

PROFESSIONAL INFORMATION
D 34.1 Amino acids. Complementary Medicine: Health Supplement.

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE
BIOGEN ACETYL-L CARNITINE
2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains	
N-acetyl-L-carnitine	500,00 mg

Sugar Free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Bovine Gelatine Capsule

4. CLINICAL PARTICULARS
4.1 Therapeutic indications

BIOGEN ACETYL-L CARNITINE helps to support and maintain healthy brain function.

4.2 Posology and method of administration

Adults: Take one (1) to 2 (two) capsules three time per day, or as recommended by your healthcare provider.

Elderly: No specific studies have been performed in older patients, but according to clinical experience dosage adjustment is not required when treating otherwise healthy, older patients.

Children and adolescents: Acetyl-L-carnitine has been safely used orally in children for up to 6 weeks (see section 4.4).

4.3 Contraindications

- If you have a hypersensitivity to the ingredients or any of the excipients listed in 6.1.
- Acetyl-L-carnitine might interfere with the activity of thyroid hormone in the body, avoid use in patients with hypothyroidism.

4.4 Special warnings and precautions for use

Orally, Acetyl-L-carnitine is generally well tolerated. If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

4.5 Interaction with other medicines and other forms of interaction

No specific drug interaction studies have been performed on **BIOGEN ACETYL-L CARNITINE** however, the pharmacokinetic properties of Acetyl-L-carnitine has been summarized.

Interactions with Medicines

- Acetyl-L-carnitine might increase the anticoagulant effects of acenocumarol.
- Acetyl-L-carnitine might increase the risk of serotonergic side effects, including serotonin syndrome and cerebral vasoconstrictive disorders, when taken with serotonergic drugs.
- Acetyl-L-carnitine might decrease the effectiveness of thyroid hormone replacement.
- Acetyl-L-carnitine might increase the anticoagulant effects of warfarin.
- Carnitine may interact with pivalate-conjugated antibiotics such as pivampicillin that are used in the long-term prevention of urinary-tract infections.
- Concomitant administration with carnitine and anticonvulsants valproic acid, phenobarbital, phenytoin, or carbamazepine has been shown to significantly reduce blood levels of carnitine may cause hepatotoxicity and increase plasma ammonia concentrations, leading to encephalopathy.

Interactions with Diseases / Impairments

- Acetyl-L-carnitine might increase the risk of mania in patients with bipolar disorder; use with caution in patients with bipolar disorder.
- Acetyl-L-carnitine in patients undergoing taxane-based chemotherapy may increase symptoms of neuropathy; avoid use for the prevention of chemotherapy-induced peripheral neuropathy.
- Acetyl-L-carnitine might interfere with the activity of thyroid hormone in the body, avoid use in patients with hypothyroidism.
- Acetyl-L-carnitine might increase the risk for seizures in patients with seizure disorders, avoid use in patients with a history of seizures.

Interactions with Foods

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting **BIOGEN ACETYL-L CARNITINE**.

4.6 Fertility, pregnancy and lactation

The safety and efficacy of **BIOGEN ACETYL-L CARNITINE** in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

Patients should exercise caution before driving or operating machinery until they are reasonably certain that **BIOGEN ACETYL-L CARNITINE** does not affect their performance.

4.8 Undesirable effects

Orally, Acetyl-L-carnitine is generally well-tolerated.

Summary of most common adverse reactions

Cardiovascular:

Less Frequent: increased blood pressure.

Dermatologic:

Less Frequent: The combined use of acetyl-L-carnitine and alpha-lipoic acid may cause rash.

Gastrointestinal disorders:

Less Frequent: Acetyl-L-carnitine may cause nausea, vomiting, hiccups, abdominal distension and gastrointestinal upset or pain. Acetyl-L-carnitine may also cause dry mouth and anorexia. The combined use of acetyl-L-carnitine and alpha-lipoic acid may cause diarrhea, constipation, and dyspepsia.

Neurologic / Central nervous system:

Less Frequent: Acetyl-L-carnitine may cause headache and insomnia.

Psychiatric:

Less Frequent: Acetyl-L-carnitine may cause agitation (restlessness and motor over activity).

Other:

One of the metabolites of acetyl-L-carnitine can cause the urine, breath, and sweat to have a fishy odour. Also, foul smelling urine has been reported following oral use of a combination of acetyl-L-carnitine and alpha-lipoic acid.

Description of selected adverse reactions

BIOGEN ACETYL-L CARNITINE may cause several adverse reactions, such as gastrointestinal disturbances, such as, digestive disorders, and constipation.

At doses of approximately 3 g / day, carnitine supplements can cause nausea, vomiting, abdominal cramps, diarrhea, and a "fishy" body odour. Rarer side effects include muscle weakness in uremic patients and seizures in those with seizure disorders.

Paediatric Population

Acetyl-L-carnitine has been safely used orally in children for up to 6 weeks.

Other special populations

No clinical data are available on the effects of **BIOGEN ACETYL-L CARNITINE** on other special populations.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit / risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

There is insufficient reliable information available about the presentation or treatment of overdose with acetyl-L-carnitine.

5. PHARMACOLOGICAL PROPERTIES

BIOGEN ACETYL-L CARNITINE helps to support and maintain healthy brain function.

Pharmacodynamic effects

Mechanism of action:

Acetyl-L-carnitine occurs naturally in the body. The body obtains some carnitine from the diet, primarily from red meats and dairy products. The body can also synthesize carnitines from the amino acids, lysine and methionine. The kidney aids in keeping carnitine levels stable. Carnitines play an important role in lipid metabolism and energy production. They are essential for normal mitochondrial function, acting as a transporter of long-chain fatty acids and acetyl CoA into the mitochondria for beta-oxidation and energy production. Acetyl-L-carnitine also binds organic acids and fragmented free fatty acids and removes them from cells, preventing cell damage.

Acetyl-L-carnitine stimulates membrane phospholipids synthesis, which leads to stabilization of cell membranes. This in turn suggests it may act as a neuromodulatory agent. It is also involved in numerous other functions such as protein and gene expression. It also plays a role in the production of nerve growth factor. It also has an effect on the N-methyl-D-aspartate (NMDA) glutamate receptors. This may be a direct effect or via activation of cholinergic receptors.

Pharmacodynamic effects:

The complete physiological effects of Acetyl-L-carnitine are still being studied. What has been discovered so far is that Acetyl-L-carnitine has positive effects on mental fatigue, neurodegenerative disorders, cognitive functions, peripheral neuropathy, and sperm motility. Specifically, in one study involving patients with HIV, patients on Acetyl-L-carnitine supplementation had increased CD4 cells, decreased lymphocyte apoptosis, improved polyneuropathy and cardiovascular damage, and decreased triglyceride and TNF alpha levels in the blood. Another study showed that Acetyl-L-carnitine increased glucose disposal in type 2 diabetic patients through possibly increasing the activity of glycogen synthase.

Pharmacokinetic properties

Absorption: Taking acetyl-L-carnitine increases plasma levels of L-carnitine and acylcarnitines.

Distribution: Circulating L-carnitine is distributed to two kinetically defined compartments: one large and slow-turnover (presumably muscle), and another relatively small and rapid-turnover (presumably liver, kidney, and other tissues). At normal dietary L-carnitine intake, whole-body turnover time in humans is 38-119 h. In vitro experiments suggest that acetyl-L-carnitine is partially hydrolyzed in enterocytes during absorption.

Metabolism: L-carnitine participates in a reversible transesterification reaction, in which an acyl group is transferred from coenzyme A to the hydroxyl group of L-carnitine. Acetyl-L-carnitine is biosynthesized in this manner.

Excretion: The kidney aids in keeping carnitine levels stable. Normally, greater than 90% of filtered carnitine is reabsorbed. If dietary intake of carnitines decreases, carnitine reabsorption becomes even more efficient.

Preclinical safety data

When used orally and appropriately, Acetyl is recognized as possibly safe.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients

Microcrystalline cellulose, Magnesium stearate and Silicon dioxide.

6.2 Shelf Life

24 Months.

6.3 Special precautions for storage

Store in a cool, dry place at or below 25 °C. Do not use after expiry date.

Keep the container tightly closed.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

6.4 Nature and contents of container

30 capsules

The container is a 175 mL PET container. The cap is a white plastic cap with a tamper evident seal.

6.5 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen
 23 Stag Road, Glen Austin, South Africa
 info@biogen.co.za
 www.biogen.co.za
 Tel: 0860 347243

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

April 2022.

JOB: BPS_AcetylL.Carnitine_30s		SIZE: 210mm x 375mm	
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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S0**

PRODUCT NAME
BIOGEN ACETYL-L CARNITINE

Each capsule contains:
N-acetyl-L-carnitine (500,00 mg)

Sugar Free.

D 34.1 Amino acids. Complementary Medicine: Health Supplement
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

Read all of this leaflet carefully because it contains important information for you.
BIOGEN ACETYL-L CARNITINE is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take **BIOGEN ACETYL-L CARNITINE** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **BIOGEN ACETYL-L CARNITINE** with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What **BIOGEN ACETYL-L CARNITINE** is and what it is used for.
2. What you need to know before you use **BIOGEN ACETYL-L CARNITINE**.
3. How to use **BIOGEN ACETYL-L CARNITINE**.
4. Possible side effects.
5. How to store **BIOGEN ACETYL-L CARNITINE**.
6. Contents of the pack and other information.

1. WHAT BIOGEN ACETYL-L CARNITINE IS AND WHAT IT IS USED FOR
BIOGEN ACETYL-L CARNITINE helps to support and maintain healthy brain function.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE BIOGEN ACETYL-L CARNITINE
Do not use BIOGEN ACETYL-L CARNITINE:

- If you have a hypersensitivity to the ingredients or any of the excipients listed in **6.1**.
- Acetyl-L-carnitine might interfere with the activity of thyroid hormone in the body, avoid use in patients with hypothyroidism.

Warnings and precautions

Special care should be taken with **BIOGEN ACETYL-L CARNITINE**. If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine.
Do not exceed the recommended dose without consulting a healthcare provider.

Children and adolescents

Acetyl-L-carnitine has been safely used orally in children for up to 6 weeks.

Other medicines and BIOGEN ACETYL-L CARNITINE

Always tell your healthcare provider if you are taking any other medicine, including complementary or traditional medicine.

It is advised to consult your doctor if you want to take **BIOGEN ACETYL-L CARNITINE** combined with other medicines or treatments such as:

- Acetyl-L-carnitine might increase the anticoagulant effects of acenocoumarol.
- Acetyl-L-carnitine might increase the risk of serotonergic side effects, including serotonin syndrome and cerebral vasoconstrictive disorders, when taken with serotonergic drugs.
- Acetyl-L-carnitine might decrease the effectiveness of thyroid hormone replacement.
- Acetyl-L-carnitine might increase the anticoagulant effects of warfarin.
- Carnitine may interact with pivalate-conjugated antibiotics such as pivampicillin that are used in the long-term prevention of urinary-tract infections.
- Concomitant administration with carnitine and anticonvulsants valproic acid, phenobarbital, phenytoin, or carbamazepine has been shown to significantly reduce blood levels of carnitine may cause hepatotoxicity and increase plasma ammonia concentrations, leading to encephalopathy.

Interactions with Diseases / Impairments

- Acetyl-L-carnitine might increase the risk of mania in patients with bipolar disorder; use with caution in patients with bipolar disorder.
- Acetyl-L-carnitine in patients undergoing taxane-based chemotherapy may increase symptoms of neuropathy; avoid use for the prevention of chemotherapy-induced peripheral neuropathy.
- Acetyl-L-carnitine might interfere with the activity of thyroid hormone in the body, avoid use in patients with hypothyroidism.
- Acetyl-L-carnitine might increase the risk for seizures in patients with seizure disorders, avoid use in patients with a history of seizures.

Interactions with Foods

Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting **BIOGEN ACETYL-L CARNITINE**.

Pregnancy, breastfeeding and fertility

The safety and efficacy of **BIOGEN ACETYL-L CARNITINE** in pregnancy and lactation has not been established.

Driving and using machinery

Patients should exercise caution before driving or operating machinery until they are reasonably certain that **BIOGEN ACETYL-L CARNITINE** does not affect their performance.

3. HOW TO USE BIOGEN ACETYL-L CARNITINE

Do not share your medicines with any other person.

Always take **BIOGEN ACETYL-L CARNITINE** exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults: Take one (1) to 2 (two) capsules three times per day, or as recommended by your healthcare provider.

Elderly: No specific studies have been performed in older patients, but according to clinical experience dosage adjustment is not required when treating otherwise healthy, older patients.

Children and adolescents: Acetyl-L-carnitine has been safely used orally in children for up to 6 weeks.

If you take more BIOGEN ACETYL-L CARNITINE than you should

No known information. In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and the rest of the **BIOGEN ACETYL-L CARNITINE** with you so the doctor will know what you have taken.

If you forget to take BIOGEN ACETYL-L CARNITINE

Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

Orally, Acetyl-L-carnitine is generally well-tolerated.

Not all side effects reported for **BIOGEN ACETYL-L CARNITINE** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **BIOGEN ACETYL-L CARNITINE**, please consult your healthcare provider for advice.

Summary of most common adverse reactions

Cardiovascular:
Less Frequent: increased blood pressure.

Dermatologic:
Less Frequent: The combined use of acetyl-L-carnitine and alpha-lipoic acid may cause rash.

Gastrointestinal disorders:
Less Frequent: Acetyl-L-carnitine may cause nausea, vomiting, hiccups, abdominal distension and gastrointestinal upset or pain. Acetyl-L-carnitine may also cause dry mouth and anorexia. The combined use of acetyl-L-carnitine and alpha-lipoic acid may cause diarrhea, constipation, and dyspepsia.

Neurologic / Central nervous system:
Less Frequent: Acetyl-L-carnitine may cause headache and insomnia.

Psychiatric:
Less Frequent: Acetyl-L-carnitine may cause agitation (restlessness and motor over activity).

Other:
One of the metabolites of acetyl-L-carnitine can cause the urine, breath, and sweat to have a fishy odour. Also, foul smelling urine has been reported following oral use of a combination of acetyl-L-carnitine and alpha-lipoic acid.

Should your general health worsen or if you experience any untoward effects while **BIOGEN ACETYL-L CARNITINE**, please consult your doctor, pharmacist or other healthcare practitioner for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Adverse Drug Reactions Reporting Form, found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **BIOGEN ACETYL-L CARNITINE**.

5. HOW TO STORE BIOGEN ACETYL-L CARNITINE

- Store at or below 25 °C.
- Protect from light and moisture.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What BIOGEN ACETYL-L CARNITINE contains
Active ingredients per capsule, Acetyl-L-carnitine.

Sugar Free.

The other ingredients are Magnesium stearate.

What BIOGEN ACETYL-L CARNITINE looks like and contents of the pack

30 capsules
The container is a 175 mL PET container. The cap is a white plastic cap with a tamper evident seal.

NAME AND ADDRESS OF REGISTRATION HOLDER:

Biogen
23 Stag Road, Glen Austin, South Africa
info@biogen.co.za
www.biogen.co.za
Tel: 0860 347243

REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

PRODUKNAAM
BIOGEN ACETYL-L CARNITINE

Elke kapsule bevat:
N-asetiel-l-karnitien (500,00 mg)

Suikervry.

D 34.1 Aminosure. Komplementêre Medisyne. Gesondheidsaanvulling.
Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir gehalte, veiligheid of beoogde gebruik nie.

Lees hierdie inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir u.
BIOGEN ACETYL-L CARNITINE is beskikbaar sonder 'n dokter se voorskrif, sodat u u gesondheid kan onderhou. U moet **BIOGEN ACETYL-L CARNITINE** nietermin steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat u dit weer lees.
- Moenie **BIOGEN ACETYL-L CARNITINE** met enige ander persoon deel nie.
- Vra u gesondheidsorgpraktisyn of apteker indien u verdere inligting of advies nodig het.

Wat is in hierdie pamflet

1. Wat is **BIOGEN ACETYL-L CARNITINE** en waarvoor dit gebruik word.
2. Wat u moet weet voordat u **BIOGEN ACETYL-L CARNITINE** gebruik.
3. Hoe om **BIOGEN ACETYL-L CARNITINE** te gebruik.
4. Moontlike nuwe-effekte.
5. Berging van **BIOGEN ACETYL-L CARNITINE**.
6. Inhoud van die verpakking en ander inligting.

1. WAT IS BIOGEN ACETYL-L CARNITINE IS EN WAARVOOR DIT GEBRUIK WORD
BIOGEN ACETYL-L CARNITINE help om gesonde breinfunksie te ondersteun en in stand te hou.

2. WAT U MOET WEET VOORDAT U BIOGEN ACETYL-L CARNITINE GEBRUIK
Moenie BIOGEN ACETYL-L CARNITINE neem:

- Indien u hipersensitief (allergies) is vir enige van die ander bestanddele gelys (sien afdeling 6).
- Asetiel-L-karnitien kan inmeng met die aktiwiteit van tiroïedhormoon in die liggaam, vermy gebruik by pasiënte met hipotiëose.

Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet toegepas word met die gebruik van **BIOGEN ACETYL-L CARNITINE**. Raadpleeg u gesondheidspraktisyn voordat u hierdie medisyne neem as u voorgeskrewe medisyne gebruik. Moet nie die aanbevole dosis oorskry sonder om 'n gesondheidsorgverskaffer te raadpleeg nie.

Kinders en adolessente

Asetiel-L-karnitien word vir tot 6 weke veilig mondelings by kinders gebruik.

Die neem van ander medisyne saam met BIOGEN ACETYL-L CARNITINE

Lig altyd u gesondheidspraktisyn in wanner u medisyne op 'n gereelde basis neem, insluitend komplementêre of tradisionele medisyne.

Dit word aanbeveel om u dokter te raadpleeg as u **BIOGEN ACETYL-L CARNITINE** wil kombineer saam met ander medisyne of behandeling soos:

- Asetiel-L-karnitien kan die antikoagulate effekte van acenocoumarol verhoog.
- Asetiel-L-karnitien kan die risiko van serotonergiese nuwe-effekte, insluitend serotoniensindroom en serebrale vasokonstriktiewe verstuurings, verhoog wanneer dit saam met serotonergiese middels geneem word.
- Asetiel-L-karnitien kan die doeltreffendheid van tiroïedhormoonvervangings vermind.
- Asetiel-L-karnitien kan die antikoagulate effekte van warfarin verhoog.
- Karnitien kan interaksie hê met pivalaat-gekonjugeerde antibiotika soos pivampisillien wat gebruik word in die langtermyn voorkoming van urineweginfeksies.
- Gelyktydige toediening met karnitien en antikonvulsante valproïensuur, fenobarbital, fenitoien of karbamasepin het getoon dat dit bloedvlakke van karnitien aansienlik verlaag, kan hepatotoksiteit veroorsaak en plasmaammoniakonsentrasies verhoog, wat tot enkefalopatie lei.

Interaksies met siektes / gestremdhede

- Asetiel-L-karnitien kan die risiko van manie verhoog by pasiënte met bipolêre versturing; gebruik met omsigtigheid by pasiënte met bipolêre versturing.
- Asetiel-L-karnitien by pasiënte wat taksaan-gebaseerde chemoterapie ondergaan, kan simptome van neuropatie verhoog; vermy gebruik vir die voorkoming van chemoterapie-geïnduseerde perifere neuropatie.
- Asetiel-L-karnitien kan inmeng met die aktiwiteit van tiroïedhormoon in die liggaam, vermy gebruik by pasiënte met hipotiëose.
- Asetiel-L-karnitien kan die risiko vir aanvalle verhoog by pasiënte met aanvalle versterings, vermy gebruik by pasiënte met 'n geskiedenis van aanvalle.

Interaksies met voedsel

Vitamiene, minerale en voedingstowwe wat van ander bronne verkry word, moet in ag geneem word wanneer **BIOGEN ACETYL-L CARNITINE** voorgeskryf / voorgestel word.

Swangerskap, borsvoeding en vrugbaarheid

Die veiligheid en doeltreffendheid van **BIOGEN ACETYL-L CARNITINE** tydens swangerskap en laktasie is nie vasgestel nie.

Bestuur en gebruik van masjinerie

Pasiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik totdat hulle redelik seker is dat **BIOGEN ACETYL-L CARNITINE** nie hul werkverrigting beïnvloed nie.

3. HOE OM BIOGEN ACETYL-L CARNITINE

Moenie u medisyne met enigiemand anders deel nie.

Neem, **BIOGEN ACETYL-L CARNITINE** altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat u dokter of apteker vir u aanbeveel het. Vra gerus u dokter of apteker indien u onseker is.

Volwassene: Neem een (1) tot twee (2) capsules driemaal daagliks, of soos aanbeveel deur jou gesondheidsorgverskaffer.

Bejaardes: Geen spesifieke studies is by ouer pasiënte uitgevoer nie, maar volgens kliniese ervaring is dosisaanpassing nie nodig wanneer anderhul gesonde, ouer pasiënte behandel word nie.

Kinders en adolessente: Asetiel-L-karnitien word vir tot 6 weke veilig mondelings by kinders gebruik.

Wat om te doen indien u meer BIOGEN ACETYL-L CARNITINE geneem het as wat u moet

Geen bekende informasie. Indien u meer **BIOGEN ACETYL-L CARNITINE** geneem het as wat u moes, of in die geval van 'n oordosis, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Neem hierdie inligtingsblad en die oorblywende **BIOGEN ACETYL-L CARNITINE** olie saam sodat die dokter kan sien wat u ingeneem het.

Indien u vergeet om BIOGEN ACETYL-L CARNITINE te neem

Moenie 'n dubbele dosis neem om te vergoed vir individuele dosisse wat vergeet is nie.

4. MOONTLIKE NUWE-EFFEKTE

BIOGEN ACETYL-L CARNITINE kan nuwe-effekte hê. Mondelings word asetiel-L-karnitien oor die algemeen goed verdra.

Nie alle nuwe-effekte wat vir **BIOGEN ACETYL-L CARNITINE** aangemeld is, is in hierdie pamflet ingesluit nie. Indien u algemene gesondheid versleg of as u enige nadelige effekte ervaar terwyl u **BIOGEN ACETYL-L CARNITINE** neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Opsomming van mees algemene nadelige reaksies

Kardiovaskulêre:
Minder gereeld: verhoogde bloeddruk.

Dermatologies:
Minder gereeld: Die gekombineerde gebruik van asetiel-L-karnitien en alfa-lipoïensuur kan uitslag veroorsaak.

Gastroïntestinale afwykings:
Minder gereeld: Asetiel-L-karnitien kan naarheid, braking, hik, abdominale distensie en gastro-intestinale ontsteltens of pyn veroorsaak. Asetiel-L-karnitien kan ook droë mond en anoreksie veroorsaak. Die gekombineerde gebruik van asetiel-L-karnitien en alfa-lipoïensuur kan diarree, hardtywigheid en dyspepsie veroorsaak.

Neurologiese/ sentrale senuweestelsel:
Minder gereeld: Asetiel-L-karnitien kan hoofpyn en slapeeloosheid veroorsaak.

Psigiatries:
Minder gereeld: Asetiel-L-karnitien kan agitatie veroorsaak (rusteloosheid en motoriese ooraktiwiteit).

Ander:
Een van die metaboliete van asetiel-L-karnitien kan veroorsaak dat die urine, asem en sweet 'n visreuk het. Ook is onwrikende urine gerapporteer na orale gebruik van 'n kombinasie van asetiel-L-karnitien en alfa-lipoïensuur. Raadpleeg u dokter, apteker of ander gene-esseer vir advies indien u algemene gesondheid vererger of as u enige ongewenste effekte ervaar terwyl **BIOGEN ACETYL-L CARNITINE** neem.

As u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, moet u dokter of apteker daarvan in kennis gestel word.

Rapportering van nuwe-effekte

Indien u nuwe-effekte ondervind, bespreek dit met u dokter of apteker. U kan ook nuwe-effekte aan SAHPRA rapporteer via die Adverse Drug Reactions Reporting Form, wat aarllyn by SAHPRA se publikasies beskikbaar is: <http://www.sahpra.org.za/Publications/Index/8>.

Deur nuwe-effekte te rapporteer kan u help om meer inligting rakende die veiligheid van **BIOGEN ACETYL-L CARNITINE** te verskaf.

5. BERGING EN WEGDOENING VAN BIOGEN ACETYL-L CARNITINE

- Bêre by of onder 25 °C.
- Beskerm teen lig en vog.
- Bêre alle medisyne buite bereik van kinders.
- Moenie gebruik ná die vervaldatum wat op die produk gedruk is nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) weggooi nie.

6. INHOUD VAN DIE VERPAKKING EN ANDER INLIGTING

Wat BIOGEN ACETYL-L CARNITINE bevat
Aktiewe bestanddele per capsule, Asetiel-L-karnitien.

Suikervry.

Die ander bestanddele is Magnesiumsteraat.

Die aanbieding en identifikasie van BIOGEN ACETYL-L CARNITINE

30 kapsules
Die verpakking is 'n 175 ml PET houer. Die prop is 'n wit plastiek prop met 'n peuter duidelike seël.

NAAM EN ADRES VAN REGISTRASIEHOUER

Biogen
Stagweg 23, Glen Austin, Suid Afrika
info@biogen.co.za
www.biogen.co.za
Tel: 0860 347243

REGISTRASIENOMMER

Sal met registrasie deur SAHPRA toegeken word.

JOB: BPS_AcetylLCarnitine_30s		SIZE: 210mm x 375mm	
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>			
COLOURS:		FINISHING:	
<input checked="" type="checkbox"/> K	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot
<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot
<input type="checkbox"/> Foil / Holographic Foil	<input type="checkbox"/> Matte	<input type="checkbox"/> Gloss	<input type="checkbox"/> Spot UV
<input type="checkbox"/> Doming	<input type="checkbox"/> Embossing		
PLEASE CHECK CAREFULLY Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.			