

**Important Safety Information**  
**Importation of Spanish-Labelled Salbutamol Aldo-Union inhalers due to Shortage of Canadian-Labelled Salbutamol**



2020/05/19

**Audience**

Healthcare professionals including General Practitioners, Allergists, Pulmonologists, Respiratory disease specialists, Emergency physicians, Pharmacists

**Key messages**

- **There is an increased demand and shortage of salbutamol metered-dose inhalers (MDIs) in Canada due to the COVID-19 pandemic.**
- **Given the medical necessity of salbutamol, Health Canada has added Spanish-labelled Salbutamol Aldo-Union metered-dose aerosol (100 mcg salbutamol /metered dose) to the List of Drugs for Exceptional Importation and Sale.**
- **The Spanish-labelled salbutamol inhalers have the same active ingredient and strength as salbutamol inhalers on the Canadian market and are used in a comparable way.**
- **While the label text of the imported salbutamol is in Spanish, a sticker will be added to the carton label including the distributor name (JAMP Pharma Corporation), contact information and unique bar code.**
- **Healthcare professionals are advised that the preparation for use instructions for the Spanish-labelled salbutamol inhaler differ from those for Canadian inhalers. Before using the Spanish-labelled salbutamol inhaler for the first time, or if the product has not been used for several days or more, 1 spray should be released into the air away from the face to ensure it is working properly.**
- **For salbutamol prescribing information, healthcare professionals should consult the product monographs for salbutamol inhalers on the Canadian market, available on [Health Canada's Web site](https://health-products.canada.ca/dpd-bdpp/index-eng.jsp) (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>).**

**Issue**

There is an increased demand for salbutamol metered-dose inhalers (MDIs) due to the COVID-19 pandemic, which has led to some manufacturers reporting [shortages](https://www.drugshortagescanada.ca) and limited supply of this product in Canada ([www.drugshortagescanada.ca](https://www.drugshortagescanada.ca)).

Given the medical necessity of salbutamol, Health Canada has added Spanish-

labelled Salbutamol Aldo-Union to the [List of Drugs for Exceptional Importation and Sale \(https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods/information-provisions-related-drugs-biocides/list.html\)](https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods/information-provisions-related-drugs-biocides/list.html).

### **Products affected**

Salbutamol Aldo-Union (Spanish labelled)  
Salbutamol sulfate metered-dose aerosol  
100 mcg salbutamol per actuation

### **Background information**

In Canada, salbutamol sulfate inhalation aerosol is indicated in adults and children 4 years and older for:

- the symptomatic relief and prevention of bronchospasm due to bronchial asthma, chronic bronchitis and other chronic bronchopulmonary disorders in patients in whom reversible bronchospasm is a complicating factor.
- the prevention of exercise-induced bronchospasm.

### **Information for patients**

Manufacturers have reported salbutamol shortages because of an increase in demand related to the current COVID-19 pandemic. Some patients will receive the Spanish-labelled salbutamol inhaler, which is being imported into Canada to help alleviate the shortage. Both Canadian and Spanish-labelled salbutamol inhalers are used in a comparable way. At this time, to manage and conserve supply, most patients should receive only one inhaler at a time when they go to refill their prescription.

Patients should contact their healthcare professional for more information.

### **Information for healthcare professionals**

The Spanish-labelled salbutamol inhaler has the same active ingredient and concentration as salbutamol inhalers on the Canadian market, and is used in a comparable way.

Healthcare professionals are advised that the preparation for use instructions for the Spanish-labelled salbutamol inhaler may differ from those for the Canadian inhalers. Before using the Spanish-labelled salbutamol inhaler for the first time, or if it has not been used for several days or more, 1 spray should be released into the air away from the face to ensure it is working properly.

Pharmacists and other healthcare professionals should:

- Inform patients that they are receiving a Spanish-labelled product.
- Print this communication and make it available to patients and caregivers upon dispensing the Spanish-labelled product.
- Review the preparation for use instructions for the Spanish-labelled inhaler with the patient when dispensing this product.

- Remind patients to continue to follow the same routine cleaning instructions as with the Canadian product.
- Supply only one inhaler at a time when patients go to refill their prescription, to manage and conserve supply.
- Consult the product monographs for salbutamol inhalers on the Canadian market, available on Health Canada's Web site (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>) for salbutamol prescribing information.

While the label text of the imported salbutamol is in Spanish, a sticker will be added to the carton label including the distributor name: JAMP Pharma Corporation, phone number, website and unique bar code.

Please see Appendix A for images of Spanish-labelled salbutamol product.

### **Action taken by Health Canada**

The Minister of Health signed the Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in relation to COVID-19. Drugs included on the [List of Drugs for Exceptional Importation and Sale](#) referenced in the Interim Order are eligible for the exceptional importation and sale provisions provided for in the Interim Order. Health Canada has added Spanish-labelled Salbutamol Aldo-Union to this list, which permits its importation and sale.

Health Canada is communicating this important safety information to healthcare professionals and Canadians via the [Recalls and Safety Alerts Database \(https://healthy Canadians.gc.ca/recall-alert-rappel-avis/index-eng.php\)](https://healthy Canadians.gc.ca/recall-alert-rappel-avis/index-eng.php) on the [Healthy Canadians Web Site](#). This communication update will be further distributed through the MedEffect™ e-Notice email notification system, as well as through our website and social media channels, including LinkedIn and Twitter.

### **Report health or safety concerns**

Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any case of serious or unexpected side effects in patients receiving Salbutamol from Aldo-Union should be reported to JAMP Pharma Corporation or Health Canada.

**JAMP Pharma Corporation**

1310, Nobel,  
Boucherville  
QC J4B 5H3

Email: [medinfo@jamppharma.com](mailto:medinfo@jamppharma.com)

Telephone: 1-866-399-9091

Fax: 1-866-399-9092

**To correct your mailing address or fax number, contact JAMP Pharma Corporation.**

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.

For other health product inquiries related to this communication, contact Health Canada at:

Regulatory Operations and Enforcement Branch

E-mail: [hc.hpce-cpsal.sc@canada.ca](mailto:hc.hpce-cpsal.sc@canada.ca)



Patrizia Franco

Senior Director, Regulatory Affairs  
JAMP Pharma Corporation

Appendix A - Images of salbutamol for spanish market

<b>SPANISH PRODUCT LABEL</b>	
	<p>No conservar a temperatura superior a 30°C. Conservar el envase en su lugar para protegerlo de la luz. No congelar.</p> <p>Leer el prospecto antes de utilizar este medicamento.</p> <p>No perforar el envase ni arrojárselo al fuego, sin cuanto aproximadamente este vacío.</p> <p>Mantener fuera de la vista y del alcance de los niños.</p> <p>Nº Reg. AEMPS 45.845</p> <p><b>MEDICAMENTO SUJETO A PRESCRIPCIÓN MÉDICA.</b></p>
<p>797183.2 TLD O</p> <p><b>Salbutamol Aldo-Unión</b> 100 microgramos / dosis suspensión para inhalación en envase a presión</p> <p>Suspensión para inhalación en envase a presión 200 dosis Vía inhalatoria Agitar antes de usar</p> <p>Aldo-Unión</p>	<p>Cada inhalación contiene 100 microgramos de salbutamol (como salbutamol sulfato). Contiene 1,1,1,2-tetrafluoroetano, ácido oleico y etanol.</p> <p>Para mayor información consultar el prospecto.</p> <p>Composición: Prin. activo: Otros ingredientes:</p> <p>Laboratorio Aldo-Unión, S.L. Carretera de Madrid, 73 28800 Salazar de los Ríos (Madrid), España.</p>
<p>797183.2 TLD O</p> <p><b>Salbutamol Aldo-Unión</b> 100 microgramos / dosis suspensión para inhalación en envase a presión</p> <p>Agitar antes de usar</p> <p>Aldo-Unión</p>	<p>797183.2 TLD O</p> <p><b>Salbutamol Aldo-Unión</b> 100 microgramos / dosis suspensión para inhalación en envase a presión</p> <p>Agitar antes de usar</p> <p>Aldo-Unión</p>
<p>4401</p> <p>Salbutamol Aldo-Unión 100 microgramos / dosis suspensión para inhalación en envase a presión</p> <p>Agitar antes de usar</p> <p>Aldo-Unión</p>	<p>797183.2 TLD O</p> <p><b>Salbutamol Aldo-Unión</b> 100 microgramos / dosis suspensión para inhalación en envase a presión</p> <p>Agitar antes de usar</p> <p>Aldo-Unión</p>
<p>In spanish only</p> <p>Salbutamol (as salbutamol sulfate) 100 mcg / dose</p> <p><b>Metered-Dose Aerosol</b></p> <p>Number 797183.2 TLD O</p> <p>200 Doses</p> <p><b>Inhalation</b></p> <p><b>Shake well before use</b></p> <p>Each inhalation contains: 100 mcg of salbutamol (as salbutamol sulfate). Non-medicinal ingredients: 1,1,1,2-tetrafluoroethane, oleic acid and ethanol.</p> <p>Do not conserve at a temperature superior to 30°C. Protect from direct sunlight and do not freeze. <b>Keep out of reach and sight of children.</b></p> <p>Aldo-Unión logo and Spain address</p>	