

Product Specification Sheet

KORSUVA[®] is the FIRST AND ONLY FDA-APPROVED prescription treatment for moderate-to-severe CKD-associated pruritus (CKD-aP) in adult hemodialysis patients

Indication

- KORSUVA[®] is indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis
- Limitations of Use: KORSUVA[®] has not been studied in patients on peritoneal dialysis and is not recommended for use in this population

How supplied

- KORSUVA[®] is supplied as a sterile, clear, and colorless solution in 1.3 mL, single-dose glass vials:
 - NDC 59353-065-01: 65 mcg/1.3 mL (50 mcg/mL) single-dose vial
 - NDC 59353-065-12: Carton containing 12 vials

Storage & handling requirements

- Store vials at 20°C to 25°C (68°F to 77°F), with excursions permitted to 15°C to 30°C (59°F to 86°F). Do not freeze
- KORSUVA[®] injection must be administered within 4 hours of syringe preparation; prepared syringes can be stored at ambient temperature of 20°C to 25°C (68°F to 77°F) until dosing
- KORSUVA[®] injection is supplied in a single-dose vial. Any unused drug remaining after injection must be discarded

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Dizziness, Somnolence, Mental Status Changes, and Gait Disturbances: These adverse reactions, including falls, have occurred in patients taking KORSUVA[®] and may subside with continued treatment. The incidence of somnolence was higher in KORSUVA[®]-treated subjects 65 years of age and older (7.0%) than in KORSUVA[®]-treated subjects less than 65 years of age (2.8%). Concomitant use of centrally acting depressant medications, sedating antihistamines, and opioid analgesics may increase the likelihood of these adverse reactions and should be used with caution during treatment with KORSUVA[®].

Risk of Driving and Operating Machinery:

Dizziness, somnolence, and mental status changes have occurred in patients taking KORSUVA[®]. KORSUVA[®] may impair mental or physical abilities needed to perform potentially hazardous activities such as driving a car and operating machinery. Advise patients not to drive or operate dangerous machinery until the effect of KORSUVA[®] on their ability to do so is known.

ADVERSE REACTIONS

The most common adverse reactions (incidence $\geq 2\%$ and $\geq 1\%$ higher than placebo) were diarrhea (9.0%), dizziness (6.8%), nausea (6.6%), gait disturbances, including falls (6.6%), hyperkalemia (4.7%), headache (4.5%), somnolence (4.2%), and mental status changes (3.3%).

FDA=U.S. Food and Drug Administration; NDC=National Drug Code.

Please see Important Safety Information on next page and in the accompanying full [Prescribing Information](#)

KORSUVA[®]
(difelikefalin) Injection
65 mcg/1.3 mL (50 mcg/mL)

How to order

KORSUVA® is available in US through the following specialty distributors:

ASD Healthcare

☎ 800 746-6273

Ordering: ✉ dialysis@asdhealthcare.com

Cardinal Health™ Metro Medical™ Distribution

☎ 800 768-2002

Account set up: ✉ customersvc@cardinalhealth.com

Ordering: 🌐 www.metromedicalorder.com

Cardinal Health™ Specialty Pharmaceutical Distribution

☎ 855 855-0708 (hospitals)

☎ 866 677-4844 (specialty & retail pharmacy)

Ordering: ✉ GMB-spd-csorderentry@cardinalhealth.com

🌐 www.cardinalhealth.com/en/solutions/specialty-distribution-services.html

IMPORTANT SAFETY INFORMATION (CONT'D)

USE IN SPECIFIC POPULATIONS

Severe Hepatic Impairment: The influence of severe hepatic impairment on the pharmacokinetics of KORSUVA® in subjects undergoing hemodialysis (HD) has not been evaluated; therefore, use of KORSUVA® in this population is not recommended.

Geriatric Use: The incidence of somnolence was higher in KORSUVA®-treated subjects aged 65 years and older (7.0%) than in KORSUVA®-treated subjects less than 65 years of age (2.8%). The incidence was comparable in both placebo age groups (3.0% and 2.1%, respectively) (see Warnings and Precautions).

Please see accompanying full [Prescribing Information](#)

Dosing & administration

- Recommended dosage is 0.5 mcg/kg based on patient dry body weight
- Administer KORSUVA® by intravenous bolus injection into the venous line of the dialysis circuit at the end of each hemodialysis session
- KORSUVA® may be given either during or after rinse back of the dialysis circuit
- KORSUVA® can be administered up to 4 hours after syringe preparation
- If a regularly scheduled hemodialysis treatment is missed, resume KORSUVA® at the end of the next treatment
- KORSUVA® is removed by the dialyzer membrane and must be administered after blood is no longer circulating through the dialyzer
- If the dose is given after rinse back, administer KORSUVA® into the venous line followed by at least 10 mL of normal saline flush

