

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-5 as Active Extrafolate-5*)	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-α-Tocopherol)	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

AnaStellar Brands (Pty) Ltd
Boskruin Business Park, Unit 15, North Wing, Ground Floor,
Bosbok Road, Randpark Ridge, 2169, Gauteng,
Republic of South Africa
+27 (0)11 792 4601

DATE OF PUBLICATION OF THE PACKAGE INSERT

August 2017

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

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

To be assigned

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

InsuMax-Q Tablets and Capsule

Read all of this leaflet carefully before you start taking InsuMax-Q

InsuMax-Q is available without a doctor's prescription, for you to treat a mild condition.

Nevertheless, you still need to use InsuMax-Q carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share InsuMax-Q with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

WHAT INSUMAX-Q CONTAINS

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-5 as Active Extrafolate-S®)	500 µg
Vitamin B6 (derived from Pyridoxine Hydrochloride)	25 mg
Vitamin B12 (derived from Cyanocobalamin)	25 µg

The other ingredients are 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

The other ingredients are 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-α-Tocopherol)	20 IU
Selenium (derived from Selenium Amino Acid Chelate)	60 µg
Zinc (derived from Zinc Oxide)	25 mg

The other ingredients are Flexicoat® orange, magnesium stearate (vegetable), maize starch, microcrystalline cellulose, povidone, shellac, silicon dioxide

WHAT INSUMAX-Q IS USED FOR

Nutritional support for conditions where Glucose Metabolism is impaired.

BEFORE YOU TAKE INSUMAX-Q

Do not take INSUMAX-Q if:

- Hypersensitive (allergic) to any of the ingredients of INSUMAX-Q.
- You suffer from chronic kidney disease or if you have high levels of calcium in either your blood or urine.
- You suffer from renal osteodystrophy with hyperphosphataemia (a bone disease caused by incorrect functioning of the kidneys).
- You have had a previous heart attack.

Take special care with INSUMAX-Q:

Take INSUMAX-Q 2 hours before or after taking any other medication.

Do not take more than the recommended dose.

This medicine is not suitable for use by children unless their treatment is being monitored by a healthcare practitioner.

Inform your doctor if you have or have had the following conditions before starting to use this medicine:

- Renal/kidney disease
- Liver disease
- A condition which causes seizures e.g. epilepsy

Inform your healthcare practitioner before using this medicine if:

- you are following a low protein diet
- you suffer from a heart disease and are planning on increasing your level of physical activity
- You are taking medicine to treat heart disease, erectile dysfunction and/or blood thinners

Taking INSUMAX-Q with food and drink:

INSUMAX-Q should be taken with food.

Pregnancy and breastfeeding:

Tell your healthcare practitioner if you are pregnant or breastfeeding before using this medicine.

Taking other medicines with INSUMAX-Q:

Always tell your healthcare professional if you are taking any other medicine. This includes complementary or traditional medicines.

Calcitonin (a hormone): effect of calcitonin may be antagonised by vitamin D.

Digoxin (a medicine used to treat heart failure): caution because hypercalcaemia caused by vitamin D may potentiate effects of digoxin, resulting in cardiac arrhythmias.

Oral Hypoglycaemics and Insulin (medicines used for diabetes): alpha lipoic acid could enhance the effects of these drugs.

4-Quinolones (a group of antibiotics): magnesium may reduce absorption of 4-quinolones.

Statins: reduce endogenous synthesis of Co-Enzyme Q10.

Tetracyclines (a type of antibiotic): magnesium may reduce absorption of tetracyclines.

Thiazide diuretics (a medicine used to treat high blood pressure and water retention/swelling): vitamin D may increase risk of hypercalcaemia.

Vitamin D analogues (alfacalcidol, calcitriol, dihydrotachysterol): increased risk of toxicity with vitamin D supplements.

HOW TO TAKE INSUMAX-Q

Do not share medicines with any other person.

You should check with your doctor or pharmacist if you are unsure on how to use INSUMAX-Q.

The usual dose is one light yellow tablet in the morning with breakfast and then one orange tablet and one white capsule in the evening with dinner.

Take 2 hours before or after taking other medications.

INSUMAX-Q should be taken daily for as long as your Healthcare Professional indicates for you to use it for.

If you take more INSUMAX-Q than you should:

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of INSUMAX-Q:

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

POSSIBLE SIDE EFFECTS

INSUMAX-Q can have side effects.

Not all side effects reported for INSUMAX-Q are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

You may experience (in exceptional circumstances) nausea, diarrhoea, constipation, indigestion, bloating and flatulence while taking INSUMAX-Q.

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

STORING AND DISPOSING OF INSUMAX-Q

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light and moisture.

Keep the blister strips in the outer carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF INSUMAX-Q

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.

IDENTIFICATION OF INSUMAX-Q

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

REGISTRATION NUMBER

To be assigned

NAME AND ADDRESS OF REGISTRATION HOLDER

AnaStellar Brands (Pty) Ltd
Boskruin Business Park, Unit 15, North Wing, Ground Floor,
Bosbok Road, Randpark Ridge, 2169, Gauteng,
Republic of South Africa
+27 (0)11 792 4601

DATE OF PUBLICATION

August 2017

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