KAPRUVIA®
(difelikefalin) Injection

Dosing and administration

Please refer to the full Summary of Product Characteristics before prescribing and administration

KAPRUVIA® is indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adult patients on haemodialysis. **KAPRUVIA® should be restricted for in-centre haemodialysis only.**

Each vial of 1 mL contains 50 micrograms difelikefalin. The recommended dose of KAPRUVIA® is **0.5 micrograms/kg dry body weight** (i.e., the target postdialysis weight). The total dose volume (mL) required from the vial should be calculated as follows: 0.01 × dry body weight (kg), rounded to the nearest tenth (0.1 mL).

KAPRUVIA® is administered **as an intravenous bolus injection** into the venous line of the dialysis circuit during rinse-back or after rinse-back:

- When **given after rinse-back**, at least 10 mL of sodium chloride 9 mg/mL (0.9%) solution for injection rinse-back volume should be administered after injection of KAPRUVIA®
- If the dose is **given during rinse-back**, no additional sodium chloride 9 mg/mL (0.9%) solution for injection is needed to flush the line

KAPRUVIA® is administered **3 times per week** at the end of haemodialysis treatment. Dosing is the same for elderly patients aged ≥65 years as adult patients. The safety and efficacy of KAPRUVIA® in children aged 0-17 years has not yet been established. No data are available. No dose adjustment is required for patients with mild or moderate hepatic impairment. KAPRUVIA® has not been studied in subjects with severe hepatic impairment and therefore not recommended for use in this patient population.

If a 4th haemodialysis dose is performed in a week, KAPRUVIA® should be administered at the end of haemodialysis per the recommended dose. **No more than 4 doses are recommended**, even if the number of dialysis treatments in a week is more than 4. Safety and efficacy of a 4th dose has not been fully established due to insufficient data.

If a regular haemodialysis treatment is missed, KAPRUVIA® should be administered at the next haemodialysis treatment. For haemodialysis treatments less than 1 hour, administration of KAPRUVIA® should be withheld until the next haemodialysis session.

TARGET DRY BODY WEIGHT RANGE (KG)	INJECTION VOLUME (ML)
40 – 44	0.4
45 – 54	0.5
55 – 64	0.6
65 – 74	0.7
75 – 84	0.8
85 – 94	0.9
95 – 104	1.0
105 – 114	1.1
115 – 124	1.2
125 – 134	1.3
135 – 144	1.4
145 – 154	1.5
155 – 164	1.6
165 – 174	1.7
175 – 184	1.8
185 – 194	1.9
≥ 195	2.0

PLEASE NOTE:

- **KAPRUVIA® should not be diluted or mixed** with other medicinal products
- Vials are for **single-use only**, discard any unused product
- KAPRUVIA® should be a clear, colourless solution, free from particles. Inspect for any particulate matter or discolouration before administration

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Adverse events should be reported. Reporting forms and information for United Kingdom can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Vifor Pharma Ltd. Tel: +44 1276 853633. E-mail: MedicalInfo_UK@viforpharma.com

Prescribing Information and Adverse Event Reporting
Scan the QR code or click here

VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA

Reference: KAPRUVIA® Summary of Product Characteristics.

CSL Vifor