



July 4, 2022

Dear Healthcare Professionals,

Audience: Patient Support Program Healthcare professionals

Subject: Abrilada Prefilled Pens (DIN 02511045) – Typographical error of the brand name on the pen label

Issue:

Abrilada 40 mg / 0.8 mL (DIN 02511045) is supplied as two single-dose prefilled pens packaged in a carton with a package insert. It has been noted that the brand name on the pen label is misspelled as 'Abrildada' as shown in the image below.



The brand name on the carton and the package insert are spelled correctly and there is no impact to product quality and no expected impact to patient safety. Pfizer has identified the root cause and has implemented corrective measures.

Pfizer Canada has advised Health Canada of the typographical error and that Pfizer will continue with the distribution of the impacted lots. See below details regarding the affected product.

Affected product:

DIN	CODE	PRODUCT NAME	PRODUCT DESCRIPTION	SIZE	UPC	AFFECTED LOT #
02511045	52456	Abrilada 40 mg / 0.8 mL	Sterile Solution for Subcutaneous (S.C.) use only	2 x prefilled pens	6210275 24562	F2202005 (Expiry date: 30- Sep-2023)
02511045	52456	Abrilada 40 mg / 0.8 mL	Sterile Solution for Subcutaneous (S.C.) use only	2 x prefilled pens	6210275 24562	F2202009 (Expiry date: 31-May-2024)
02511045	52456	Abrilada 40 mg / 0.8 mL	Sterile Solution for Subcutaneous (S.C.) use only	2 x prefilled pens	6210275 24562	F2203001 (Expiry date: 31-May-2024)
02511045	52456	Abrilada 40 mg / 0.8 mL	Sterile Solution for Subcutaneous (S.C.) use only	2 x prefilled pens	6210275 24562	F2203006 (Expiry date: 31-May-2024)
02511045	52456	Abrilada 40 mg / 0.8 mL	Sterile Solution for Subcutaneous (S.C.) use only	2 x prefilled pens	6210275 24562	F2203007 (Expiry date: 31-May-2024)

Information for Healthcare Professionals (and their patients):

Following the review of this issue, it was concluded that there is no impact to product quality and no expected impact to patient safety.

Patients should be advised that:

- There is a typographical error of the brand name on the pen label ('Abrildada' instead of 'Abrilada').
- The quality of the product is not impacted by this typographical error and is safe to use.
- The pen label correctly identifies
 - the Drug Identification Number (DIN 02511045),
 - the drug substance (adalimumab), and
 - the dosage (40 mg / 0.8 mL).
- The brand name is spelled correctly on the carton and package insert.
- As indicated in the package insert, the prefilled pens are to be stored in the original carton until use.
- Consult the package insert for the proper use of this product.
- They should not stop treatment and should consult their healthcare provider should they have any concerns.

If you have any questions or concerns, please contact Pfizer Canada by calling 1-800-463-6001.

Report health or safety concerns:

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of serious or unexpected side effects in patients receiving Abrilada should be reported to Pfizer Canada ULC or Health Canada.

Pfizer Canada ULC
17300 Trans-Canada Highway
Kirkland, QC
H9J 2M5
Telephone: 1-866-723-7111
Fax: 1-855-242-5652

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) (<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.

Sincerely,

DocuSigned by:

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Vratislav Hadrava M.D., Ph.D.
Vice President & Medical Director
Pfizer Canada ULC