or fax to 1-866-767-5865

To correct your mailing address or fax number, contact Janssen Inc.

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 this communication, please contact Health Canada at:

Marketed Health Products Directorate
E-mail: mhpd_dpssc_public@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Should you have any questions or require additional information regarding the use of DURAGESIC[®] MAT, please contact Janssen Inc. Medical Information Department at 1-800-567-3331 or 1-800-387-8781 from 8:30 a.m. to 4:30 p.m. Monday to Friday Eastern Standard Time (EST). A copy of this letter is also available on the Janssen website at www.janssen.ca and on the Health Canada website at www.healthy Canadians.gc.ca.

Sincerely,



Cathy Lau, Ph.D.
Vice President
Regulatory Affairs and Quality Management

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DURAGESIC® MAT Patches

Text Colour Changes to a Single, Dark Ink for all strengths

Current
Multi-Colour Ink

New
Dark Green Ink

DURAGESIC
12 mcg/h
(FENTANYL
TRANSDERMAL)



DURAGESIC
12 mcg/h
(FENTANYL
TRANSDERMAL)

DURAGESIC
25 mcg/h
(FENTANYL
TRANSDERMAL)



DURAGESIC
25 mcg/h
(FENTANYL
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DURAGESIC
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DURAGESIC
50 mcg/h
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DURAGESIC
75 mcg/h
(FENTANYL
TRANSDERMAL
SYSTEM)



DURAGESIC
75 mcg/h
(FENTANYL
TRANSDERMAL
SYSTEM)

DURAGESIC
100 mcg/h
(FENTANYL
TRANSDERMAL
SYSTEM)



DURAGESIC
100 mcg/h
(FENTANYL
TRANSDERMAL
SYSTEM)