

**Importation of Saudi Arabia-labelled ORENCIA® (abatacept) Injection
Single-Dose Pre-filled syringes for subcutaneous injection due to the current
Shortage of Canadian-authorized ORENCIA® SC for Injection**

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Dear pharmacists, wholesalers, and customers

There is a critical shortage of ORENCIA SC for Injection in Canada. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of Bristol-Myers Squibb's Saudi Arabia-labelled ORENCIA SC, with English and Arabic labels, by Bristol-Myers Squibb Canada.

Health Canada has accepted the addition of Bristol-Myers Squibb's product to the [List of drugs for exceptional importation and sale](#).

In Canada, ORENCIA SC for Injection is indicated for the treatment of Adult Rheumatoid Arthritis (RA) and the treatment of adult patients with active psoriatic arthritis (PsA).

The Saudi Arabia-labelled product has the **same active ingredient, strength, dosage form, volume, product formulation and route of administration** as the Canadian-authorized products.

The product labels, however, differ in the following ways:

- Indication and dosing associated with pediatric population. Orencia SC administered subcutaneously is not authorized for use in children and adolescents in Canada.
- Contraindication: In Canada, the use of Orencia SC is contraindicated for patients with, or at risk of, sepsis syndrome, such as immunocompromised and HIV+ patients.
- Live vaccine in pregnant women: Administration of live vaccines to infants exposed to abatacept in utero is not recommended for 10 weeks following the mother's last exposure to abatacept during pregnancy.

- The approved shelf life for the Saudi Arabia batch differs from the approved shelf life for Canadian Orencia. Therefore, the revised expiry date of **August 2025** applied on the redressed SA-Orencia units **MUST BE USED**.

The Saudi Arabia-labelled product **MUST** be used in the same manner as the Canadian-authorized product, regardless of the information found on the Saudi-Arabia labels. Health care professionals should refer to the Canadian Product Monograph for ORENCIA SC available in English and French on the [Drug Product Database](#). The database contains information on the appropriate use of the product, including the:

- indications
- contraindications
- warnings and precautions
- adverse reactions
- dosage and administration
- storage conditions
- handling instructions

Information on the imported product

Brand name	Dosage form, strength, and route of administration	Product description and packaging	Country of authorization, Name of Foreign Authority and identifying code	Authorization holder	DEL holder/ Importer in Canada
Orencia SC Abatacept	125 mg/ml solution for subcutaneous injection	Single-dose, disposable prefilled syringes with BD Ultrasafe Passive TM Needle Guard with Flange Extenders. Cartons of 4.	Saudi Arabia, Saudi Food and Drug Authority 1-960-14	Bristol-Myers Squibb	Bristol-Myers Squibb Canada

Images of the Saudi Arabia-labelled product can be found in the Appendix below.

Health care professionals are advised that aspects of the inner and outer labels and packaging of Saudi Arabia-labelled product may differ from marketed ORENCIA SC in Canada. **Proper selection of the intended product must be verified to avoid confusion with other products and prevent medication errors.**

The key attributes from the Canadian inner and outer labels which are **absent** from the Saudi Arabia inner and outer labels, include:

- Drug Identification Number (DIN)
- Name and address of the Canadian DIN holder and Importer
- Corresponding text in French
- Reference to the Canadian website (www.bms.com/ca) for the Canadian Product Monograph

All unit packaging of the Saudi Arabia-labelled ORENCIA SC will include a unique barcode affixed to the unit package (on a plastic bag) that scans in medication management systems in Canada (refer to the images in the Appendix below). In addition, all units will include an additional label providing the expiry date (August 2025) to be used.

The **PIN 09858343** has been approved for processing in pharmacy.

Reporting adverse drug reactions

Adverse drug reactions associated with the use of Orencia SC should be reported to Bristol-Myers Squibb Canada, or to Health Canada by visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or by calling toll-free at 1-866-234-2345.

Questions or concerns

For questions or concerns about US-labelled ORENCIA SC, please contact Bristol-Myers Squibb Canada at **1-866-463-6267**.

Appendix

Saudi Arabia-labelled Orenzia SC for Injection syringe and Carton Labels:

ORENCIA® 1 mL
أورينسيا®
(abatacept) Injection
125 mg/mL
For Subcutaneous Use Only
للحقن تحت الجلد فقط
 Bristol-Myers Squibb Company

X43328X
 b07:
 Mfg.:
 EXP:

Dosing and usage:
 For subcutaneous use only. Inject ORENCIA® once weekly using one prefilled syringe. Do not reuse the syringe. See Bilingual (English/Arabic) Patient Insert and Instructions for Use for more details.

Week	
1	
2	
3	
4	

- Remove one prefilled syringe from the refrigerator or 30 to 60 minutes before your injection.
- Do not remove the needle cover until you are ready to inject.
- Please write the dates of your weekly injections in the spaces provided.

Be sure to read the enclosed complete ORENCIA® Bilingual (English/Arabic) Patient Insert and Instructions for Use before your first self-injection.

ORENCIA® is a registered trademark of Bristol-Myers Squibb Company. BD UltraSafe Passive™ is a trademark of Becton, Dickinson and Company.

DO NOT REMOVE THE PREFILLED SYRINGE BY ITS PLUNGER OR NEEDLE COVER.

أورينسيا® (أباتاكت) حقن

محتوى الصندوق:

- 4 حقن جرعة واحدة ORENCIA® مع إبرة مضمونة مع الحماية
- إدراج تعليمات الاستخدام (الإنجليزية/العربية)

معلومات إضافية:

125 ملغ/ملي
 حقن جرعة واحدة مع إبرة مضمونة مع الحماية

Unit Packaging for the Saudi Arabia-labelled Orendia SC Injection



Dominique Lavallée

Sincerely,
Dominique Lavallée