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 drugÂ 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**Â target dry body weight in kilograms**Â 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 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^{0}C

References

Korsuva SPC 08/2021

Therapeutic classification

Kappa opioid receptor agonist