

Initiation of therapy may be prompted by trough (pre-dialysis) plasma levocarnitine concentrations that are below normal (40 to 50 µmol/L). Dose adjustments should be guided by trough (pre-dialysis) levocarnitine concentrations, and downward dose adjustments (e.g. to 5 mg/kg after dialysis) may be made as early as the third or fourth week of therapy.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

COMPATIBILITY AND STABILITY

Levocarnitine Injection, USP is compatible and stable when mixed in parenteral solutions of Sodium Chloride 0.9% or Lactated Ringer's in concentrations ranging from 250 mg/500 mL (0.5 mg/mL) to 4200 mg/500 mL (8 mg/mL) and stored at room temperature (25°C) for up to 24 hours in PVC plastic bags.

HOW SUPPLIED: Levocarnitine Injection, USP is available in 5 mL and 20 mL single-dose vials. Each 5 mL vial contains 1 g/5 mL and each 20 mL vial contains 4 g/20 mL (200 mg/mL).

NDC 0517-1045-05	1 gram/5 mL (200 mg/mL) Single-Dose Vial	Packages of 5
NDC 0517-1075-01	4 grams/20 mL (200 mg/mL) Single-Dose Vial	Individually boxed

Store at or below 25°C (77°F) (See USP). Do not freeze. Store vials in carton until their use to protect from light. Discard unused portion of an opened vial, as the formulation does not contain a preservative.

REFERENCES

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