

To all healthcare professionals

There is an increased demand in Canada for hydromorphone injectable formulations as a result of the COVID-19 pandemic, with shortages being reported.

Given the medical necessity of injectable hydromorphone in Canada, Health Canada has added German-labelled Hydromorphon Ethypharm Kalceks (2 mg/mL hydromorphone hydrochloride solution for injection/infusion) in 1 mL ampoules to the List of Drugs for Exceptional Importation and Sale.

Please consult the following 5 pages for all the information.

Best regards,

Sukhad Juneja

Senior Vice President-Global Portfolio
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Important Safety Information
Importation of German-labelled Hydromorphon Ethypharm Kalceks
(Hydromorphone Hydrochloride Solution for Injection) due to Potential
Shortage of Canadian-labelled HYDRomorphone



2020/08/31

Audience

Healthcare professionals including pharmacists, anesthesiologists, critical care physicians, emergency physicians, pain physicians, oncologists, and palliative care specialists.

Key messages

- **There is an increased demand in Canada for hydromorphone injectable formulations as a result of the COVID-19 pandemic, with shortages being reported.**
- **Given the medical necessity of injectable hydromorphone in Canada, Health Canada has added German-labelled Hydromorphon Ethypharm Kalceks (2 mg/mL hydromorphone hydrochloride solution for injection/infusion) in 1 mL ampoules to the List of Drugs for Exceptional Importation and Sale.**
- **Healthcare professionals are advised to take additional care to help prevent serious medication errors and patient harm given the following:**
 - **TALLman lettering of the drug name, HYDRomorphone, a strategy normally used in Canada to accentuate the difference in its name from morphine, is absent from the German label (see Appendix A).**
- **Healthcare professionals are advised to use the Canadian-labelled prescribing information as a reference (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>), taking into consideration the following differences:**
 - **In Canada, hydromorphone products are indicated for use in patients aged 18 years and above. In Germany, Hydromorphon Ethypharm Kalceks products are indicated for use in patients aged 12 years and above.**
 - **In Canada, hydromorphone injection is authorized for subcutaneous, intramuscular or slow intravenous administration. German-labelled Hydromorphon Ethypharm Kalceks is labelled for subcutaneous and intravenous routes of administration only. However, there are no qualitative or quantitative differences in the drug product formulation between the German-labelled product and the Canadian-labelled product.**

Issue

There is an increased demand for hydromorphone injectable formulations in Canada as a result of the COVID-19 pandemic. Some manufacturers have reported shortages of this product (www.drugshortagescanada.ca).

Given the medical necessity of injectable hydromorphone, Health Canada has added German-labelled Hydromorphon Ethypharm Kalceks 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

Manufacturer	Product	Strength/ Packaging	Route of administration	Identifying code in authorizing country
AS KALCEKS	Hydromorphon Ethypharm Kalceks (Hydromorphone Hydrochloride)	2 mg/mL 1 mL ampoules	Subcutaneous Intravenous	2201455.00.00 (Germany)

Canadian importer: Innomar Strategies Inc.

Canadian distributor: JAMP Pharma Corporation

German manufacturer: Ethypharm Kalceks

Refer to **Appendix A** for images of the German-labelled hydromorphone product.

Background information

Canadian-labelled Hydromorphone Hydrochloride Injection (2 mg/mL) is indicated for use in patients aged 18 years and above for the relief of moderate to severe pain. The use of hydromorphone hydrochloride injection 2 mg/mL is not recommended in patients under 18 years of age as its safety and efficacy has not been studied in the pediatric population.

Increased demand for hydromorphone hydrochloride injection as a result of the COVID-19 pandemic has led to reported shortages and limited supply of this product in Canada. The temporary importation of German-labelled Hydromorphon Ethypharm Kalceks (2 mg/mL hydromorphone hydrochloride solution for injection/infusion) in 1 mL ampoules will maximize the amount of this product available to COVID-19 patients in Canada and help mitigate the current market shortage.

Information for healthcare professionals

Healthcare professionals are advised to take additional care to help prevent serious medication errors and patient harm given the following:

- In Canada, the use of TALLman lettering of the drug name, HYDRomorphone, is a risk minimization strategy recommended for the labelling of hydromorphone products to help accentuate the difference in its name compared to morphine, the medication with which it is commonly confused. TALLman lettering is not used for the German-labelled hydromorphone products.

Healthcare professionals are advised to use the Canadian-labelled prescribing information as a reference (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>), taking into consideration the following differences:

- In Canada, hydromorphone products are **indicated for use in patients aged 18 years and above**. In Germany, Hydromorphon Ethypharm Kalceks products are indicated for use in patients aged 12 years and above.
- In Canada, hydromorphone injection **is approved for subcutaneous, intramuscular or slow intravenous administration**. The foreign labels include the subcutaneous and intravenous routes of administration only. However, there are no qualitative or quantitative differences in the drug product formulation between the German-labelled product and the Canadian-labelled product.

Proper selection of the intended product must be confirmed to avoid confusion with other injectable products, including other opioid injections.

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](https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods.htm) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods.htm>). 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 hydromorphone hydrochloride solution for injection to this list, which permits the importation and sale of German-labelled Hydromorphon Ethypharm Kalceks 2 mg/mL solution for injection/infusion.

Health Canada has worked with JAMP Pharma Corporation to prepare this alert for hydromorphone hydrochloride. Health Canada is communicating this important safety information to healthcare professionals via the [Recalls and Safety Alerts Database](#) on the Healthy Canadians Web Site (<https://healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php>). This communication update will be further distributed through the MedEffect™ e-Notice email notification system.

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 Hydromorphon Ethypharm Kalceks should be reported to JAMP Pharma Corporation or Health Canada.

JAMP Pharma Corporation

1310, Nobel,
Boucherville
QC J4B 5H3

Email: 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](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) (<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.

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



Patrizia Franco
Senior Director, Regulatory Affairs
JAMP Pharma Corporation

Appendix A – Images of Hydromorphone Hydrochloride 2 mg/mL for German market

GERMAN PRODUCT LABEL	
<p>In German only</p>	
<p>Each 1 mL ampoule contains 2 mg Hydromorphone Hydrochloride</p>	
<p>Controlled drug for adult use only</p>	
<p>Narcotic Analgesic</p>	
<p>Number 2 mg/mL: Zul.-Nr. 2201455.00.00</p>	
<p>2 mg/mL: box of 10 ampoules x 1 mL</p>	
<p>For intravenous and subcutaneous use</p>	
<p>Sterile solution for injection/infusion</p>	
<p>Medicinal ingredient: Hydromorphone hydrochloride</p>	
<p>Non-medicinal ingredients: Citric acid, sodium citrate, sodium chloride, sodium hydroxide solution, hydrochloric acid and water for injection.</p>	
<p>Store: 15-30°C. Protect from light. Discard unused portion.</p>	
<p>Keep out of reach of children.</p>	
<p>Kalceks logo</p>	