

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



July 28, 2014

**Subject: DURAGESIC® MAT (fentanyl transdermal system) – New ink colour (dark green) on all patch strengths**

Janssen Inc., in consultation with Health Canada, would like to inform you about possible 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). If you are a current user of DURAGESIC® MAT, you should be aware that one shade of dark green ink, intended to make it easier to see the patch, will now be used on all strengths. The product carton and pouch will still use the different colours of ink to help in differentiating patch strengths.

To ensure your safety, please note the following important information:

- **Dosing errors (overdose or underdose) are possible with this change from different ink colours to the same colour (dark green) for all patch strengths.**
- **When handling DURAGESIC® MAT patches:**
  - **You should check the carton and the pouch to confirm the dosage strength. The ink colour on the patch can no longer be used to identify patch strength when putting a patch on or taking one off.**
  - **You should not remove patch from the pouch until you are ready to use it.**
  - **You should check the dosage strength printed on the patch before using it.**
  - **If using more than one patch, you should check the dosage strength printed on each patch when putting a patch on or taking one off.**
- **For a short period, patches with the old and new ink will be in the market at the same time.**

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

Patches with the new dark green colour ink will enter the market in late July.

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

DURAGESIC<sup>®</sup> MAT is used for 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 overdose can lead to serious or life-threatening breathing problems.
- Signs of overdose may include tiredness, extreme sleepiness or sedation; inability to think, talk or walk normally; and feeling faint, dizzy or confused, seizure and hallucinations.
- You should remove the patch and seek medical attention immediately with any signs and symptoms of overdose.

#### **Signs of Underdose:**

- Signs of underdose may include inadequate pain relief and withdrawal symptoms such as, nausea, vomiting, diarrhea, anxiety and shivering.

#### **How to reduce risks of 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.

#### **Storage:**

- To reduce the risks of accidental contact, DURAGESIC<sup>®</sup> MAT should be kept in a safe place, out of the sight and reach of children before, during and after use.

#### **Use:**

- DURAGESIC<sup>®</sup> MAT should not be applied in front of children, since they may copy your actions.

#### **Disposal:**

- After removing, the used patch should be folded in half so that the adhesive side of the patch adheres to itself, and should be immediately packaged in such a way as to prevent accidental contact with others, including children and pets until it can be returned to a pharmacy for proper disposal.
- DURAGESIC<sup>®</sup> MAT should never be thrown away in household trash where children and pets can find them, as used patches can still contain a considerable amount of drug. Returning to a pharmacy via a take back program is best.

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

Janssen Inc. has provided this information to doctors and pharmacists across Canada. Product details are included in the DURAGESIC® MAT consumer information document, available at <http://www.janssen.ca>. For more information, patients should consult their healthcare professional.

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

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Or call toll free at 1-866-825-7122

Or email to [dsscan@joica.jnj.com](mailto:dsscan@joica.jnj.com)

Or fax to 1-866-767-5865

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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) 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\\_dpdc.public@hc-sc.gc.ca](mailto:mhpd_dpdc.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](http://www.janssen.ca) and on the Health Canada website at [www.healthycanadians.gc.ca](http://www.healthycanadians.gc.ca).

**DURAGESIC® MAT Patches**  
**Text Colour Changes to a Single, Dark Ink for all strengths**

**Current**                      **New**  
**Multi-Colour Ink**              **Dark Green Ink**

