

FIASP® (insulin aspart injection) FlexTouch®, Penfill® and Vial Presentations Change in label design and colour components

Novo Nordisk Canada Inc.
June 04, 2018, 08:00 ET

IMPORTANT INFORMATION:

- There is a potential risk of mix up between Fiasp® and other insulin medicines due to similar label design and other plastic components of the Fiasp® FlexTouch®, Penfill® and vial.
- Novo Nordisk has changed the Fiasp® label design and colour components to ensure Fiasp® is more clearly differentiated from other insulin products. There have been no changes to Fiasp® other than the updated design and colour scheme.

In Canada, Fiasp® is available in the following presentations: pre-filled FlexTouch® pens, Penfill® cartridges designed for use with Novo Nordisk insulin delivery devices and vials.

PRODUCTS CHANGED:

- Fiasp® FlexTouch®
- Fiasp® Penfill®
- Fiasp® Vial

Please see below for an illustration of the current and updated Fiasp® FlexTouch® presentation. Similar changes have also been applied to the Penfill® and vial presentations.

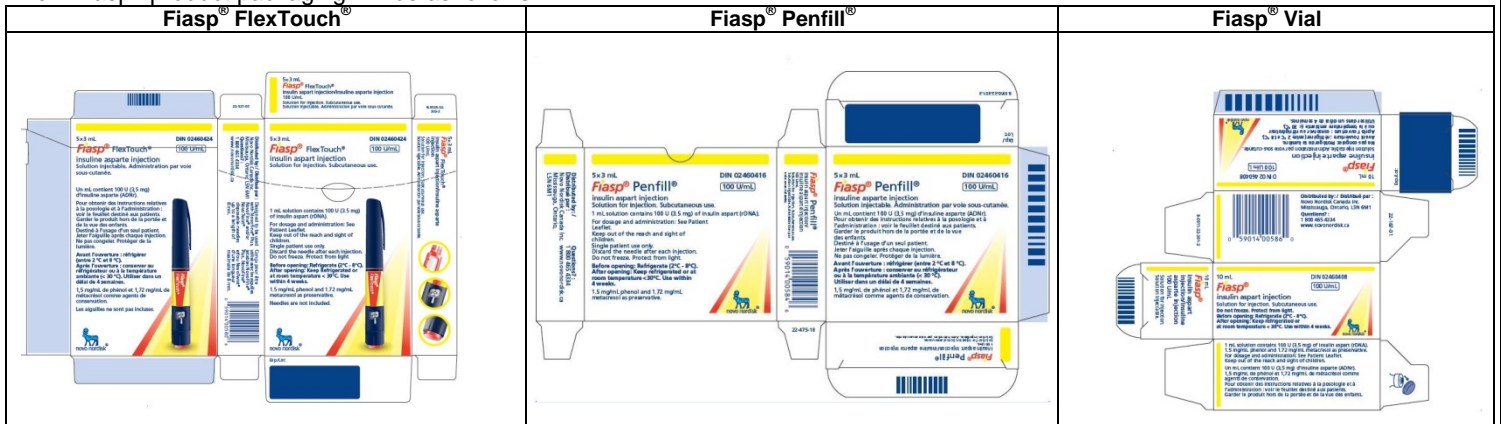
Current product colours (yellow and white):



New updated product colours (red and yellow):



New Fiasp® product packaging will be as follows:



INFORMATION FOR CONSUMERS TO BE INFORMED BY HEALTHCARE PROFESSIONALS:

In order to reduce the risk of accidental mix-ups, it is very important to ensure that patients are instructed to always check the insulin label carefully when they receive it at the pharmacy and before each injection. Patients should be instructed to always read the name of the insulin on the FlexTouch® pen, Penfill® cartridges or vial to make sure that they are administering the correct insulin each time.

As with all insulin products, patients must always be instructed to read the patient information carefully and be appropriately trained in the correct use of FlexTouch® pens, Penfill® cartridges and vials.

Patients who are blind or have poor vision must be instructed to always get help/assistance from another person who has good vision and is trained to use the insulin device.



ACTION TAKEN BY HEALTH CANADA:

Health Canada has reviewed and approved the updated label for Fiasp[®] on the FlexTouch[®], Penfill[®] and Vial presentations.

Report health or safety concerns:

Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Adverse reaction reporting related to any Novo Nordisk product, including medication errors should be reported to Novo Nordisk Canada Inc., or to Health Canada.

Novo Nordisk Canada Inc.

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Email: nnci-drugsafety@novonordisk.com

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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) 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_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 Fiasp[®], please contact Novo Nordisk customer service centre at 1-800-465-4334. A coloured copy of this letter is also available on the Novo Nordisk Canada Web site (<http://www.novonordisk.ca/>) and on the Health Canada Web site (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>).

REFERENCES:

1. Fiasp[®] (fast-acting insulin aspart injection), Novo Nordisk Canada Inc., Product Monograph, February 09, 2018

Sincerely,

Original Signed by

Dr. Keval Chandarana MBBS, PhD, BSc

Associate Director, Medical Affairs and Medical Information

Novo Nordisk Canada Inc.

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