3. Give by IV injection over 2-3 minutes.

Intermittent intravenous infusion

Preparation and administration

1. Withdraw the required dose.
2. May be infused undiluted, or added to a suitable volume of compatible infusion fluid.
3. The solution should be clear and colourless to light straw coloured. Inspect visually for particulate matter or discoloration prior to administration and discard if present.
4. Give by IV infusion over 30 minutes (loading dose) or 10-30 minutes (subsequent doses).

ADMINISTRATION IN CHILDREN.

In the treatment of primary and secondary carnitine deficiency and organic acidaemias in children, levocarnitine is given in doses similar to those used in adults, see Uses and Administration, above. In the USA, an initial oral dose of 50 mg/kg daily is suggested for infants and children, increased gradually if necessary to a maximum of 3 g daily. The BNFC suggests that carnitine may also be given to neonates and children up to 18 years of age by intravenous infusion for primary deficiency and organic acidaemias, diluted in sodium chloride 0.9%, or glucose 5 or 10%; an initial dose of I OO mg/kg over 30 minutes is followed by a continuous infusion of 4 mg/kg per hour.

ADVERSE EFFECTS AND PRECAUTIONS: -

Gastrointestinal disturbances such as nausea, vomiting, diarrhoea, and abdominal cramps have been reported after the use of levocarnitine. Body odour has also been noticed in some patients, possibly due to the formation of the metabolite trimethylamine, Decreasing the dosage may reduce or eliminate these effects; oral levocarnitine should be consumed slowly to decrease gastrointestinal disturbances. Seizures have been reported. Patients with severe renal impairment should not be given high oral doses of levocarnitine for long periods, because of the accumulation of the metabolite's trimethylamine and trimethylamine-N-oxide. This is said not to occur to the same extent after intravenous dosage. Diabetic patients given carnitine while receiving insulin or hypoglycaemic drugs should be monitored for hypoglycaemia.

Pregnancy

Levocarnitine is classified as Category B, meaning animal studies have not shown fetal risk. Levocarnitine injection is generally considered safe for use during pregnancy when clearly needed and prescribed by a doctor, often used to treat primary deficiency. Animal studies indicate no evidence of fetal harm, but controlled human data is limited.

Nursing Mothers

Levocarnitine Injection in nursing mothers has not been specifically studied. Studies in dairy cows indicate that the concentration of levocarnitine in milk is increased following exogenous administration of levocarnitine. In nursing mothers receiving levocarnitine, any risks to the child of excess carnitine intake need to be weighed against the benefits of levocarnitine supplementation to the mother. Consideration may be given to discontinuation of levocarnitine treatment or of nursing.

Overdose

There have been no reports of levocarnitine overdosage. If necessary, stop administration and give supportive therapy as appropriate.

Storage: - Store below 25°C. Protect from light, do not freeze.

Improper Storage may deteriorate the product

Keep the medicine out of reach of children.

Presentation: - Each pack contain 5 ml ampoule of Levocarnitine Injection USP (1 g/ 5 ml)

is pack in I tray & 10 Inner carton pack in a outer pack along with pack Insert.

Manufactured by:

AMERICAN REMEDIES
Care & Cure with Research

American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)
ICO: American Remedies LLC, DE, USA

Gala No. 105 to 111, 1st Flr., Bldg. No. E-15/A,
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Scan for Batch Certificate

For the use of a Registered Medical Practitioner or a Hospital or Laboratory only.

Rx Levocarnitine Injection USP

AMERICAN
CARNIVITE
Injection

1 g / 5 ml

INFUSION CONCENTRATE
FOR I.V. SLOW DRIP INFUSION

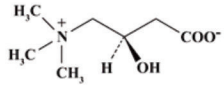
Composition:-

Each 5 ml Contains: -

Levocarnitine	USP	1.0 g.
Water for Injection	IP	q.s.

Description:-

Levocarnitine Injection USP is a carrier molecule in the transport of long-chain fatty acids across the inner mitochondrial membrane. The chemical name of levocarnitine is 3-carboxy-2(R)-hydroxy-N,N,N-trimethyl-1- propanaminium, inner salt. Levocarnitine is a white crystalline, hygroscopic powder. It is readily soluble in water, Its chemical Formula is $C_7H_{15}NO_3$. And the Structural formula is.:



Levocarnitine

PHARMACOLOGY

Pharmacokinetics

Oral doses of levocarnitine are absorbed slowly and incompletely from the small intestine. Bioavailability has been reported to be only about 10 to 15 %, with peak plasma concentrations occurring about 3 to 4 hours after an oral dose. Plasma concentrations after oral doses represent the sum of endogenous and exogenous material. Levocarnitine does not appear to bind to plasma proteins. It is mainly eliminated by the kidneys, undergoing extensive tubular reabsorption. After intravenous doses, levocarnitine appears to undergo minimal metabolism. Levocarnitine given orally may undergo degradation in the gastrointestinal tract, leading to the formation of metabolites such as trimethylamine-N-oxide and y-butyrobetaine, recovered in the urine and faeces, respectively.

Elimination half-life is 17.4 hours.

USES AND ADMINISTRATION

Carnitine is an amino acid derivative that is an essential cofactor of fatty acid metabolism. Carnitine is used in the treatment of primary carnitine deficiency and in carnitine deficiency secondary to a variety of defects of intermediary metabolism or other conditions such as haemodialysis. Both the 1- and the DL-isomers have been used, but it is believed that only levocarnitine is effective and in addition, that DL-carnitine supplementation can lead to carnitine deficiency.

In the UK, depending on the condition, up to 200 mg/kg daily of levocarnitine is given orally, in 2 to 4 divided doses.

Rarely, higher doses of up to 400 mg/kg daily may be needed. In the USA, lower doses up to about 3 g daily are recommended. When given intravenously, up to 100 mg/kg daily is given in 3 to 4 divided doses by slow intravenous injection over 2 to 3 minutes. Higher intravenous doses have been given, but are associated with an increased incidence of adverse effects.

Similar doses are used in children, although initial dose recommendations may vary in different countries,

INTRAVENOUS INJECTION

Preparation and administration

1. Withdraw the required dose.
2. The solution should be clear and colourless to light straw coloured. Inspect visually for particulate matter or discoloration prior to administration and discard if present.