Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

AMINOGARD granules (Amino acids and vitamins granules)

2. Qualitative and quantitative composition

Each 5 g contains:

L-Isoleucine	USP	100 mg
L-Leucine	USP	125 mg
L-Valine	USP	75 mg
L-Lysine Hydrochloride	USP	150 mg
L-Methionine	USP	25 mg
L-Threonine	USP	25 mg
L-Phenylalanine	USP	50 mg
L-Tryptophan	USP	5 mg
L-Proline	USP	25 mg
L-Glutamine	USP	150 mg
L-Arginine	USP	100 mg
Thiamine Hydrochloride	BP	5 mg
Riboflavin Sodium Phosphate Equivalent to Riboflavin	BP	5 mg
Pyridoxine Hydrochloride	BP	1.5 mg
Folic Acid	BP	0.5 mg
Cyanocobalamin (as gelatin coated)	BP	5 mcg

Appropriate overages of Vitamins added to compensate the loss during storage

For the full list of excipients, see section 6.1

3. Pharmaceutical form

Orange yellow to pale yellow coloured, flavoured, free flowing granular powder.

4. Clinical particulars

4.1 Therapeutic indications

AMINOGARD granules are indicated as nutritive supplement in pregnant women, malnourished children, elderly and convalescing patients.

4.2 Posology and method of administration

One sachet may be taken twice daily. Not recommended for children below 2 years.

Dissolve whole of the contents of the sachet in 200ml of water or milk or juice and consume immediately.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients Branched chain amino acid in AMINOGARD Granules is contraindicated in those with the rare inborn errors of metabolism like Maple Syrup Urine Disease.

4.4 Special warnings and precautions for use

AMINOGARD granules should be used cautiously in severe hepatic diseases. Appropriate laboratory tests, especially those for the monitoring of liver functions and renal functions, should be performed periodically during the course of use of the product. AMINOGARD granules should be given with caution to very sick children due to the risk of inducing hyperphenylalaninemia.
Phenylketonurics: Contains Phenylalanine.

Excipients warnings:
Aspartame: This medicinal product contains Aspartame which is a source of Phenylalanine, hence caution is recommended when prescribing to very sick patients due to risk of inducing Phenylalaninemia.
Maltitol: This medicinal product contains Maltitol. May have a mild laxative effect.
Parahydroxybenzoate and their esters: The medicinal product contains Methyl parahydroxybenzoate and Propyl parahydroxybenzoate. May cause allergic reactions (possibly delayed).
This medicinal product contains flavouring agent with approved generally recognized as safe (GRAS)- FEMA- JEFCA ingredients.

4.5 Interaction with other medicinal products and other forms of interaction

No known drug interactions have been reported, Folic acid can reduce the plasma concentration of Phenytoin.

4.6 Pregnancy and Lactation

Women of childbearing potential: Studies not available
Contraception in males and females: Studies not available
Pregnancy: Amino-acid supplementation in pregnancy can cause meaningful reduction in the incidence of IUGR in mothers having risk factors for delivering growth retarded fetus and thereby improve perinatal outcome. (J Obstet Gynecol Ind Vol. 54, No. 3: May/June 2004 Pg 243-245). Hence AMINOGARD Granules can be given for pregnant women as recommended by the physician.
Breastfeeding: Safety and efficacy of this formulation in lactating mothers have not been established.
Fertility: Studies not available

4.7 Effects on ability to drive and use machines

Intake of AMINOGARD granules was not found to have any effect on the ability to drive and use machines.

4.8 Undesirable effects

Paediatric population - Studies not available

In generally AMINOGARD granules is well tolerated. Nausea and rarely, patients may exhibit hypersensitivity to one or more amino acids.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via the relevant national regulatory authority pharmacovigilance.

4.9 Overdose

Overdosage is extremely unlikely if the dosage recommendations are followed. However, in case of accidental overdose, symptomatic treatment is advised.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Nutritive Supplement (Aminoacids/minerals/vitamins, combinations)

ATC code: V06DE

AMINOGARD granules provide biologically utilizable source material for protein synthesis when used with concentrated calorie sources (such as hypertonic dextrose or fat emulsion), electrolytes, vitamins, and minerals. Administered orally after appropriate dilution or with minimal calorie supplementation, it enhances the conservation of body protein. Over the long haul, AMINOGARD granules will help keep the muscles primed for top performance and the body conditioned for greater fitness and overall health. A constantly adequate supply of the amino acids will enable the body needs and will help to achieve a better fat-to-muscle ratio. Increased quantities of essential micronutrients (Thiamine, Riboflavin, Pyridoxine, Folic acid, Cyanocobalamin etc.) are required for the success of are anticatabolic or anabolic strategy as micronutrient depletion occurs after trauma or in convalescing condition.

Branched chain amino acids (BCAA)

The **branched-chain amino acids (BCAAs)** comprise the three essential amino acids l-leucine, l-isoleucine and l-valine. 'Branched chain' refers to their chemical structure, which sets them apart from other amino acids. In humans, about 15-25% of total protein intake is BCAA's, and dairy products are particularly high in them. BCAA's make up 35-40% of the essential amino acids in body protein and 14% of the total amino acids in skeletal muscle. Branched-chain amino acids are considered essential amino acids because human beings cannot survive unless these amino acids are present in the diet. Branched chain amino acids use multiple mechanisms to achieve the desired effects. The “Central Fatigue Theory” is the basis for the understanding of how BCAAs decrease fatigue, increase energy levels and improve mental performance. When the body is stressed, such as during exercise, blood levels of BCAAs decrease and fatty acid levels increase to supply the needed energy. The extra fatty acids must be transported and require albumin for the job. For this to occur, tryptophan must be removed from the albumin. This facilitates the transport of tryptophan, a precursor of serotonin, into the brain and finally it is converted to serotonin. Serotonin is responsible for feelings of physical and mental fatigue, sleepiness, and lethargy.

BCAAs are also used for energy by immune cells so when the levels of BCAAs are increased, then the activity of the immune system can also be increased. This can help decrease the amount of time it takes to recover after exercise and decrease muscle soreness by more completely healing muscles and surrounding tissues. In addition, they can help improve the overall functioning of the immune system, which can be evidenced by the reduction in the amount of upper respiratory tract infections.
Finally, BCAAs are used to prevent muscle protein breakdown. This anti-catabolic effect is possible because the body is able to retain a positive nitrogen balance by providing additional nitrogen from these essential amino acids.

L- Lysine
This amino acid is an essential amino acid, which means that humans cannot synthesize it. Its codons are AAA and AAG. L-Lysine is a base, as are arginine and histidine. The Îµ-amino group often participates in hydrogen bonding and as a general base in catalysis. Common posttranslational modifications include methylation of the Îµ-amino group, giving methyl-, dimethyl-, and trimethyllysine. The latter occurs in calmodulin. Other posttranslational modifications include acetylation. Collagen contains hydroxylysine which is derived from lysine by lysyl hydroxylase. O-Glycosylation of lysine residues in the endoplasmic reticulum or Golgi apparatus is used to mark certain proteins for secretion from the cell.
Proteins of the herpes simplex virus are rich in L-arginine, and tissue culture studies indicate an enhancing effect on viral replication when the amino acid ratio of L-arginine to L-lysine is high in the tissue culture media. When the ratio of L-lysine to L-arginine is high, viral replication and the cytopathogenicity of herpes simplex virus have been found to be inhibited. L-lysine may facilitate the absorption of calcium from the small intestine.

L- Methionine
It is sulfur containing essential amino acid that is important in many body functions. It is a chelating agent for heavy metals. [*PubChem*] It is used for protein synthesis including the formation of SAMe, L-homocysteine, L-cysteine, taurine, and sulfate.
L-Methionine is a principle supplier of sulfur which prevents disorders of the hair, skin and nails; helps lower cholesterol levels by increasing the liver's production of lecithin; reduces liver fat and protects the kidneys; a natural chelating agent for heavy metals; regulates the formation of ammonia and creates ammonia-free urine which reduces bladder irritation; influences hair follicles and promotes hair growth. L-methionine may protect against the toxic effects of hepatotoxins, such as acetaminophen. Methionine may have antioxidant activity.
The mechanism of the possible anti-hepatotoxic activity of L-methionine is not entirely clear. It is thought that metabolism of high doses of acetaminophen in the liver lead to decreased levels of hepatic glutathione and increased oxidative stress. L-methionine is a precursor to L-cysteine. L-cysteine itself may have antioxidant activity. L-cysteine is also a precursor to the antioxidant glutathione. Antioxidant activity of L-methionine and

metabolites of L-methionine appear to account for its possible anti-hepatotoxic activity. Recent research suggests that methionine itself has free-radical scavenging activity by virtue of its sulfur, as well as its chelating ability.

L-Threonine

L-Threonine makes up collagen, elastin, and enamel protein. It aids proper fat metabolism in the liver, helps the digestive and intestinal tracts function more smoothly, and assists in metabolism and assimilation. L-Threonine is a precursor to the amino acids glycine and serine. It acts as a lipotropic in controlling fat build-up in the liver. May help combat mental illness and may be very useful in indigestion and intestinal malfunctions. Also, threonine prevents excessive liver fat. Nutrients are more readily absorbed when threonine is present.

L-Threonine is an essential amino acid that helps to maintain the proper protein balance in the body. It is important for the formation of collagen, elastin, and tooth enamel, and aids liver and lipotropic function when combined with aspartic acid and methionine.

L-Phenylalanine

An essential aromatic amino acid that is a precursor of melanin; dopamine; noradrenalin (norepinephrine), and thyroxine. [PubChem] Used by the brain to produce Norepinephrine, a chemical that transmits signals between nerve cells and the brain; keeps you awake and alert; reduces hunger pains; functions as an antidepressant and helps improve memory.

The mechanism of L-phenylalanine's putative antidepressant activity may be accounted for by its precursor role in the synthesis of the neurotransmitters norepinephrine and dopamine. Elevated brain norepinephrine and dopamine levels are thought to be associated with antidepressant effects. The mechanism of L-phenylalanine's possible antivitiligo activity is not well understood. It is thought that L-phenylalanine may stimulate the production of melanin in the affected skin.

L- Tryptophan

An essential amino acid that is necessary for normal growth in infants and for nitrogen balance in adults. It is a precursor of indole alkaloids in plants. It is a precursor of serotonin (hence its use as an antidepressant and sleep aid). It can be a precursor to niacin, albeit inefficiently, in mammals. [PubChem]. Tryptophan may be useful in increasing serotonin production, promoting healthy sleep, managing depression by enhancing mental and emotional well-being, managing pain tolerance and managing weight.

Tryptophan is critical for the production of the body's proteins, enzymes and muscle tissue. It is also essential for the production of niacin, the synthesis of the neurotransmitter serotonin and melatonin. Tryptophan supplements can be used as natural relaxants to help relieve insomnia. Tryptophan can also reduce anxiety and depression and has been shown to reduce the intensity of migraine headaches. Other promising indications include the relief of chronic pain, reduction of impulsivity or mania and the treatment of obsessive or compulsive disorders. Tryptophan also appears to help the

immune system and can reduce the risk of cardiac spasms. Tryptophan deficiencies may lead to coronary artery spasms. Tryptophan is used for those who do not seem to respond well to conventional antidepressants. It may also be used to treat those afflicted with seasonal affective disorder (a winter-onset depression). Tryptopan serves as the precursor for the synthesis of serotonin (5-hydroxytryptamine, 5-HT) and melatonin (N-acetyl-5-methoxytryptamine). A number of important side reactions occur during the catabolism of tryptophan on the pathway to acetoacetate. An important side reaction in liver is a transamination and several rearrangements to produce limited amounts of nicotinic acid, which leads to production of a small amount of NAD^+ and $NADP^+$.

L-Glutamine

It is a non-essential amino acid present abundantly throughout the body and is involved in many metabolic processes. It is synthesized from glutamic acid and ammonia. It is the principal carrier of nitrogen in the body and is an important energy source for many cells. [PubChem] It is used for nutritional supplementation, also for treating dietary shortage or imbalance. Like other amino acids, glutamine is biochemically important as a constituent of proteins. Glutamine is also crucial in nitrogen metabolism. Ammonia (formed by nitrogen fixation) is assimilated into organic compounds by converting glutamic acid to glutamine. The enzyme which accomplishes this is called glutamine synthetase. Glutamine can then be used as a nitrogen donor in the biosynthesis of many compounds, including other amino acids, purines, and pyrimidines.

Supplemental L-glutamine's possible immunomodulatory role may be accounted for in a number of ways. L-glutamine appears to play a major role in protecting the integrity of the gastrointestinal tract and, in particular, the large intestine. During catabolic states, the integrity of the intestinal mucosa may be compromised with consequent increased intestinal permeability and translocation of Gram-negative bacteria from the large intestine into the body. The demand for L-glutamine by the intestine, as well as by cells such as lymphocytes, appears to be much greater than that supplied by skeletal muscle, the major storage tissue for L-glutamine. L-glutamine is the preferred respiratory fuel for enterocytes, colonocytes and lymphocytes. Therefore, supplying supplemental L-glutamine under these conditions may do a number of things.

L-Proline

It is a non-essential amino acid that is synthesized from glutamic acid. It is an essential component of collagen and is important for proper functioning of joints and tendons. [PubChem]

L-Proline is extremely important for the proper functioning of joints and tendons and also helps maintain and strengthen heart muscles. L-Proline is a major amino acid found in cartilage and is important for maintaining youthful skin as well as repair of muscle, connective tissue and skin damage. It is also essential for the immune system, and for necessary balance of this formula. It is an essential component of collagen and is important for proper

functioning of joints and tendons. L-Proline is extremely important for the proper functioning of joints and tendons. Helps maintain and strengthen heart muscles. Glycogenic, by L-Proline oxidase in the kidney, it is ring-opened and is oxidized to form L-Glutamic acid. L-Ornithine and L-Glutamic acid are converted to L-Proline via L-Glutamic acid-gamma-semialdehyde. It is contained abundantly in collagen, and is intimately involved in the function of arthrosis and chordae.

L-Arginine

L-Arginine is a precursor for nitric oxide (NO) synthesis. NO is a ubiquitous mediator that is formed by a family of enzymes named NO synthesis. In the brain, NO acts as a neurotransmitter; in the immune system, NO acts as a mediator of host defense; and in the cardiovascular system, NO mediates the protective effects of the intact endothelium, acting as a vasodilator and endogenous antiatherogenic molecule. L-Arginine plasma levels are not significantly reduced in most disease conditions, except end-stage renal failure during hemodialysis treatment. In several controlled clinical trials, long-term administration of L-arginine has been shown to improve the symptoms of cardiovascular disease. However, in other trials L-arginine was not beneficial, and in a recent study, the authors reported higher mortality of subjects receiving L-arginine than those receiving placebo. Recently it became clear that endogenous levels of asymmetric dimethylarginine (ADMA), a competitive inhibitor of L-arginine metabolism by NO synthase, may determine a subject's response to L-arginine supplementation. L-Arginine appears to exert no effect in subjects with low ADMA levels, whereas in subjects with high ADMA levels, L-arginine restores the L-arginine/ADMA ratio to normal levels and thereby normalizes endothelial function. In conclusion, the effects of L-arginine supplementation on human physiology appear to be multicausal and dose-related. Doses of 3–8 g/d appear to be safe and not to cause acute pharmacologic effects in humans.

Vitamin B_1 (Thiamine)

Thiamine (as the coenzyme, thiamine pyrophosphate) is associated with carbohydrate metabolism. Thiamine pyrophosphate also acts as a co-enzyme in the direct oxidative pathway of glucose metabolism. In thiamine deficiency, pyruvic and lactic acids accumulate in the tissues. The pyruvate ion is involved in the biosynthesis of acetylcholine via its conversion to acetyl co-enzyme A through a thiamine-dependent process. In thiamine deficiency, therefore, there are effects on the central nervous system due either to the effect on acetylcholine synthesis or to the lactate and pyruvate accumulation. Deficiency of thiamine results in fatigue, anorexia, gastro-intestinal disturbances, tachycardia, irritability and neurological symptoms. Gross deficiency of thiamine (and other Vitamin B group factors) leads to the condition beri-beri.

Vitamin B_2 (Riboflavin)

Riboflavin is phosphorylated to flavine mononucleotide and flavine adenine dinucleotide, which act as co-enzymes in the respiratory chain and in

oxidative phosphorylation. Riboflavin deficiency presents with ocular symptoms, as well as lesions on the lips and at the angles of the mouth.

Vitamin B_6 (Pyridoxine)

Pyridoxine, once absorbed, is rapidly converted to the co-enzymes, pyridoxal phosphate and pyridoxamine phosphate, which play an essential role in protein metabolism. Vitamin B_6 or pyridoxine is a coenzyme for enzymes involved in amino acid metabolism. Deamination, transamination, and decarboxylation of amino acids are required for synthesis, oxidation, and degradation of critical amino acid derived molecules that participate in hematological, neurological, humoral, and inflammatory processes. As a result, activities sensitive to pyridoxine status include neurotransmitter function, heme synthesis, conversion of tryptophan to niacin, immunoglobulin synthesis, and hormone production. Convulsions and hypochromic anaemia have occurred in infants deficient in pyridoxine.

Folic Acid

- Folic acid is reduced in the body to tetrahydrofolate which is a co-enzyme for various metabolic processes, including the synthesis of purine and pyrimidine nucleotides and hence in the synthesis of DNA. It is also involved in some amino acid conversion and in the formation and utilisation of formate. Deficiency of folic acid leads to megaloblastic anaemia. Folate (folacin or folic acid) participates as a coenzyme in reactions that require transfer of a single carbon moiety in different oxidative states as a methenyl, methylene, or methyl group. In the absence of sufficient folic acid, uridine is substituted for thymidine resulting in hypomethylated DNA. These hypomethylated areas create fragile sites on chromosomes that exhibit vulnerability to breakage. In light of this, poor folate status has been linked to development of cancer. Increased intake of folate is also recommended for women of child-bearing age to prevent neural tube defects such as spinal bifida. Good periconceptional maternal folate status can reduce the risk of these defects in offspring by 50%. Folate (with vitamin B_{12}) is required for conversion of homocysteine to methionine. Elevated plasma homocysteine levels are a risk factor for atherosclerosis.

Vitamin B_{12} (Cyanocobalamin)

Vitamin B_{12} is present in the body mainly as methylcobalamin and as adenosylcobalamin and hydroxocobalamin. These act as co-enzymes in the trans methylation of homocysteine to methionine; in the isomerization of methylmalonyl co-enzyme to succinyl co-enzyme and with folate in several metabolic pathways respectively. Deficiency of Vitamin B_{12} interferes with haemopoiesis and produces megaloblastic anaemia.

5.2 Pharmacokinetic properties

Amino acids:

Unlike fats and carbohydrates, Amino acids require the removal of amine group. Removal of amine group occurs through a 2 step process

– transamination reaction & oxidative deamination. All excess Amino acids are deaminated. This results in the production of ammonia, which is toxic and is eliminated via urea cycle. Urea cycle occurs in liver resulting in the formation of urea, which is eliminated by excretion as urine.

Liver is the major site of nitrogen metabolism in the body. The carbon skeletons are generally conserved as carbohydrate via gluconeogenesis, or as fatty acid via fatty acid synthesis pathways. In this respect Amino acids fall into three categories: glucogenic, ketogenic or glucogenic and ketogenic. Glucogenic Amino acids are those that give rise to a net production of pyruvate or TCA cycle intermediates, such as α - ketoglutarate or oxaloacetate, all of which are precursors to glucose via gluconeogenesis. All Amino acids except Lysine and Leucine are at least partly glucogenic. Lysine and Leucine are the only Amino acids that are solely ketogenic, giving rise only to acetylCoA or acetoacetylCoA, neither of which can bring about net glucose production.

A small group of Amino acids comprised of Isoleucine, Phenylalanine, Threonine, Tryptophan and Tyrosine give rise to both glucose and fatty acid precursors and are thus characterized as being glucogenic and ketogenic. Finally, it should be recognized that Amino acids have a third possible fate. During times of starvation the reduced carbon skeleton is used for energy production, with the result that it is oxidized to CO2 and H2O.

Vitamin B1 (Thiamine): Thiamine is absorbed from the gastro-intestinal tract and is widely distributed to most body tissues. Amounts in excess of the body's requirements are not stored but excreted in the urine as unchanged Thiamine or its metabolites.

Vitamin B2 (Riboflavin): Riboflavin is absorbed from the gastro-intestinal tract and in the circulation is bound to plasma proteins. It is widely distributed. Little is stored and excess amounts are excreted in the urine.

Vitamin B6 (Pyridoxine): Pyridoxine is absorbed from the gastro-intestinal tract and converted to the active pyridoxal phosphate which is bound to plasma proteins. It is excreted in the urine as 4-pyridoxic acid.

Folic Acid: Folic acid is absorbed mainly from the proximal part of the small intestine. Folate polyglutamates are considered to be deconjugated to monoglutamates during absorption. Folic acid rapidly appears in the blood where it is extensively bound to plasma proteins. Some Folic acid is distributed in body tissues, some is excreted as folate in the urine and some is stored in the liver as folate.

Vitamin B_{12} (Cyanocobalamin): Cyanocobalamin is absorbed from the gastro-intestinal tract and is extensively bound to specific plasma proteins. A study with labelled Vitamin B_{12} showed it was quickly taken up by the intestinal mucosa and held there for 2-3 hours. Peak

concentrations in the blood and tissues did not occur until 8-12 hours after dosage with maximum concentrations in the liver within 24 hours. Cobalamin is stored in the liver, excreted in the bile and undergoes enterohepatic recycling. Part of a dose is excreted in the urine, most of it in the first eight hours.

5.3 Preclinical safety data

Toxicities of Amino acids have not been studied methodically. Retardation of growth and other detrimental effects that result from feeding excessive amounts of single amino acids have usually been attributed to amino acids toxicities. In numerous instances contradictory reports may be found in the literature as to the toxicity of certain amino acids or of the isomers of amino acids.

AMINOGARD granules contain a unique mixture of Branched chain amino acids, essential & non-essential amino acids, vitamins

Toxicity of Vitamins

There is very little danger of consuming toxic levels of water soluble vitamins like B complex because they are soluble in water; their elimination from the body is very efficient.

Vitamin B1 (Thiamine)

Thiamine toxicity is uncommon; as excesses are readily excreted, although long-term supplementation of amounts larger than 3 gram have been known to cause toxicity.

Vitamin B2 (Riboflavin)

The limited capacity to absorb orally administered riboflavin precludes its potential for harm. Riboflavin intake of many times the RDA is without demonstrable toxicity. A normal yellow discoloration of the urine is seen with an increased intake of this vitamin - but it is normal and harmless.

Vitamin B6 (Pyridoxine)

Supplementation should be controlled as extreme dosage, such as in excess of 2,000 mg per day, may cause neurological damage. People on medication for Parkinson's disease should be careful about taking Vitamin B6 as it can inactivate levodopa.

Vitamin B9 (Folic acid)

Too much folic acid may mask a Vitamin B12 deficiency. Regular high intake of folic acid may cause digestive upset, energy loss and insomnia.

B_{12} (Cyanocobalamin)

Toxicity not established.

6. Pharmaceutical Particulars

6.1 List of Excipients

Maltodextrin, Maltitol, Citric acid monohydrate, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Thiourea, Aspartame, Vitamin E Dry Powder, Magnesium stearate, Flavour Capsil vanilla, Flavour Capsil American Ice cream & Flavour Capsil Butter scotch.

6.2 Incompatibilities

None

6.3 Shelf-Life

24 months

6.4 Special Precautions for storage

Store below 30°C. Protected from light. KEEP OUT OF REACH OF CHILDREN

6.5 Nature and Content of container

5 g printed poly laminated aluminium foil sachet, 10 such sachets packed in an outer carton with package insert.

6.6 Special precautions for disposal and other handling

None

7. Marketing Authorization Holder

Prisma Pharma FZE
P.O.Box 17269
Jebel Ali Free Zone
Dubai,
U.A.E.

8. Marketing Authorization Number

H2010/19953/552/R1

9. Date of first authorization/renewal of the authorization

29/03/2026

10. Date of revision of the text

29/03/2026