Difelikefalin Intravenous injection for adults



Who can administer

May be administered by registered competent doctor or nurse/midwife

Important information

Unlicensed productÂ

- Supplied on compassionate use by renal specialists
- Patient must be informed of unlicensed status before it is administered to them

Available preparations

0.075mg per 1.5mL vial (0.05mg/ml)

A volume of 1.3mL is extractable from each vial

Methods of intravenous administration

Intravenous bolus injection

- Do not mix or dilute the injection solution prior to administration
- The drug is removed by the dialyser membrane and must be administered after blood is no longer circulating through the dialyser
- Administer by intravenous bolus injection into the venous line of the dialysis circuit at the end of each HD session
 - The dose may be given either during or after rinse back of the dialysis circuit.
 - If the dose is given after rinse back, administer it into the venous line followed by at least 10 mL of Sodium chloride 0.9% flush
 - If the dose is given during rinse back, no additional Sodium chloride 0.9% is needed to flush the line
 - The dose must be administered within 60 minutes of the completion of the syringe preparation.Â
 Discard any unused product

Dose in adults

Moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis

- The recommended dose is 0.5 mcg/kg at the end of each HD session (see next point re weight to use)
- The dose/kg is determined by patient's target dry body weight in kilograms See Table 1.Â
- If a regularly scheduled HD treatment is missed, resume administration of the drug at the end of the next HD treatment

| Table 1: Injection volume based on Target Dry Weight | |
|--|-----------------------|
| Target Dry Body Weight Range (kg) | Injection volume (mL) |
| 36-44 | 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 |
| 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 |
| 195-204 | 2 |
| * Total Injection Volume (ml) — Patient Target Dry | |

^{*} Total Injection Volume (mL) = Patient Target Dry Body Weight (kg) x 0.01, rounded to the nearest tenth (0.1 mL).

Use this formula for patient target dry body weight outside of the ranges in above table

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Further information

• Difelikefalin has not been studied in patients on peritoneal dialysis and is not recommended for use in this population

Storage

Store below 25°C

References

Korsuva SPC 08/2021

Therapeutic classification

Kappa opioid receptor agonist