PROFESSIONAL INFORMATION

SCHEDULING STATUS
To be assigned

PROPRIETARY NAME AND DOSAGE FORM
InsuMax-Q Tablets and Capsule

COMPOSITION
InsuMax-Q is comprised of 3 Components:

Component 1:

Each Light Yellow Inositol & B-Complex Combination Tablet contains	
Inositol (as Myo-Inositol)	1 000 mg
Inositol (as D-Chiro-Inositol)	25 mg
Folate (derived from 5-Methyltetrahydrofolate-S as Active Extrafolate-S®)	500 µg
Vitamin B6 (derived from Pyridoxine Hydrochloride)	25 mg
Vitamin B12 (derived from Cyanocobalamin)	25 µg

Excipients: Flexicoat® light yellow, magnesium stearate (vegetable), maize starch, microcrystalline cellulose, povidone, shellac, silicon dioxide

Component 2:

Each White Co-Enzyme Q10 & Magnesium Combination Capsule contains	
Co-Enzyme Q10 (as Ubidecarenone)	150 mg
Magnesium (derived from Magnesium oxide)	150 mg
Vitamin D3 (as Cholecalciferol)	1 000 IU

Excipients: hard-gel vegetable capsule, magnesium stearate (vegetable), maize starch, silicon dioxide

Component 3:

Each Orange Amino Acid & Anti-Oxidant Combination Tablet contains	
Amino Acids	
L-Arginine (derived from L-Arginine hydrochloride)	800 mg
L-Carnitine (as L-Carnitine-L-Tartrate)	125 mg
Anti-Oxidants	
Alpha Lipoic Acid (as Alpha Lipoic Acid)	50 mg
Vitamin C (as Ascorbic acid)	250 mg
Vitamin E (as dl-αTocopherol)	20 IU
Selenium (derived from Selenium Amino Acid Chelate)	60 µg
Zinc (derived from Zinc Oxide)	25 mg

Excipients: Flexicoat® orange, magnesium stearate (vegetable), maize starch, microcrystalline cellulose, povidone, shellac, silicon dioxide

PHARMACOLOGICAL CLASSIFICATION
Complementary Medicine: Health Supplement
34.12 Multiple substance formulation

PHARMACOLOGICAL ACTION
Pharmacodynamics:

Alpha Lipoic Acid: Alpha Lipoic Acid is a naturally-occurring sulphur-containing cofactor, which functions as a potent anti-oxidant and cofactor for various enzymes in energy-producing metabolic reactions of the Krebs cycle. It also appears to improve recycling of other anti-oxidant compounds, including Vitamin C, Vitamin E and Co-Enzyme Q10.

L-Arginine: L-Arginine plays a role in the formation of important physiologic factors, including nitric oxide (NO, a vasodilator), urea (an excretory product), creatine (required for storage of high-energy phosphates), all proteins (as a part of the structures), and growth hormone release.

L-Carnitine: Carnitine regulates long-chain fatty acid transport across cell membranes; facilitates beta-oxidation of long-chain fatty acids and keto acids; and transportation of acyl CoA compounds. L-Carnitine is also thought to have anti-oxidant properties as it helps to support fat metabolism and oxidation.

Co-Enzyme Q10: Co-enzyme Q10 is involved in electron transport and supports synthesis of adenosine triphosphate (ATP) in the mitochondrial membrane and thus plays a vital role in intracellular energy production. It is a fat-soluble anti-oxidant that helps to stabilise cell membranes, preserving cellular integrity and function. It also helps to regenerate Vitamin E to its anti-oxidant form. It has immune-stimulant activity.

Folic Acid: Folates are involved in a number of single carbon transfer reactions, especially in the synthesis of purines and pyrimidines (and hence the synthesis of deoxyribonucleic acid (DNA)), glycine and methionine. They are also involved in some amino acid conversions and the formation and utilisation of formate. Deficiency leads to impaired cell division (effects most noticeable in rapidly regenerating tissues).

Inositol: Plays an important role as the structural basis for a number of secondary messengers in eukaryotic cells, including inositol phosphates, phosphatidylinositol (PI) and phosphatidylinositol phosphate (PIP) lipids.

Magnesium: Magnesium is an essential cofactor for enzymes requiring adenosine triphosphate (ATP) (these are involved in glycolysis, fatty acid oxidation and amino acid metabolism). It is also required for the synthesis of ribonucleic acid (RNA) and replication of deoxyribonucleic acid (DNA); neuromuscular transmission; and calcium metabolism.

Selenium: Selenium functions as an integral part of the enzyme glutathione peroxidase and other seleno-proteins. Glutathione peroxidase prevents the generation of oxygen free radicals that cause the destruction of polyunsaturated fatty acids in cell membranes.

Vitamin B6: Vitamin B6 is converted in erythrocytes to pyridoxal phosphate and, to a lesser extent, pyridoxamine phosphate. It acts as a cofactor for enzymes that are involved in more than 100 reactions affecting protein, lipid and carbohydrate metabolism. Pyridoxal phosphate is also present in the synthesis of several neurotransmitters; the metabolism of several vitamins (e.g. the conversion of tryptophan to niacin); and haemoglobin and sphingosine formation.

Vitamin B12: Vitamin B12 is active in the recycling of folate coenzymes and the degradation of valine. It is also required for nerve myelination, cell replication, haematopoiesis and nucleoprotein synthesis.

Vitamin C: The functions of Vitamin C are based mainly on its properties as a reducing agent. It is required for the formation of collagen and other organic constituents of the intercellular matrix in bone, teeth and capillaries; and the optimal activity of several enzymes. Vitamin C also acts as an antioxidant (reacting directly with aqueous free radicals), which is important in the protection of cellular function and to enhance the intestinal absorption of non-haem iron.

Vitamin D: Vitamin D is essential for promoting the absorption and utilisation of calcium and phosphorus and normal calcification of the skeleton. Along with parathyroid hormone (PTH) and calcitonin, it regulates serum calcium concentration by altering serum calcium and phosphate blood levels as needed, and mobilising calcium from bone. It maintains neuromuscular function and various other cellular processes, including the immune system and insulin production.

Vitamin E: Vitamin E is an antioxidant, protecting polyunsaturated fatty acids in membranes and other critical cellular structures from free radicals and products of oxidation. It works in conjunction with dietary selenium (a cofactor for glutathione peroxidase), and also with vitamin C and other enzymes, including superoxide dismutase and catalase.

Zinc: Zinc is an essential component of over 200 enzymes. It plays an important role in the metabolism of proteins, carbohydrates, lipids and nucleic acids. It is a cofactor in a range of biochemical processes, including the synthesis of DNA, RNA and protein.

INDICATIONS
Nutritional support for conditions where Glucose Metabolism is impaired.

CONTRAINDICATIONS
Hypersensitivity to any of the ingredients, including excipients.

InsuMax-Q should not be used by persons suffering from:
- conditions associated with hypercalcaemia and hypercalciuria, and in renal impairment (chronic);
- renal osteodystrophy with hyperphosphataemia (risk of metastatic calcification);
- Do not use if you have had a previous heart attack/myocardial infarction.

WARNINGS AND SPECIAL PRECAUTIONS
Take 2 hours before or after taking other medications.

The indicated daily dose should not be exceeded.

Not suitable for children unless under the direct supervision of a healthcare provider.

Consult a health care practitioner if your cardiovascular condition worsens.

Consult your health care practitioner prior to use if you are pregnant or breastfeeding.

Consult a health care practitioner prior to use if you have a renal/kidney disease, liver disease, a seizure disorder or if you are following a low protein diet.

Consult a health care practitioner prior to use if you suffer from a cardiovascular disease and are attempting an increase in physical activity.

Consult your health care practitioner prior to use if you taking medication for cardiovascular disease, erectile dysfunction, and/or blood thinners.

Alpha Lipoic Acid should be used with caution in persons predisposed to hypoglycaemia, including persons on antidiabetic medication.

High doses of Co-Enzyme Q10 should be used with caution in patients on Warfarin.

Consumers should discontinue use and consult a healthcare provider if they experience symptoms of low blood sugar such as sweating, paleness, chills, headache, dizziness and/or confusion.

INTERACTIONS
Always check with your Doctor or Pharmacist before taking any medicines if you are pregnant or breastfeeding.
Calcitonin: effect of calcitonin may be antagonised by vitamin D.
Digoxin: caution because hypercalcaemia caused by vitamin D may potentiate effects of digoxin, resulting in cardiac arrhythmias.
Oral Hypoglycaemics and Insulin: alpha lipoic acid could enhance the effects of these drugs.
4-Quinolones: magnesium may reduce absorption of 4-quinolones.
Statins: reduce endogenous synthesis of Co-Enzyme Q10.
Tetracyclines: magnesium may reduce absorption of tetracyclines.
Thiazide diuretics: vitamin D may increase risk of hypercalcaemia.
Vitamin D analogues (alfacalcidol, calcitriol, dihydrotachysterol): increased risk of toxicity with vitamin D supplements.

PREGNANCY AND LACTATION
If you are pregnant or breastfeeding, consult a healthcare practitioner prior to use.

DOSAGE AND DIRECTIONS FOR USE
For oral use.

Morning: Take one Light Yellow Inositol & B-Complex Combination Tablet with Breakfast.

Evening: Take one White Co-Enzyme Q10 & Magnesium Combination Capsule and one Orange Amino Acid & Anti-Oxidant Combination Tablet with Dinner.

Take 2 hours before or after taking other medications.

SIDE EFFECTS
Some people (as a rare exception) may experience gastrointestinal discomfort (such as diarrhoea).

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Vitamin D could (in exceptional circumstances) cause toxicity; the margin of safety is very narrow. There is a wide variation in tolerance to vitamin D.
Excessive intake leads to hypercalcaemia and its associated effects. These include apathy, anorexia, constipation, diarrhoea, dry mouth, fatigue, headache, nausea and vomiting, thirst and weakness. Later symptoms are often associated with calcification of soft tissues and include bone pain, cardiac arrhythmias, hypertension, renal damage (increased urinary frequency, decreased urinary concentrating ability; nocturia, proteinuria), psychosis (rare) and weight loss.
If an overdose is suspected, the medicine should be stopped immediately.

IDENTIFICATION
Component 1: Light Yellow Inositol & B-Complex Combination Tablets
Component 2: White Co-Enzyme Q10 & Magnesium Combination Capsules
Component 3: Orange Amino Acid & Anti-Oxidant Combination Tablets

PRESENTATION
A cardboard carton containing blister strips of 30 Light Yellow Inositol & B-Complex Combination Tablets, 30 White Co-Enzyme Q10 & Magnesium Combination Capsules and 30 Orange Amino Acid & Anti-Oxidant Combination Tablets.

STORAGE INSTRUCTIONS
Store at or below 25 °C.
Protect from light and moisture.
Keep the blister strips in the outer carton.
KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER
To be assigned

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
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This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.