

# L-carnit

( Levocarnitine 1g )

1g / 5ml

ایل-کارنٹ

( لیووکارنٹین ۱گرام )

دریدی انجکشن

## PATIENT INFORMATION LEAFLET

L-CARNIT 1g/5ml Solution For I.V. Injection

Sterile, Apyrogen

Administered IV use.

**Active Substance:** Each 5 MI Ampoule Contains 1g Levocarnitine.

**Excipients :** Hydrochloric Acid, Water For Injection

**Read all of this LEAFLET carefully before you start using this medicine**

**because it includes special information for you.**

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others.
- If you go to doctor or hospital at the time of using this medicine, please tell your doctor.
- Please follow the instructions exactly. Do not use another **high or low doses** out of recommended.

### In This Leaflet

1. **What L-CARNIT Is And What It Is Used For?**
2. **Before You Use L-CARNIT**
3. **How To Use L-CARNIT?**
4. **Possible Side Effects**
5. **How To Store L-CARNIT?**

#### 1. What L-CARNIT Is And What It Is Used For?

L-CARNIT Is A Drug Containing The Active Substance Called Levocarnitine. Levocarnitine Is A Compulsory, Natural Substance Required For Mammalian Energy Metabolism. It Makes The Entrance Of Fatty Acids Into Mitochondria (An Intracellular Organelle) Easy To Provide Energy Production Required Especially For Tissues Such As Cardiac Muscle And Skeletal Muscles.

L-CARNIT Is Presented In 5 MI Amber Coloured Ampoule. It Has A Clear, Colourless Solution, Practically Free From Particles Appearance. L-CARNIT Is Used In The Treatment Of Following Conditions:

- Primary Carnitine Deficiency
- Carnitine Deficiency In Haemodialysis Patients.

#### 2. Before You Use L-CARNIT

##### Do Not Use L-CARNIT:

- If You Are Hypersensitive To Any Of The Components Of L-CARNIT

##### TAKE SPECIAL CARE With L-CARNIT :

- Levocarnitine Administration May Result In Hypoglycaemia (Low Blood Sugar) In Diabetic Patients Receiving Either Insulin Or Hypoglycaemic Oral Treatment (An Oral Treatment To Lower Blood Sugar). In These Patients, Blood Sugar Levels Should Be Monitored Regularly.
- Intravenous L-CARNIT Treatment Is Administered If You Have An Acute Insufficiency And/Or Are Unable To Take

Drug Orally. When You In A Convenient Position, Oral Treatment Should Be Started.

- During The Treatment With L-CARNIT, Your Doctor May Control Your Clinical Response To The Drug, Vital Signs, Blood Chemistry, Blood And Urine Periodically And May Adjust Dosage, If Necessary.
- If You Are A Dialysis Patient And Have Severe Renal Failure, Since L-CARNIT Elimination Does Not Occur By Kidneys, You Should Not Use Oral Formulations At Higher Doses For A Long Time Due To The Accumulation Of Main Metabolites Of The Durg (Trimethylamine (TMA) And Trimethylamine-N-Oxide (TMAO)) In Blood. Such This Accumulation Leads To Trimethylamine, Which Causes A Strong "Fishy Odor" In Urine, Breath And Sweat. This Phenomena Does Not Occur Intravenous Administration
- An Increase In Your INR (Blood Clotting Values) Values May Be Seen If You Are Using Drugs (Coumarinic Drugs, I.E. Warfarin) That Prevent Blood Clotting With L-CARNIT. Therefore, Your Blood Tests (Clotting Tests And Other Tests) Should Be Controlled Weekly At The Beginning And Monthly At Later Periods Until Your Values Become Normal.

If Any Of These Warnings Applies To You Or Even If Any Time In The Past, Please Consult Your Doctor.

#### TAKING L-CARNIT With Food And Drink

No Data Is Available.

#### Pregnancy

*Consult Your Doctor Or Pharmacist Before Using The Medicine.*

An Appropriate Birth Control Administrations Should Be Recommended To Women Having Childbearing Potential.

Levocarnitine Should Be Used In Pregnant Women Only If The Benefit Is Superior To The Potential Risks That May Occur In Baby To Be Born. L-CARNIT Should Not Be Used In Pregnancy Period Until It Is Necessary.

*If You Notice That You Are Pregnant During Treatment, Consult Your Doctor Or Pharmacist Immediately.*

#### Breast-Feeding

*Consult Your Doctor Or Pharmacist Before Using The Medicine.*

Levocarnitine Should Be Used In Breast-Feeding Women Only If The Benefit For Mother Is Superior Than The Risks That May Occur In Infant.

#### Driving And Using Machines

L-CARNIT Does Not Affect Your Ability To Drive Or Use Machines Negatively.

#### Important Information About Some Of The Ingredients Of L-CARNIT

If You Do Not Have Hypersensitivity To The Ingredients In L-CARNIT Content, No Negative Effect Depending On These Ingredients Is Expected.

#### Using With Other Medicines

L-CARNIT Administration May Result In Hypoglycaemia (Low Blood Sugar) In Diabetic Patients Receiving Either Insulin Or Hypoglycaemic Oral Treatment (An Oral Treatment To Lower Blood Sugar). Therefore, If You Are A Diabetic Patients, Consult Your Doctor.

An Increase In Your INR (Blood Clotting Values) Values May Be Seen If You Are Using Drugs (Coumarinic Drugs, I.E. Warfarin) That Prevent Blood Clotting With L-CARNIT. Therefore, Your Blood Tests (Clotting Tests And Other Tests) Should Be Controlled Weekly At The Beginning

And Monthly At Later Periods Until Your Values Become Normal. *Please Inform Your Doctor Or Pharmacist If You Are Taking At Present Or Have Recently Taken Any Other Medicines Including Medicines Without A Prescription.*

### 3. How To Use L-CARNIT?

#### Instructions For Proper Using And Dose/Administration Frequency:

Intravenous L-CARNIT Treatment Is Administered If You Have An Acute Insufficiency And/Or Are Unable To Take Drug Orally. When You In A Convenient Position, Oral Treatment Should Be Started.

Your Doctor Will Carefully Calculate The Injection Amount Of L-CARNIT That You Should Be Given And This Dose May Vary Depending On Your Response To The Treatment. The Doctor May Take Blood And Urine Samples To Check The Amount Of The Drug In Your Body.

Your Doctor Will Administer L-CARNIT Slowly Into Your Vein Over A Period Of 2-3 Minutes.

#### If You Use More L-CARNIT Then You Should

An Exposure With L-CARNIT Depending On Overdose Has Not Been Reported. An Overdose May Cause Diarrhea. In This Case, The Dose Should Be Decreased And Supplemental Treatment Should Be Administered.

*If You Use More L-CARNIT Than You Should, Talk To Your Doctor Or Pharmacist.*

#### If You Forget To Use L-CARNIT

*Do Not Take A Double Dose To Make Up For A Forgotten Dose.*

#### Effects That May Occur When Treatment With L-CARNIT Is Terminated

Levocarnitine Is A Physiological Product And Therefore, It Does Not Show A Habit Or Addiction Risk.

#### 4. Possible Side Effects

Like All Medicines, Side Effects May Occur In The Ones Who Are Sensitive To The Ingredients In L-CARNIT Content.

#### If You Notice Any Of The Following, Inform Your Doctor IMMEDIATELY Or Contact The Emergency Department Of Your Nearest Hospital:

Seizure (Loss Of Consciousness, Spasms Over Body, Difficulty In Breathing)

These Are All Very Serious Side Effects. You May Need Urgent Medical Attention.

Side Effects Are Shown As Listed In The Categories Below:

Very Common : It May Be Seen At Least 1 In 10 Patients.

Common : It May Be Seen Less Than 1 In 10 Patients, But More Than 1 In 100 Patients.

Uncommon: It May Be Seen Less Than 1 In 100 Patients, But More Than 1 In 1000 Patients.

Rare : It May Be Seen Less Than 1 In 1000 Patients, But More Than 1 In 10000 Patients.

Very Rare : It May Be Seen Less Than 1 In 10000 Patients.

Not Known : It Could Not Be Predicted With The Available Data.

#### Rare:

- Nausea,
- Vomiting,
- Diarrhea,
- Stomach Cramps
- A Body Smell Like A Fishy Odour (It May Be Lessened By Decreasing The Dose Or May Disappear.)

#### Not Known:

- Mild Muscle Weakness Symptoms (In Patients Whose Urea Ratio Of Blood Is Above Normal)

*Please Inform Your Doctor Or Pharmacist If You Experience Any Side Effect That Is Not Included In This Patient Information Leaflet.*

#### 5. How To Store L-CARNIT

*Keep L-CARNIT Out Of The Reach And Sight Of Children And In Its Package. Store Below 25°C At Room Temperature.*

#### Use In Accordance With The Expiry Date.

*Do Not Use L-CARNIT After The Expiry Date On The Package.*

#### FOLLOWING DATA IS FOR HEALTH PERSONNEL WHO WILL ADMINISTER THIS DRUG:

##### Primary Carnitine Deficiency

The Recommended Daily Dose Is Generally 100 Mg Per Kg Of Body Weight. Daily Dose Will Be Given To You In 3-4 Divided Doses.

##### Secondary Carnitine Deficiency In Patients On Hemodialysis (Blood Dialysis):

A Dose Of 20 mg Per Kg Of Body Weight Should Be Administered As Indicated Above After Each Dialysis Session (Assuming Three Sessions Per Week). The Treatment Should Be At Least Three Months. This Is The Time Required For Free Carnitine To Reach Normal Muscle Levels Again. If Significant Clinical Benefit Has Been Gained By The First Course Of Intravenous L-CARNIT, Then Daily 1 G L-CARNIT Oral Solution Can Be Used As A Maintenance Therapy.

##### Administration Route And Method:

L-CARNIT Is Administered Into Vein And Muscle.

L-CARNIT Is Administered Into Vein Slowly Over 2-3 Minutes Or Drop By Drop. The Drug Should Be Administered All Day Long In 3-4 Hours Intervals.

##### Various Age Groups:

**Use In Children:** In Children And Infants, Daily Dose Is 50-100 Mg Levocarnitine Per Kg. The Dose Is Up To 3 G Daily.

##### Geriatric Population:

No Special Case For Use In Geriatric Population Is Available.

##### Special Use Cases:

**Renal Failure:** 1 Ampoule (1 G Levocarnitine) L-CARNIT (Three Times A Week) Into Vein For Patients On Hemodialysis After Each Dialysis Session Is Sufficient.

**Hepatic Failure:** No Special Case For Use In Patients With Hepatic Failure Is Available.

*Please Tell Your Doctor Or Pharmacist If You Have An Impression That The Effect Of L-CARNIT Is Too Strong Or Weak.*

خوراک :- ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات :- روشنی، گرمی اور نمی سے محفوظ رکھیں۔ تمام ادویات بیٹوں کی پہنچ سے دور رکھیں۔ ۲۵ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

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