
Instructions for Use for Healthcare Professionals
Handling Kanuma

The following information is intended for healthcare professionals only:

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Each vial of KANUMA is intended for single use only. KANUMA has to be diluted with sodium chloride 9 mg/ml (0.9%) solution for infusion using aseptic technique.
The diluted solution should be administered to patients using a low-protein binding infusion set equipped with an in-line, low-protein binding 0.2 µm filter, with a surface area of greater than 4.5 cm^2 as available in order to avoid filter occlusion.

Preparation of the sebelipase alfa infusion

KANUMA should be prepared and used according to the following steps. Aseptic technique should be used.

a. The number of vials to be diluted for infusion should be determined based on the patient's weight and prescribed dose.
b. It is recommended to allow KANUMA vials to reach a temperature between 15 °C and 25 °C prior to dilution to minimise the potential for the formation of sebelipase alfa protein particles in solution. The vials should not be left outside the refrigerator longer than 24 hours prior to dilution for infusion. The vials should not be frozen, heated or microwaved and should be protected from light.
c. The vials should not be shaken. Prior to dilution, the concentrate in the vials should be inspected visually; the concentrate should be clear to slightly opalescent, colourless to slightly coloured (yellow). Due to the proteinaceous nature of the medicinal product, slight flocculation (e.g., thin translucent fibres) may be present in the vial concentrate and is acceptable for use.
d. Do not use if the concentrate is cloudy, or if foreign particulate matter is present.
e. Up to 10 ml of concentrate should be slowly withdrawn from each vial and diluted with sodium chloride 9 mg/ml (0.9%) solution for infusion. See Table 1 for recommended total infusion volumes by weight range. The solution should be mixed gently, and not be shaken.

Table 1: Recommended infusion volumes*

	1 mg/kg dose	**3 mg/kg dose**	**5 mg/kg dose****
Weight range (kg)	**Total infusion volume (ml)**	**Total Infusion Volume (mL)**	**Total Infusion Volume (mL)**
1-2.9	4	8	12
3-5.9	6	12	20
6-10.9	10	25	50
11-24.9	25	50	150
25-49.9	50	100	250
50-99.9	100	250	500
100-120.9	250	500	600

* The infusion volume should be based on the prescribed dose and should be prepared to a final sebelipase alfa concentration of 0.1-1.5 mg/ml.
** For patients with LAL Deficiency presenting within the first 6 months of life who do not achieve an optimal clinical response with a dose of 3 mg/kg.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.