

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

<sup>Pr</sup>**KORSUVA**<sup>®</sup>

#### Difelikefalin injection

Read this carefully before you start taking **KORSUVA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **KORSUVA**.

#### What is **KORSUVA** used for?

**KORSUVA** is used to treat itching (i.e., pruritus) in adults with chronic kidney disease on hemodialysis.

#### How does **KORSUVA** work?

**KORSUVA** contains the active substance difelikefalin. **KORSUVA** works by relieving the need for scratching yourself.

#### What are the ingredients in **KORSUVA**?

Medicinal ingredients: difelikefalin

Non-medicinal ingredients: acetic acid, sodium acetate trihydrate, sodium chloride, water for injections

#### **KORSUVA** comes in the following dosage forms:

Solution, 50 mcg difelikefalin (as acetate) per 1 mL.

#### Do not use **KORSUVA** if:

- You are allergic to difelikefalin or to any of the ingredients in **KORSUVA** (see list of Non-medicinal ingredients).

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you receive **KORSUVA**. Talk about any health conditions or problems you may have, including if you:**

- are pregnant, think you are pregnant or plan to become pregnant. It is not known if **KORSUVA** may harm your unborn baby;
- are breastfeeding or plan to breastfeed. It is not known if **KORSUVA** can pass into your milk and harm your baby. Talk to your healthcare professional about the best way to feed your baby if you take **KORSUVA**;
- have an increased potassium level in the blood;
- have or have had heart weakness or a heart rhythm disorder;
- have problems with your liver;
- have reduced function of the blood-brain barrier (such as cancer in the brain or the central nervous system, or a disease of the central nervous system like multiple sclerosis)

- or dementia) as this might increase your risk of side effects;
- are using medicines that could increase the risk of drowsiness or dizziness, such as:
    - medicines that slow down brain activity such as those that help with sleep disturbances and anxiety;
    - medicines to treat allergies, cold, nausea and/or vomiting called sedating antihistamines;
    - strong painkillers, called opioid analgesics.

**Other warnings you should know about:**

Falls can occur during treatment with **KORSUVA**.

Dizziness and drowsiness have occurred in patients taking **KORSUVA**. If you are 65 years or older, you may be more likely to experience drowsiness. Give yourself time after taking **KORSUVA** to see how you feel before driving a vehicle or using machinery.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with KORSUVA:**

There are no known drug interactions.

**How to take KORSUVA:**

- Your healthcare professional will add **KORSUVA** into the venous line of the dialysis circuit 3 times per week at the end of a hemodialysis session.
- No more than 4 doses of **KORSUVA** per week should be given even if the number of hemodialysis treatments in a week exceeds 4.

**Usual dose:**

The recommended dose of **KORSUVA** is 0.5 mcg/kg. Your healthcare professional will determine the right dose for you, based on your body weight.

If a dialysis treatment is unfinished, your doctor will decide whether it is better for you to receive **KORSUVA** after the unfinished dialysis session or wait until your next dialysis treatment.

**Overdose:**

If you think you, or a person you are caring for, have received too much **KORSUVA**, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you miss a regular hemodialysis treatment, **KORSUVA** should be given at the next hemodialysis treatment at the same dose.

## What are possible side effects from using KORSUVA?

These are not all the possible side effects you may have when taking **KORSUVA**. If you experience any side effects not listed here, tell your healthcare professional.

Common side effects ( $\geq 1\%$  and  $< 10\%$ ):

- Sensation in the skin or mouth such as tingling prickling, burning or numbness, decreased feeling or sensitivity
- Headache
- Nausea, diarrhea
- Change in how you walk (your gait) and falls
- High blood potassium level (seen in blood tests)
- Back pain

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b>			
Dizziness		X	
Drowsiness		X	
<b>UNCOMMON</b>			
Chest pain, shortness of breath due to heart weakness or feeling of irregular heart beat			X
Mental status changes (including feeling confused)		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products 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.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

Store **KORSUVA** at room temperature (15°C - 30°C). Do not freeze. Do not use **KORSUVA** after the expiry date which appears right after the word "EXP" on the label or carton.

Keep out of reach and sight of children.

### If you want more information about KORSUVA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes

this Patient Medication Information by visiting the Health Canada website:  
(<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website  
([www.otsukacanada.com](http://www.otsukacanada.com)), or by calling 1-877-341-9245.

This leaflet was prepared by Otsuka Canada Pharmaceutical Inc.

Last prepared AUG 12, 2022