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 60 minutes 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

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

INDICATION

KORSUVA is indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD).

Limitation of Use: KORSUVA has not been studied in patients on peritoneal dialysis and is not recommended for use in this population.

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.

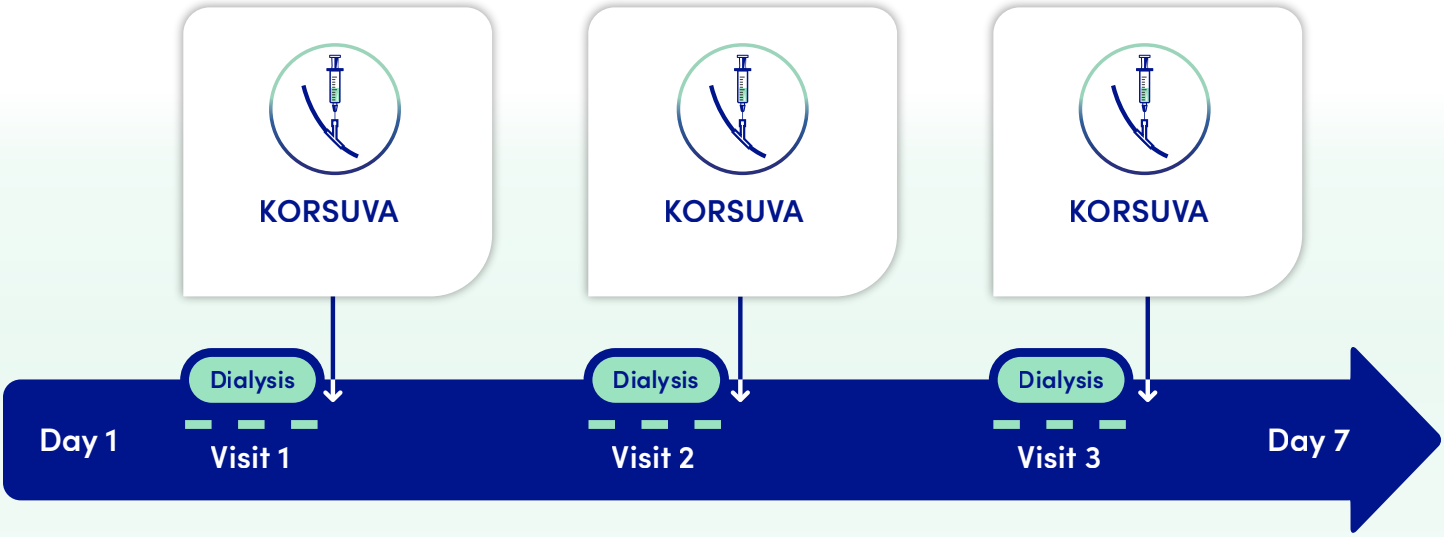
Risk of Driving and Operating Machinery: Dizziness, somnolence, and mental status changes have occurred in patients taking KORSUVA. KORSUVA may impair the mental or physical abilities needed to perform potentially hazardous activities such as driving a car and operating machinery. Advise patients not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

Please see additional Important Safety Information on reverse side and accompanying full Prescribing Information.

KORSUVA™
(difelikefalin) Injection
65 mcg/1.3 mL (50 mcg/mL)

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 60 minutes 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



IMPORTANT SAFETY INFORMATION (CONT'D)

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥2% and ≥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%).

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 additional Important Safety Information on reverse side and accompanying full Prescribing Information.

VIFOR PHARMA

KORSUVA™
(difelikefalin) Injection
65 mcg/1.3 mL (50 mcg/mL)