Difelikefalin

Also called: Korsuva; CR845

What it is

A selective kappa opioid receptor agonist with limited entry into the central nervous system, given intravenously after each hemodialysis session. Approved as Korsuva in 2021 for moderate-to-severe itch caused by chronic kidney disease.

Approval status

FDA Approved. Approved in the US as Korsuva (difelikefalin), NDA 214916, first approved August 23, 2021, for moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis (Drugs@FDA via openFDA and the Korsuva label, read October 2, 2026).

Dosing, as printed in the page's Recommended Dosing box

Manufacturer's recommended dosing (FDA label)

From the prescribing information. Other doses studied, if any, are in the full dosing data below.

Protocol and source	Dose	Frequency	Duration	Route
Label: haemodialysis itch **[Approved label]** Korsuva (difelikefalin) injection US prescribing information (DailyMed set 0c7b81f2-0fd3-47cb-8b0f-185e07f19c87, effective August 26, 2025)	0.5 µg/kg (target dry weight)	After each dialysis session (typically 3 times a week)	Ongoing	Intravenous (dialysis line)

Used in human trials

No manufacturer dose exists for this use: these are amounts given in published trials, not recommendations.

Protocol and source	Dose	Frequency	Duration	Route
Oral, notalgia paresthetica (2023) **[Human study]** PMID 36780675	2 mg	Twice daily	8 weeks	Oral

Educational information, not medical advice. Each dose above is tagged with its source: an approved label, a published human study, animal data, or amounts reported by users. None is a recommendation for you. An unapproved compound has no established safe or effective human dose, and products sold for "research use only" are not made or tested for people. Talk to a doctor before acting on anything on this site, including before you start, stop or change any medicine or dose.

Key human evidence

The first 3 of the 15 human studies carded on the page (19 study cards in all):

• **KALM-1: 378 patients on hemodialysis** (Human, 2020). Difelikefalin 0.5 µg/kg three times a week for 12 weeks gave a drop of at least 3 points in worst-itch score in 49.1% against 27.9% on placebo, and a 4-point drop in 37.1% against 17.9%; diarrhoea, dizziness and vomiting were more common. **PMID 31702883**

• **Japan: 178 patients** (Human, 2023). After 4 weeks, the itch score fell 2.06 points against 1.09 on placebo; treatment-related adverse events occurred in 15% against 3%, mostly gastrointestinal. **PMID 38320524**

• **Itch relief and quality of life, 914 patients** (Human, 2024). In pooled phase 3 data, quality-of-life scores improved more on difelikefalin than placebo, and most in those whose itch fell by at least 3 points. **PMID 39421431**

Interactions

A PubMed search for interaction studies of this compound with any drug (October 3, 2026, 1 record) found none in people. That is not evidence that it is safe to combine with anything.

Side effects and cautions

Reported side effects	Contraindications and cautions
• Diarrhoea, dizziness and vomiting (KALM-1) • Constipation and abdominal discomfort (Japan trial) • Headache and dizziness with the oral form • Falls and gait disturbance (6.6% against 5.4% in pooled data) • Mental status changes (3.3% against 1.4%), more likely with other sedating medicines (1 more on the page)	• Dizziness, sleepiness, mental status changes and unsteady walking • Caution with driving or operating machinery until the effect is known • Not studied in peritoneal dialysis • Tested athletes — see the Sport (WADA) row below

Five questions to ask

1. Is Difelikefalin right for me, and is the labelled dose on this sheet right for my weight, age, kidney and liver function?
2. Here are the medicines and supplements I take. Do any of them interact with Difelikefalin? This sheet records none published, which does not mean none exist.
3. Which side effects should make me stop and call you, for example diarrhoea?
4. Do any of the cautions on this sheet apply to me, such as: Dizziness, sleepiness, mental status changes and unsteady walking?
5. What should we check before I start and while I am on it (blood tests, blood pressure, weight), and how often?

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