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ADMINISTRATIVE INFORMATION FOR OLIGOCARE TABLETS

1.5.1 SUMMARY OF PRODUCT CHARECTERISTICS

1. NAME OF MEDICINAL PRODUCT
Oligocare Tablets

2. QUALITATIVE QUANTITATIVE FORMULA

ITEM	DRUG NAME	SCALE MG PER TABLET	STD QTY PER 1000 TAB	FUNCTION
1	**AMINO ACID GRANULATION:**			
2	L-Carnitine Tartrate	50 mg	50.000 g	Active
3	L-Arginine USP	10 mg	10.000 g	Active
4	L- Glutathione BP	2.5 mg	2.500 g	Active
5	Microcrystalline Cellulose BP (PH 101)	50 mg	50.000 g	Diluent
6	Ethylcellulose USP (10 cps)	4.5 mg	4.500 g	Coating agent
7	Methylene Chloride	q.s.	Approx 70.000 g	Solvent
	MINERAL GRANULATION:			
8	Elemental Zinc Use: Zinc Sulphate Monohydrate USP	7.5 mg 20.5875 mg	20.588 g	Active
9	Elemental Selenium Use: Sodium Selenate Anhydrous	100 mcg 0.239 mg	0.239 g	Active
10	Elemental Iron Use: Ferrous Fumarate BP	5 mg 15.21 mg	15.210 g	Active
11	Elemental Copper Use: Copper Sulphate Pentahydrate USP Copper Sulphate (In House Dried)	1 mg 3.929 mg 2.795 mg	3.929 g 2.795 g	Active

12	Elemental Manganese Use: Manganese Sulphate Monohydrate USP	2 mg 6.152 mg	6.152 g	Active
13	Dibasic Calcium Phosphate BP	22.98 mg	22.980 g	Diluent
14	Microcrystalline Cellulose BP (PH 101)	50 mg	50.000 g	Diluent
15	Polyvinylpyrrolidone BP (PVP K-30)	7 mg	7.000 g	Binder
16	Maize Starch BP (for paste)	10.47 mg	11.00 g	Binder
17	Purified Water BP	q.s.	Approx. 50.000 g	Solvent
	VITAMIN GRANULATION:			
18	Folic Acid BP (Contains 100% Excess)	250 mcg	0.500 g	Active
19	Thiamine Nitrate BP (Vitamin B1) (Contains 50% Excess)	5 mg	7.500 g	Active
20	Pyridoxine Hydrochloride BP (Contains 40% Excess)	5 mg	7.000 g	Active
21	Ginseng Extract Use: Siberian Ginseng Extract (0.8%)	10 mg	10.000 g	Active
22	Vitamin E Acetate BP# Use: Vitamin E Acetate (50% Dry Powder) (Contains 30% Excess)	12.5 mg 25 mg	32.500 g	Active
23	Dibasic Calcium Phosphate BP	50 mg	50.000 g	Diluent
24	Polyvinylpyrrolidone BP (PVP K-30)	6.5 mg	6.500 g	Binder
25	Maize Starch (Dried)	23.5 mg	23.500 g	Diluent
26	Isopropyl Alcohol BP	q.s.	Approx 50.000 g	Solvent
	COENZYME Q 10 GRANULATION:			
27	Ubidecarenone USP-NF (Coenzyme Q10) (Contains 20% Excess)	2.5 mg	3.000 g	Active

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28	Polysorbate 80 BP (Tween 80)	3 mg	3.000 g	Solubilizing agent
29	Ascorbic Acid BP	0.5 mg	0.500 g	Antioxidant
30	Disodium Edetate BP	3 mcg	0.003 g	Chelating agent
31	Purified Water BP	q.s.	Approx. 2.500 g	Solvent
32	Stearic Acid BP	9.2 mg	9.200 g	Lubricant
33	Microcrystalline Cellulose BP (PH 101)	15 mg	15.000 g	Diluent
34	Dibasic Calcium Phosphate BP	15 mg	15.000 g	Diluent
35	Colloidal Anhydrous Silica BP	2 mg	2.000 g	Glidant
	LUBRICATION:			
36	Vitamin C Use: Vitamin C (96% coated) (Contains 90% Excess)	75 mg 78.125 mg	148.438 g	Active
37	Vitamin A Use: Vitamin A Acetate BP (500 IU/mg) (Contains 50% Excess)	1250 IU 2.5 mg	3.750 g	Active
38	Methylcobalamin (Contains 140% Excess)	750 mcg	1.800 g	Active
39	Lycopene Use: Lycopene 6% Beadlets	2 mg 33.333 mg	33.333 g	Active
40	Maize Starch (Dried)	15 mg	15.000 g	Diluent
41	Sodium Starch Glycolate BP	24 mg	24.000 g	Disintegrant
42	Microcrystalline Cellulose BP (PH 102)	158 mg	158.000 g	Diluent
43	Colloidal Anhydrous Silica BP	11.4 mg	11.400 g	Glidant
44	Purified Talc BP	7.5 mg	7.500 g	Lubricant
45	Magnesium Stearate BP	7.5 mg	7.500 g	Lubricant
	PROTECTIVE COATING			
46	Insta Moistshield (IC-MS-5950)	12.5 mg	12.500 g	
47	Isopropyl Alcohol BP	q.s.	Approx	Solvent

			90.000 g	
48	Methylene Chloride	q.s.	Approx 160.000 g	Solvent
	COLOUR COATING			
49	Wincoat WT- 01912 Brown	22.5 mg	22.500 g	Colour coating material
50	Isopropyl Alcohol BP	q.s.	Approx 195.000 g	Solvent
51	Methylene Chloride	q.s.	Approx 360.000 g	Solvent

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3. PHARMACEUTICAL FORM
Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Indications of Oligocare are following:
- Increases sperm count
- Improves sperm motility
- Improves sperm morphology
- Reduces oxidative stress
- Corrects nutritional deficiency associated with male infertility

4.2 Posology and method of administration
As directed by Physician

4.3 Contraindications
Contraindicated in patients with hypersensitivity to any of the ingredients used in the formulation of Oligocare.

4.4 Special warnings and precautions for use
None

4.5 Fertility, pregnancy and lactation
The drug in not recommended in pregnant & breast feeding women

4.6 Effects on ability to drive and use machines
None

4.7 Overdose
Do not exceed the recommended doses. In case of overdosage consult the physician immediately.

4.8 Interaction with other medicinal products and other forms of interactions
Drug-drug interaction is a situation in which another drug affects the activity of a drug when both are administered together. This drug interacts with the following drugs and drug classes:

Anticoagulant e.g. warfarin

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Drugs for diabetes

Drugs for high cholesterol (e.g. atorvastatin, lovastatin)

Drugs for high blood pressure

Other drugs like anisindione, dicumarol, Miradon (anisindione)

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5. Pharmacological properties

5.1 Pharmacodynamic properties

Mechanism of Action of Zinc
Zinc acts as a cofactor for more than 70 different enzymes. Zinc dependent enzymes are involved in the metabolism of carbohydrates, lipids, and proteins. Zinc facilitates wound healing, normal growth rates, normal skin hydration and maintains senses of taste and smell. It provides normal growth and tissue repair. It also helps in development of cell mediated immunity

Mechanism of Action of Vitamin C
Vitamin C exerts it`s action by influencing the biologic oxidations and reductions used in cellular respirations. It directly stimulates collagen synthesis and maintains intracellular connective tissue. It involves in various metabolic reactions such as 1).Hydroxylation of praline and lysine residues of protocollagen which is essential for formation and stabilization of collagen triple helix,2).hydroxylation of carnitine, 3).Conversion of folic acid to folinic acid, 4).biosynthesis of adrenal steroids, catecholamine's, oxytocin, and ADH, 5).Metabolism of cyclic nucleotides and prostaglandins. Vitamin C is important in resistance to infections.

Mechanism of Action of Vitamin B-Complex
Vitamin B-complex are group of vitamins, which include Thiamine (B1),Riboflavin (B2),Niacin(B3), Pantothenic acid (B5), Pyridoxine (B6), Cyanocobalamin (B12), Folic acid and Biotin.These vitamins are essential for the breakdown of carbohydrates into glucose (this provides energy for the body), the breakdown of fats and proteins (which aids the normal functioning of the nervous system), muscle tone in the stomach and intestinal tract, Skin, Hair, Eyes, Mouth and Liver

L-Arginine:
L-Arginine (2-amino-5-guanidinovaleric acid) is the precursor of nitric oxide, an endogenous messenger molecule involved in a variety of endothelium-mediated physiological effects in the vascular system. Acute and chronic administration of L-arginine has been shown to improve endothelial function in animal models of hypercholesterolemia and atherosclerosis. L-Arginine also improves endothelium-dependent vasodilation in humans with hypercholesterolemia and atherosclerosis. The responsiveness to L-arginine depends on the specific cardiovascular disease studied, the vessel segment, and morphology of the artery. The pharmacokinetics of L-arginine have recently been investigated. Side effects are rare and mostly mild and dose dependent. The mechanism of action of L-arginine may involve nitric oxide synthase substrate provision, especially in patients with elevated levels of the endogenous NO synthase inhibitor asymmetric dimethylarginine. Endocrine effects and unspecific reactions may contribute to L-arginine-induced vasodilation after higher doses. Several long-term studies have been performed that show that chronic oral administration of L-arginine or intermittent infusion therapy with L-arginine can improve clinical symptoms of cardiovascular disease in man

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L Carnitine

Levocarnitine can be synthesized within the body from the amino acids lysine or methionine. Vitamin C (ascorbic acid) is essential to the synthesis of carnitine. Levocarnitine is a carrier molecule in the transport of long chain fatty acids across the inner mitochondrial membrane. It also exports acyl groups from subcellular organelles and from cells to urine before they accumulate to toxic concentrations. Only the L isomer of carnitine (sometimes called vitamin BT) affects lipid metabolism. Levocarnitine is handled by several proteins in different pathways including carnitine transporters, carnitine translocases, carnitine acetyl transferases and carnitine palmitoyltransferases

L- Glutathione

GSH is an extremely important cell protectant. It directly quenches reactive hydroxyl free radicals, other oxygen-centered free radicals, and radical centers on DNA and other biomolecules. GSH is a primary protectant of skin, lens, cornea, and retina against radiation damage and other biochemical foundations of P450 detoxification in the liver, kidneys, lungs, intestinal, epithelia and other organs.

GSH is the essential cofactor for many enzymes that require thiol-reducing equivalents, and helps keep redox-sensitive active sites on enzyme in the necessary reduced state. Higher-order thiol cell systems, the metallothioneins, thioredoxins and other redox regulator proteins are ultimately regulated by GSH levels—and the GSH/GSSG redox ratio. GSH/GSSG balance is crucial to homeostasis—stabilizing the cellular biomolecular spectrum, and facilitating cellular performance and survival.

5.2 Pharmacokinetic properties

L-carnitine

Absorption Absolute bioavailability is 15% (tablets or solution). Time to maximum plasma concentration was found to be 3.3 hours.

Distribution

The steady state volume of distribution (Vss) of an intravenously administered dose, above endogenous baseline levels, was calculated to be 29.0 +/- 7.1L. However this value is predicted to be an underestimate of the true Vss.

Elimination:

Following a single intravenous dose, 73.1 +/- 16% of the dose was excreted in the urine during the 0-24 hour interval. Post administration of oral carnitine supplements, in addition to a high carnitine diet, 58-65% of the administered radioactive dose was recovered from urine and feces in 5-11 days.

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Zinc Sulphate
Absorption: Poorly absorbed orally.
Distribution: Zinc is distributed mainly in to skeletal muscle, skin, bone, pancreas, kidney, liver, retina, prostate, RBC, and WBC.
Excretion**:** Excreted mainly through intestine; only 2% loss in the urine.

Vitamin A
Except when liver function is impaired, Vitamin A is readily absorbed. B-carotene is Provitamin A and is the biological precursor to Vitamin A. It is converted to Vitamin A (Retinol) in the liver; retinol is emulsified by bile salts and phospholipids and absorbed in a micellar form. Part is conjugated with glucuronic acid in the kidney and part is metabolised in the liver and kidney, leaving30 to 50% of the dose for storage in the liver. It is bound to a globulin in the blood. Metabolites of Vitamin A are excreted in the faeces and the urine.

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 (Riboflavine)
Riboflavine 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. In the body riboflavin is converted to flavine mononucleotide (FMN) and then to flavine adenine dinucleotide (FAD).

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.

Vitamin C (Ascorbic Acid)
Ascorbic acid is readily absorbed from the gastro-intestinal tract and is widely distributed in the body tissues. Ascorbic acid in excess of the body's needs is rapidly eliminated in the urine and this elimination is usually accompanied by a mild diuresis.

Vitamin E
Vitamin E is absorbed from the gastro-intestinal tract. Most appears in the lymph and is then widely distributed to all tissues. Most of a dose is slowly excreted in the bile and the remainder is eliminated in the urine as glucuronides of tocopheronic acid or other metabolites.

Folic Acid

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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.

Selenium
Although it has been established that selenium is essential to human life, very little information is available on its function and metabolism.

Copper Sulfate (Copper)
Copper is absorbed from the gastro-intestinal tract and its major route of excretion is in the bile

Magnesium Oxide (Magnesium)
Magnesium salts are poorly absorbed from the gastro-intestinal tract; however, sufficient magnesium
will normally be absorbed to replace deficiency states. Magnesium is excreted in both the urine and the faeces but excretion is reduced in deficiency states.

Manganese Sulfate (Manganese)
Manganese salts are poorly absorbed.
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6. Pharmaceutical particulars
6.1 List of excipients
Microcrystalline Cellulose (pH101)
Microcrystalline Cellulose (pH102)
Ethyl cellulose (10 cps)
Methylene Chloride
Dibasic Calcium Phosphate
Polyvinylpyrrolidone (PVP K-30)
Maize Starch
Purified Water
Maize Starch (Dried)
Polysorbate 80
Ascorbic Acid
Disodium Edetate
Stearic Acid
Colloidal Anhydrous Silica
Sodium Starch Glycolate
Purified Talc
Magnesium Stearate

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Instamoist shield IC-MS-5950
Isopropyl Alcohol BP
Wincoat WT- 01912 Brown

6.2 Incompatibilities
None

6.3 Shelf life
24 months

6.4 Special precautions for storage
Store below 30 ^{0}C.