Product Summary

1. Name of the medicinal product
Renerve Plus® Caps

2. Qualitative and quantitative composition
Each Soft Gelatin Capsule contains
Mecobalamin 1500 mcg.
Alpha Lipoic Acid USP 200 mg.
Folic Acid IP 1.5 mg.
Inositol 100 mg
Chromium polynicotinate 200 mcg
Seleno Methionine 55 mcg
Zinc Monomethionine 25 mg

3. Pharmaceutical form
Soft gelatin capsule

4. Clinical particulars
The clinical particulars associated with Renerve Plus® Caps were not reported. Hence all events appearing after administration of Renerve Plus® Caps should be considered as due to the combination.
However, the following information is known when the individual components were given as stand alone treatments.

4.1 Therapeutic indications
Mecobalamin
I. Peripheral Neuropathies
II. Megaloblastic Anaemia caused by Vitamin B12 deficiency.
**Alpha Lipoic Acid**

Lipoic acid shows evidence of being effective in the treatment of diabetic neuropathy and may be useful in treating some other aspects of diabetes. It may help prevent the oxidation of LDL cholesterol and may be protective, generally, against oxidative stress and, specifically, against atherosclerosis, ischemia-reperfusion injury and various radiologic and chemical toxins. It may also be useful in some inborn metabolic disorders. There is less evidence that it might be helpful in some neurodegenerative conditions. There is preliminary evidence that it might have some immune-modulating effects. It has been suggested that lipoic acid may slow aging of the brain and that it may be an anti-aging substance, in general.

**Folic acid**

Folic acid is indicated for the treatment of megaloblastic anaemia due to folic acid deficiency. It is also used for prophylaxis in chronic haemolytic states, in renal dialysis, and in drug induced folate deficiency.

Folic acid is used for the prevention of recurrence of neural tube defects.

**Inositol**

- Supplementing with inositol may improve certain neuropathies like diabetic neuropathy.

- Panic disorder. Inositol shows some promise for controlling panic attacks and the fear of public places or open spaces (agoraphobia). One study found that inositol is as effective as a prescription medication. However, large-scale clinical trials are needed before inositol’s effectiveness for panic attacks can be proven.

- Obsessive-compulsive disorder (OCD). There is some evidence that people with OCD who receive inositol by mouth for 6 weeks experience significant improvement.

- Polycystic ovary syndrome (PCOS). Taking a particular form of inositol (isomer D-chiro-inositol) by mouth seems to lower triglyceride and testosterone levels, modestly decrease blood pressure, and promote ovulation in obese women with polycystic ovary syndrome.

- In premature infants known as “acute respiratory distress syndrome,” when given intravenously (by IV).

- Psoriasis brought on or made worse by lithium drug therapy. Inositol doesn’t seem
to help psoriasis in people not taking lithium.

**Chromium**
Taking chromium by mouth is effective for preventing chromium deficiency.

**Zinc**
Zinc deficiency. Zinc deficiency might occur in people with severe diarrhea, conditions that make it hard for the bowel to absorb food, liver cirrhosis and alcoholism, after major surgery, and during long-term use of tube feeding in the hospital. Taking zinc by mouth or giving zinc intravenously (by IV) helps to restore zinc levels in people who are zinc deficient. However, taking zinc supplements regularly is not recommended.

### 4.2 Posology and method of administration
Renerve Plus® Caps are for oral use only. The dose and frequency is as prescribed by the physician. There is no specific information available for use in special populations.

### 4.3 Contraindications
Known hypersensitivity to any of the active constituents.

### 4.4 Special warnings and precautions for use
There are no special warnings and precautions available regarding the use of Renerve Plus® Caps. However, it is advised to check the individual labels of each of the active ingredients for special warnings and precautions.

**Folic acid**
Folate should not be routinely used in patients receiving coronary stents. Caution should be exercised when administering folic acid to patients who may have folate dependent tumours. Folic acid is removed by haemodialysis. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

**Alpha-lipoic acid**
Because of lack of long-term safety data, alpha-lipoic acid should be avoided by pregnant women and nursing mothers. Those with diabetes and problems with glucose intolerance are cautioned that supplemental alpha-lipoic acid may lower blood
glucose levels. Blood glucose should be monitored and anti-diabetic drug dose adjusted, if necessary, to avoid possible hypoglycemia.

**Inositol**

**Bipolar disorder:** There is some concern that taking too much inositol might make bipolar disorder worse. There is a report of a man with controlled bipolar disorder being hospitalized with extreme agitation and impulsiveness (mania) after drinking several cans of an energy drink containing inositol, caffeine, taurine, and other ingredients (Red Bull Energy Drink) over a period of 4 days. It is not known if this is related to inositol, caffeine, taurine, a different ingredient, or a combination of the ingredients.

**Chromium**

**Kidney disease:** There are at least three reports of kidney damage in patients who took chromium picolinate. Chromium supplements should not be taken in the presence of kidney disease.

**Liver disease:** There are at least three reports of liver damage in patients who took chromium picolinate. Chromium supplements should not be taken in the presence of liver disease.

**Diabetes:** Chromium might lower blood sugar levels too much if taken along with diabetes medications. In the presence of diabetes, chromium products should be used cautiously and blood glucose levels closely monitor. Dose adjustments to diabetes medications might be necessary.

**Chromate/leather contact allergy:** Chromium supplements can cause allergic reactions in people with chromate or leather contact allergy. Symptoms include redness, swelling, and scaling of the skin.

**Behavioral or psychiatric conditions such as depression, anxiety, or schizophrenia:** Chromium might affect brain chemistry and might make behavioral or psychiatric conditions worse.

**Selenomethionine**

Adequate information is not available

**Zinc**

**Alcoholism:** Long-term, excessive alcohol drinking is linked to poor zinc absorption in the body.
**Diabetes**: Large doses of zinc can lower blood sugar in people with diabetes. People with diabetes should use zinc products cautiously.

**Hemodialysis**: People receiving hemodialysis treatments seem to be at risk for zinc deficiency and might require zinc supplements.

**HIV (human immunodeficiency virus)/AIDS**: Use zinc cautiously if you have HIV/AIDS. Zinc use has been linked to shorter survival time in people with HIV/AIDs.

**Syndromes in which it is difficult for the body to absorb nutrients**: People with malabsorption syndromes may be zinc deficient.

**Rheumatoid arthritis (RA)**: People with RA absorb less zinc.

### 4.5 Interaction with other medicinal products and other forms of interaction

**Mecobalamin**
None supplied.

**Alpha Lipoic Acid**
Supplemental alpha-lipoic acid may lower blood glucose levels. Those with diabetes on anti-diabetic medication should have their blood glucose monitored and anti-diabetic drug dose appropriately adjusted, if necessary, to avoid possible hypoglycemia.

**Folic acid**
Absorption of folic acid may be reduced by sulfasalazine.
Concurrent administration with cholestyramine may interfere with folic acid absorption.
Patients on prolonged cholestyramine therapy should take folic acid 1 hour before or 4 to 6 hours after receiving cholestyramine.
Antibiotics may interfere with the microbiological assay for serum and erythrocyte folic acid concentrations and may cause falsely low results. Trimethoprim or sulfonamides, alone or in combination as co-trimoxazole, may reduce the effect of folic acid and this may be serious in patients with megaloblastic anaemia.
Serum levels of anticonvulsant drugs (phenytoin, phenobarbital, primidone) may be reduced by administration of folate and therefore patients should be carefully monitored by the physician and the anticonvulsant drug dose adjusted as necessary. Fluorouracil toxicity may occur in patients taking folic acid and this combination should be avoided.
Edible clay or antacids containing aluminium or magnesium may reduce folic acid absorption. Patients should be advised to take antacids at least two hours after administration of folic acid.

Folic acid may reduce intestinal absorption of zinc (of particular importance in pregnancy).

**Chromium**

**Moderate interactions**

*Insulin interacts with Chromium*

Chromium might decrease blood sugar. Insulin is also used to decrease blood sugar. Taking chromium along with insulin might cause your blood sugar to be too low. Monitor your blood sugar closely. The dose of your insulin might need to be changed.

*Levothyroxine interacts with Chromium*

Taking chromium with levothyroxine might decrease how much levothyroxine that the body absorbs. This might make levothyroxine less effective. To help avoid this interaction, levothyroxine should be taken 30 minutes before or 3-4 hours after taking chromium.

**Minor interactions**

*NSAIDs (Nonsteroidal anti-inflammatory drugs) interacts with Chromium*

NSAIDs are anti-inflammatory medications used for decreasing pain and swelling. NSAIDs might increase chromium levels in the body and increase the risk of adverse effects. Avoid taking chromium supplements and NSAIDs at the same time. Some NSAIDs include ibuprofen, indomethacin, naproxen, piroxicam, aspirin, and others.

**Zinc**

Moderate interactions

*Antibiotics (Quinolone antibiotics) interacts with Zinc*

Zinc might decrease how much antibiotic the body absorbs. Taking zinc along with some antibiotics might decrease the effectiveness of some antibiotics. To avoid this interaction take zinc supplements at least 1 hour after antibiotics. Some of these antibiotics that might interact with zinc include ciprofloxacin, enoxacin, norfloxacin, sparfloxacin, trovafloxacin, and grepafloxacin.
Antibiotics (Tetracycline antibiotics) interacts with Zinc

Zinc can attach to tetracyclines in the stomach. This decreases the amount of tetracyclines that can be absorbed. Taking zinc with tetracyclines might decrease the effectiveness of tetracyclines. To avoid this interaction take zinc 2 hours before or 4 hours after taking tetracyclines. Some tetracyclines include demeclocycline, minocycline, and tetracycline.

Cisplatin interacts with Zinc

Cisplatin is used to treat cancer. Taking zinc along with EDTA and cisplatin might increase the effects and side effects of cisplatin.

Penicillamine interacts with Zinc

Penicillamine is used for Wilson's disease and rheumatoid arthritis. Zinc might decrease how much penicillamine your body absorbs and decrease the effectiveness of penicillamine.

4.6 Pregnancy and lactation

Mecobalamin

The usual precautions should be observed when administering drugs during pregnancy, especially in the first trimester.

However animal studies are insufficient with respect to effects on pregnancy/ and-or/ embryonal/foetal development/ and-or/ parturition/ and-or/ postnatal development (see section 5.3). The potential risk for humans is unknown (see section 4.8).

Alpha Lipoic Acid

Because of lack of long-term safety data, alpha-lipoic acid should be avoided by pregnant women and nursing mothers.

Folic acid

Pregnancy

Folic acid deficiency during pregnancy may lead to the appearance of foetal malformations. Imbalance in folate requiring trophoblast cells may also lead to detachment of the placenta.

Very high doses of folic acid have been shown to cause foetal abnormalities in rats; however, harmful effects in the human foetus, mother or the pregnancy have not been reported following ingestion of folic acid.

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Lactation
Folic acid is excreted in breast milk.
No adverse effects have been observed in breast-fed infants whose mothers were receiving folic acid.

Inositol
Pregnancy and breast-feeding: Not enough is known about the use of inositol during pregnancy and breast-feeding. Stay on the safe side and avoid use.

Chromium
Pregnancy and breast-feeding: Chromium is likely safe to use during pregnancy and breast-feeding when taken by mouth in amounts that are equal to or less than “adequate intake” (AI) levels. Chromium is possibly safe to use during pregnancy in amounts higher than the AI levels. However, pregnant women should not take chromium supplements during pregnancy or breast-feeding unless advised to do so by their healthcare provider.

Zinc
Zinc is likely safe for most pregnant and breast-feeding women when used in the recommended daily amounts (RDA). However, zinc is possibly unsafe when used in high doses by breast-feeding women and likely unsafe when used in high doses by pregnant women. Pregnant women over 18 should not take more than 40 mg of zinc per day; pregnant women age 14 to 18 should not take more than 34 mg per day. Breast-feeding women over 18 should not take more than 40 mg of zinc per day; breast-feeding women age 14 to 18 should not take more than 34 mg per day.

4.7 Effects on ability to drive and use machines
None known.

4.8 Undesirable effects
Mecobalamin
Adverse reactions were reported in 13 of 2,872 patients (0.45 %). (At the end of the reexamination period)
(1) Clinically significant adverse reactions (incidence unknown)
Anaphylactoid reaction such as decrease in blood pressure or dyspnea, may occur.
Patients should be carefully observed. In the event of such symptoms, treatment should be discontinued immediately and appropriate measures taken.

(2) Other adverse reactions

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<table>
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<tbody>
<tr>
<td>Hypersensitivity</td>
<td>&lt;0.1%</td>
<td>Incidence unknown</td>
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<tr>
<td>Others</td>
<td>Rash</td>
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<td></td>
<td>Headache and hot sensation</td>
<td>Diaphoresis and pain/induration at the site of intramuscular injection</td>
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Note: In the event of such symptoms, treatment should be discontinued.

**Alpha Lipoic Acid**

To date, alpha-lipoic acid in doses up to 600 milligrams daily has been well tolerated.

**Folic acid**

Folic acid is generally well tolerated although the following side effects have been reported:

*Blood and lymphatic system disorders:*

Folic acid may worsen the symptoms of co-existing vitamin B12 deficiency and should never be used to treat anaemia without a full investigation of the cause.

*Immune system disorders:*

Allergic reactions

*Gastrointestinal disorder:*

Abdominal distension, flatulence, anorexia and nausea.

**Inositol**

Inositol is possibly safe for most adults. It can cause nausea, tiredness, headache, and dizziness.

**Chromium**

Chromium is likely safe for most adults when taken by mouth in doses up to 1000 mcg daily for up to 6 months. Chromium is possibly safe for most adults when used for longer periods of time. Some people experience side effects such as skin irritation, headaches, dizziness, nausea, mood changes and impaired thinking, judgment, and coordination.
**Zinc**

Zinc is likely safe for most adults when applied to the skin, or when taken by mouth in amounts not larger than 40 mg daily. Routine zinc supplementation is not recommended without the advice of a healthcare professional. In some people, zinc might cause nausea, vomiting, diarrhea, metallic taste, kidney and stomach damage, and other side effects. Using zinc on broken skin may cause burning, stinging, itching, and tingling. Zinc is possibly safe when taking by mouth in doses greater than 40 mg daily. There is some concern that taking doses higher than 40 mg daily might decrease how much copper the body absorbs. Decreased copper absorption may cause anemia.

Zinc is possibly unsafe when inhaled through the nose, as it might cause permanent loss of smell. In June 2009, the US Food and Drug Administration (FDA) advised consumers not to use certain zinc-containing nose sprays after receiving over 100 reports of loss of smell. The maker of these zinc-containing nose sprays has also received several hundred reports of loss of smell from people who had used the products. Avoid using nose sprays containing zinc.

**4.9 Overdose**

**Chromium**

High doses have been linked to more serious side effects including blood disorders, liver or kidney damage, and other problems. It is not known for sure if chromium is the actual cause of these side effects.

**Zinc**

Taking high amounts of zinc is likely unsafe. High doses above the recommended amounts might cause fever, coughing, stomach pain, fatigue, and many other problems.

Taking more than 100 mg of supplemental zinc daily or taking supplemental zinc for 10 or more years doubles the risk of developing prostate cancer. There is also concern that taking large amounts of a multivitamin plus a separate zinc supplement increases the chance of dying from prostate cancer.

Taking 450 mg or more of zinc daily can cause problems with blood iron. Single doses of 10-30 grams of zinc can be fatal.

No cases of overdosage were reported with other components.
5. Pharmacological properties

5.1 Pharmacodynamic properties

The pharmacodynamic properties of Renerve Plus® Caps are not known. However, for some components, the properties are as follows

**Mecobalamin**
- It is a Neurotropic and acts as a growth promoter for nerve cells, a property which helps to regenerate Central and Peripheral nervous tissue damaged in disorder such as diabetic peripheral neuropathy.
- It acts as a methyl donor for the synthesis of Lecithin, a major component of the Myelin sheath.
- It facilitates methylation of t-RNA which play a fundamental role in protein synthesis and stimulates methionine synthesis and helps to restore normal levels of RNA in nerve cells.
- It acts as a co-factor in the enzyme methionine synthase which regenerates methionine thus generating an increased supply of S-Adenosyl Methionine (SAMe) and SAMe protects from Neurotoxicity.
- It normalizes Nerve cell conduction by healing the damaged nerve cells and restores delayed synaptic transmission and diminished neurotransmitters to normal.
- It improves the excitability of the nerve fibres and thus improves the neurotransmission.

**Alpha Lipoic Acid**

Alpha-lipoic acid and its reduced metabolite, dihydrolipoic acid (DHLA), form a redox couple and may scavenge a wide range of reactive oxygen species. Both alpha-lipoic acid and DHLA can scavenge hydroxyl radicals, the nitric oxide radical, peroxynitrite, hydrogen peroxide and hypochlorite. Alpha-lipoic acid, but not DHLA, may scavenge singlet oxygen, and DHLA, but not alpha-lipoic acid, may scavenge superoxide and peroxyl reactive oxygen species. Alpha-lipoic acid has been found to decrease urinary isoprostanes, O-LDL and plasma protein carbonyls, markers of oxidative stress. Further, alpha-lipoic acid and its redox couple DHLA have been found to have antioxidant activity in aqueous, as well as in lipophilic regions, and in extracellular and intracellular environments. Finally, with regard to alpha-lipoic acid's antioxidant activity,
alpha-lipoic acid appears to participate in the recycling of other important biologic antioxidants, such as vitamins E and C, ubiquinone and glutathione. Exogenous alpha-lipoic acid has been shown to increase ATP production and aortic blood flow during reoxygenation after hypoxia in a working heart model. It is thought that this is due to its role in the oxidation of pyruvate and alpha-ketoglutarate in the mitochondria, ultimately enhancing energy production. This activity, and possibly its antioxidant activity, may account for its possible benefit in diabetic polyneuropathy.

**Folic acid**
The mucosa of the duodenum and upper part of the jejunum are rich in dihydrofolate reductase, where folates and folic acid are absorbed. Once absorbed, folic acid is rapidly reduced and then methylated to form tetra-hydrofolic acid derivatives which are rapidly transported to the tissues.

5.2 Pharmacokinetic properties
The pharmacokinetic properties of Renerve Plus® Caps are not known. However, for some components, the properties are as follows

**Alpha Lipoic Acid**
Most pharmacokinetic studies have been performed in animals. Alpha-lipoic acid is absorbed from the small intestine and distributed to the liver via the portal circulation and to various tissues in the body via the systemic circulation. The natural R-entantiomer is more readily absorbed than the L-entantiomer and is the more active form. Alpha-lipoic acid readily crosses the blood-brain barrier. It is found, after its distribution to the various body tissues, intracellularly, intramitochondrialy and extracellularly. Alpha-lipoic acid is metabolized to its reduced form, dihydrolipoic acid (DHLA), by mitochondrial lipoamide dehydrogenase. DHLA, together with lipoic acid, form a redox couple. It is also metabolized to lipoamide, which functions as the lipoic acid cofactor in the multienzyme complexes that catalyze the oxidative decarboxylations of pyruvate and alpha-ketoglutarate. Alpha-lipoic acid may be metabolized to dithiol octanoic acid, which can undergo catabolism.

**Folic acid**
Folic acid is readily absorbed following oral dosage, and is extensively bound to plasma proteins.
5.3 Preclinical safety data

Alpha Lipoic Acid

In animal models and culture studies, lipoic acid has demonstrated antioxidant properties that help reduce or eliminate a sequence of events that include reduced endo-neural blood flow and oxygen tension, which are pre-requisites of neuropathy. In addition, some of these studies have revealed favorable lipoic acid effects that appear to be independent of its antioxidant properties, including increased glucose uptake, promotion of new neurite growth and chelation of transition metals thought to play a role in diabetic neuropathy. In some animal experiments, lipoic acid, administered for up to three months, significantly reversed the increase in nerve vascular resistance and the decrease in nerve blood flow in diabetic rats. Nerve conduction velocity was entirely restored in some nerve groups after three months of treatment. Human clinical trials have been encouraging. In one of these studies, subjects received 200 milligrams of intravenous lipoic acid daily. After 21 days, significant pain reduction was achieved in most subjects. In a larger, multi-center, double-blind, randomized, placebo-controlled study of 328 patients with type 2 diabetes, significant improvements were recorded in several clinical measures of diabetic polyneuropathy, including pain, numbness, paresthesia and burning sensations. These results were evident after three weeks of intravenous lipoic acid given five times weekly in doses of 600 and 1200 milligrams. Nerve conduction velocity has not been shown to improve in the short-term human studies conducted so far. One group of researchers has suggested that proof of neurophysiological improvement in these neuropathies may emerge from long-term lipoic acid supplementation studies, as has been the case in some animal model studies. "A period of several years," they have observed, "is required to slow progress of diabetic neuropathy due to normalization of blood glucose levels." There is evidence, too, that lipoic acid may help prevent or slow the development of the atherosclerosis for which diabetics are at higher risk. It may do this, in part, through a gene-regulatory mechanism that helps prevent endothelial cell activity that has been implicated in the progression of atherosclerosis. With respect to atherosclerosis, in general, lipoic acid's antioxidant and metabolic effects appear to offer some protection, as demonstrated in various animal models. Recently, researchers demonstrated, in a 16-week randomized trial, that lipoic acid, in oral doses of 600 milligrams daily for eight weeks, significantly inhibits the oxidation of LDL-cholesterol in healthy human subjects. The
supplements also significantly reduced levels of F-2 isoprostanes, markers of oxidative stress. In this study, lipoic acid proved to be superior to vitamin E in decreasing levels of plasma protein carbonyls. Protein oxidation and LDL-cholesterol oxidation are implicated in heart disease. Various animal studies have suggested that lipoic acid can prevent or reduce cell and tissue damage in heart attacks and stroke. There is extensive animal work showing that lipoic acid can exert significant protective effects against ischemia-reperfusion injury. Lipoic acid is believed to work in this context, at least in part, through its antioxidant properties and its reported ability to increase cellular levels of glutathione that are typically depleted by the reactive oxygen species formation that characterizes ischemia-reperfusion. More research is needed to further elucidate these mechanisms and determine whether these results will apply in humans. Animal work is also suggestive of some modest benefit from lipoic acid in the treatment of various neurodegenerative disorders, including Parkinson's disease, Alzheimer's disease, amyotrophic lateral sclerosis and Huntington's disease. Results to date, however, remain inconclusive. Clinical studies are needed. There is some evidence that children afflicted with inborn errors of pyruvate metabolism may derive some benefit from lipoic acid treatment. Those with Wilson's disease, a genetic disorder characterized by disturbed copper metabolism, may be helped by lipoic acid as well. The supplement has also proved useful in conferring some protection against cadmium poisoning and hexane inhalation. It has also been used in some liver toxicities, such as Amanita phalloides mushroom poisoning. Lipoic acid's role in immunity is not well understood. There are reports that it can augment antibody response in some animal models of immunosuppression. This research warrants followup. Claims that lipoic acid slows aging of the brain and is an anti-aging substance generally seem to be related to its potent antioxidant properties. Direct proof of anti-aging is lacking, but there is some animal work suggestive of some possible anti-aging effects. Rats were fed a lipoic-acid supplemented diet to see whether the substance can reverse age-related declines in metabolism and mitochondrial function. Un-supplemented aged rats (24 to 26 months) exhibited ambulatory activity, said to be a general measure of metabolic activity, that was threefold lower than that of young controls. But this decline was significantly reversed in similarly aged rats supplemented with lipoic acid for two weeks. Hepatocytes from untreated aged rats, compared with hepatocytes of young controls (three to five months), had significantly lower oxygen consumption and mitochondrial membrane potential. But in
supplemented aged rats, hepatocytes, by the same measures, were comparable to those of the young controls. Lipoic acid supplementation was reported to completely reverse age-related declines in hepatocyte ascorbic acid and glutathione levels. There was additional evidence of decreased oxidative damage in the lipoic-acid supplemented aged rats. The researchers concluded: "Little is known about whether lipoic acid may be an effective anti-aging supplement in humans. The present findings using rats would suggest that lipoic acid supplementation may be a safe and effective means to improve general metabolic activity and increase antioxidant status, affording increased protection against external oxidative and xenobiotic insults with age." Again, further study is needed.

**Folic acid**

Toxicity studies in animals (rats and rabbits) have shown that massive doses (100mg/kg upwards) produce precipitation of folate crystals in renal tubules, particularly proximal tubules and ascending limb of the loop of Henle. Tubular necrosis is followed by recovery.

6. **Pharmaceutical particulars**

6.1 **Incompatibilities**

None supplied

6.2 **Shelf life**

As mentioned on the packaging material

6.3 **Special precautions for storage**

As mentioned on the packaging material

**Administrative data**

7. **Marketing authorisation holder**

Strides Shasun Limited

Opp IIM, Bilekahalli,

Bannerghatta Road,

Bengaluru – 560 076, India

8. **Toll free number for reporting**

1800 4190601
9. Date of text
28th December 2016

10. References
- http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2435522/