

November 30, 2021

**Importation of France-labelled JORVEZA® (Budesonide) 1 mg Orodispersible Tablets distributed by AVIR Pharma Due to Shortage of Canadian-labelled JORVEZA 1 mg Orodispersible Tablets**

Dear Healthcare Professional,

**Key messages**

- AVIR Pharma is experiencing a shortage of JORVEZA (budesonide) 1 mg orodispersible tablets (ODT) on the Canadian market.
- Given the medical necessity of this product in Canada and to help mitigate the current shortage, Health Canada has not objected to the temporary importation and distribution of one lot of Dr. Falk Pharma GmbH's France-labelled JORVEZA 1 mg ODT by AVIR Pharma.
- The France-labelled product has the **same active ingredient, dosage form and route of administration** as the Canadian-authorized product, but the two products **differ with respect to the contraindications, dosage for maintenance of remission, and storage conditions**. A summary of these differences can be found below under the Information for healthcare professionals section.
- **The France-labelled product can be used in the same manner as the Canadian-authorized product. Healthcare professionals should refer to the Canadian Product Monograph for JORVEZA 1 mg ODT available on the Health Canada Drug Product Database (<https://health-products.canada.ca/dpd-bdpp/info.do?lang=en&code=98367>) for information on proper use including the indications, contraindications, dosage and administration, and storage conditions.**

**Imported product**

Product Name	Product Description and Packaging Format	Country of Origin and Identifying Code	EU Market Authorization Holder / Canadian Importer and Distributor	Lot Number	Expiry
JORVEZA	1 mg budesonide orodispersible tablets  Cartons containing blisters of 90 orodispersible tablets (9 x 10 orodispersible tablets)	France  34009 302 001 9 3	Dr. Falk Pharma GmbH (Germany) / Laboratoire Riva Inc. (importer), AVIR Pharma Inc. (distributor)	L20004C	11/2022

In Canada, JORVEZA is indicated for the induction and maintenance of clinico-pathological remission in adults with eosinophilic esophagitis.

**Information for healthcare professionals**

The France-labelled product has the **same active ingredient, dosage form and route of administration** as the Canadian-authorized product, but the two products **differ with respect to the contraindications, dosage for maintenance of remission, and storage conditions**. These differences can be found in the summary table below in **bolded** text.

	<b>France-labelled JORVEZA 1 mg ODT</b>	<b>Canadian-authorized JORVEZA 1 mg ODT</b>
<b>Contraindications</b>	Contraindicated in patients with hypersensitivity to the active substance or to any of the excipients.	Contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any nonmedicinal ingredient, or component of the container or <b>have uncontrolled infections or active tuberculosis.</b>
<b>Dosage – Maintenance of Remission</b>	The recommended daily dose is 1 mg budesonide as one 0.5-mg-tablet in the morning and one 0.5-mg tablet in the evening or <b>2 mg budesonide as one 1-mg-tablet in the morning and one 1-mg-tablet in the evening, depending on the individual clinical requirement of the patient.</b>  A maintenance dose of 1 mg budesonide twice daily is recommended for patients with a long standing disease history and/or high extent of <b>esophageal inflammation in their acute disease state.</b>	The recommended daily dose is 1 mg budesonide as one 0.5-mg-tablet in the morning and one 0.5-mg-tablet in the evening.
<b>Storage Conditions</b>	<b>Do not store above 25°C.</b> Store in the original package in order to protect from light and moisture.	<b>Store at room temperature (15°C to 25°C).</b> Store in the original package in order to protect from light and moisture.

The France-labelled product can be used in the same manner as the Canadian-authorized product. Healthcare professionals should refer to the Canadian Product Monograph for JORVEZA 1 mg ODT available on the Health Canada Drug Product Database (<https://health-products.canada.ca/dpd-bdpp/info.do?lang=en&code=98367>) for information on proper use including the indications, contraindications, dosage and administration, and storage conditions.

Please note that a copy of the Canadian Patient Medication Information leaflet, which can be distributed to the patient for reference purposes, is provided with each unit of France-labelled JORVEZA 1 mg ODT.

The carton and blister labels of the France-labelled product are labelled in French only; English-translated text of the carton and vial labels can be found below along with the images of the France-labelled product.

The France-labelled product does not have a Drug Identification Number (DIN) or the Pr symbol (“Pr” stands for “prescription”). Please note that a UPC barcode is provided with each box of France-labelled JORVEZA 1 mg ODT which can be scanned in medication management systems in Canada. When scanned, the UPC barcode will show the same product information as the Canadian-authorized JORVEZA 1 mg ODT.

Information about France-labelled JORVEZA 1mg ODT for healthcare professionals is available for reference in English and French and can be found in the European Medicines Agency Summary of Product Characteristics at:

- English: [https://www.ema.europa.eu/en/documents/product-information/jorveza-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/jorveza-epar-product-information_en.pdf)
- French: [https://www.ema.europa.eu/en/documents/product-information/jorveza-epar-product-information\\_fr.pdf](https://www.ema.europa.eu/en/documents/product-information/jorveza-epar-product-information_fr.pdf)

A copy of this risk communication is available to healthcare professionals in both English and French at: <https://www.avirpharma.com/our-products/>.

**Report health or safety concerns**


Adverse drug reactions associated with the use of JORVEZA 1 mg ODT should be reported to AVIR Pharma Inc. by calling 1-888-430-0436 or to Health Canada at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html> or by calling toll-free at 1-866-234-2345.

Best regards,



Olivier St-Denis  
President

**Images of the France-labelled JORVEZA 1 mg ODT and  
English-translations of the Outer Carton and Blister Label Text**

France Outer Carton Label	English Translation
 <p>Jorveza® 1 mg, comprimés orodispersibles budesonide</p> <p>Voie orale. <b>Ne pas mâcher ni avaler.</b> À utiliser conformément aux indications du médecin. Lire la notice avant utilisation.</p> <p>90 comprimés orodispersibles</p>	<p>Jorveza® 1 mg, orodispersible tablets budesonide</p> <p>Each tablet contains 1 mg budesonide. Contains sodium. Refer to insert for more information.</p>
 <p>Jorveza 1 mg Liste I</p> <p><b>RESPECTER LES DOSES PRESCRITES</b></p> <p>Uniquement sur ordonnance Médicament autorisé N°: 34009 302 001 9 3 Prescription initiale annuelle réservée aux spécialistes en hépato-gastro-entérologie. Renouvellement non restreint.</p> <p><b>JORVEZA + GROSSESSE = DANGER</b></p> <p>Ne pas utiliser chez: - l'adolescente ou la femme en âge de procréer, et sans contraception efficace - la femme enceinte sauf en l'absence d'alternative thérapeutique</p>	<p>Jorveza 1 mg Liste I Respect prescribed doses Prescription only Authorized medication No: 34009 302 001 9 3 Annual initial prescription reserved to hepato-gastro-enterology specialists. Non-restricted renewal. <b>JORVEZA+PREGNANCY=DANGER</b> Do not use in:</p> <ul style="list-style-type: none"> <li>- teenage girl or woman of childbearing age, without adequate contraception</li> <li>- pregnant woman unless there is no therapeutic alternative</li> </ul>
<p>DR. FALK PHARMA GmbH  Leinenweberstr. 5 79108 Freiburg Allemagne</p> <p>EU/1/17/1254/004</p> <p>À conserver à une température ne dépassant pas 25 °C. À conserver dans l'emballage d'origine, à l'abri de la lumière et de l'humidité. <b>Tenir hors de la vue et de la portée des enfants.</b></p>	<p>DR. FALK PHARMA GmbH Leinenweberstr. 5, 79108 Freiburg, Germany EU/1/17/1254/004 Store at a temperature not exceeding 25°C. Store in the original packaging, protect from light and humidity. Keep out of sight and reach of children.</p>
 <p>Jorveza® 1 mg, comprimés orodispersibles budesonide</p> <p>Voie orale. <b>Ne pas mâcher ni avaler.</b> À utiliser conformément aux indications du médecin. Lire la notice avant utilisation.</p> <p>90 comprimés orodispersibles</p>	<p>Jorveza® 1 mg, orodispersible tablets budesonide</p> <p>Oral administration. Do not chew or swallow Use per doctor instructions. Read insert before use.</p> <p>90 orodispersible tablets</p>
 <p>Jorveza® 1 mg, comprimés orodispersibles budesonide</p>	<p>Jorveza® 1 mg, Orodispersible tablets budesonide</p>
France Blister Label	English Translation
 <p>Jorveza® 1 mg, comprimés orodispersibles budesonide Dr. Falk Pharma GmbH</p>	<p>Jorveza® 1 mg, orodispersible tablets budesonide Dr. Falk Pharma GmbH</p>