

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1.NAME OF FINISHED PHARMACEUTICAL PRODUCT:

FERTILION - M

(Lycopene, Coenzyme Q 10, Multivitamins, Mineral, Amino acids with Korean ginseng Capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

2.1 Qualitative Declaration:

S.No	Ingredients	Function
1	Lycopene 6%	Antioxidant
2	Co-enzyme Q 10	Antioxidant
3	L-Glutathione	Antioxidant
4	Vitamin E	Vitamin
5	Vitamin C	Vitamin
6	L-Carnitine	Amino Acids
7	Zinc	Anti-Inflammatory Properties
8	Vitamin B9	Mineral
9	Iron	Vitamin
10	Vitamin B6	Mineral
11	Manganese	Vitamin
12	Selenium	Mineral
13	Vitamin D3	Mineral
14	Vitamin B1	Vitamin
15	Thiamine Nitrate	Vitamin
16	Methylcobalamine	Vitamin
17	Retinol	Vitamin
18	Light Magnesium Oxide	Emulsifying agent
19	Butylated Hydroxy anisole	Anti oxidant
20	Butylated Hydroxy toluene	Anti oxidant
21	Hydrogenated Vegetable oil	Suspending agent
22	Lecithin	Emollient
23	Refined soya oil	Diluent

SHELL MATERIALS

S.No	Ingredients	Function
24	Gelatin	Gelling Agent
25	Glycerol	Plasticizer
26	Liquid Sorbitol (Non-Crystallizing)	Plasticizer
27	Methyl Hydroxy Benzoate	Preservative
28	Fumaric Acid	Acidity Regulator
29	Red oxide of iron	Colouring Agent
30	Black oxide of iron	Colouring Agent
31	Purified Water	Solvents

2.2 Quantitative Declaration :

2, 50,000 capsules

S.No	Ingredients	Label claim mg/cap	Overage in %	Added mg/ cap	Added kg/ batch	Function
FILL MATERIALS						
1.	Lycopene 6%	10.00	10	183.340	45.835	Antioxidant
2.	Co-enzyme Q 10	50.00	10	55.000	13.750	Antioxidant
3.	L-Glutathione	50.00	---	50.000	12.500	Antioxidant
4.	Vitamin E	12.50	5	---	---	Vitamin
	As dl alpha tocopheryl acetate			13.125	3.281	
5.	Vitamin C	75	10	---	---	Vitamin
	As Ascorbic acid			82.500	20.625	
6.	L-Carnitine	50.00	---	50.000	12.500	Amino Acids
7.	Korean Ginseng Extract	10.00	---	10.000	2.500	Anti-Inflammatory Properties
8.	Zinc	7.50	---	---	---	Mineral
	as Zinc sulphate Monohydrate			20.600	5.150	
9.	Vitamin B9	1.50	50	---	---	Vitamin
	As Folic Acid			2.250	0.563	
10.	Iron	5.00	---	---	---	Mineral
	as Ferrous fumarate			15.215	3.804	
11.	Vitamin B6	5.00	10	---	---	Vitamin
	As Pyridoxine HCl			5.500	1.375	

12.	Manganese	2.00	---	---	---	Mineral
	As Manganese sulphate monohydrate			6.152	1.538	
13.	Selenium	100mcg	---	---	---	Mineral
	As Selenious acid			0.163	40.750 gm	
14.	Vitamin D3	12.5mcg	30	0.016	4.063 gm	Vitamin
15.	Vitamin B1	5.00mg	15	---	---	Vitamin
	Thiamine Nitrate			5.750	1.438	
16.	Methylcobalamine	750mcg	50	1.125	281.250 gm	Vitamin
17.	Retinol	375mcg	10	---	---	Vitamin
	As Vitamin A Palmitate			0.808	0.202	
18.	Light Magnesium Oxide	---	---	30.000	7.500	Emulsifying agent

S.No	Ingredients	Label claim mg/cap	Overage in %	Added mg/ cap	Added kg/ batch	Function
19.	Butylated Hydroxy anisole	---	---	0.080	20.000 gm	Anti oxidant
20.	Butylated Hydroxy toluene	---	---	0.080	20.000 gm	Anti oxidant
21.	Hydrogenated Vegetable oil	---	---	10.000	2.500	Suspending agent
22.	Lecithin	---	---	20.000	5.000	Emollient
23.	Refined soya oil	---	---	188.296	47.074	Diluent
SHELL MATERIALS¹						
24.	Gelatin ²	---	---	212.735	53.184	Gelling Agent
25.	Glycerol	---	---	79.157	19.789	Plasticizer
26.	Liquid Sorbitol (Non-Crystallizing)	---	---	24.737	6.184	Plasticizer
27.	Methyl Hydroxy Benzoate	---	---	0.693	0.173	Preservative
28.	Fumaric Acid	---	--	2.474	0.619	Acidity Regulator
29.	Red oxide of iron	---	---	1.113	0.278	Colouring Agent
30.	Black oxide of iron	---	---	3.092	0.773	Colouring Agent
31.	Purified Water	---	---	36.000	9.000	Solvents

¹ In the batch formula excess material is added to compensate process loss. Process loss due to Cooking tank wastages, Placebo wastages, Service tank/spreader box retention, Net Wastage

² Gelatin is derived from Bovine bones free from skulls, spinal cord and vertebrae. Country of origin – India.

Abbreviation:

BP : British Pharmacopoeia

USP : United States Pharmacopoeia

IHS : In-House Specification

1 Current pharmacopoeial monographs are implied.

2 In the batch formula excess material is added to compensate process loss. Process loss due to Cooking tank wastages, Placebo wastages, Service tank/spreader box retention, Net Wastage & Miscellaneous

3 Gelatin is derived from Bovine bones free from skulls, spinal cord and vertebrae. Country of origin – India.

3. PHARMACEUTICAL FORM

Brown coloured oblong shaped opaque soft gelatin capsules containing red coloured oily mass.

4. CLINICAL PARTICULARS**4.1 Therapeutic indications**

Increases sperm count and semen volume

Improves sperm quality and motility

Improves sperm morphology

Reduces Oxidative stress

Prevents spermatozoa from oxidative damage

Enhances male fertility

Improves overall reproductive health

Beneficial for treating Oligospermia

Maintains normal hormonal balance

Improves testosterone production

4.2 Posology and method of administration

Dosage:

As directed by the Physician

Method of administration: Oral

4.3 Contraindications

Fertilion-M, is contraindicated if the user is known to be hypersensitivity to any of the ingredient in the formulation.

4.4 Special Warning & Precaution for use

Special Warning: Keep out of reach of children.

Precaution: Not recommended.

4.5 Interaction with other medicinal products and other forms of Interactions:

Coenzyme Q 10

Coenzyme Q10 may help to reduce the toxic effects on the heart caused by daunorubicin (Cerubidin) and doxorubicin (Adriamycin), two chemotherapy medications that are commonly used to treat several kinds of cancer.

Methylcobalamin

Drugs such as metformin, proton pump inhibitors and H2 receptor antagonist can interfere with the absorption of Methylcobalamin

Folic Acid

Drugs that can interfere with folic acid metabolism include cimetidine, antacids, and sulfasalazine. Folic acid can increase the metabolism of anti-seizure medications, including carbamazepine and Phenobarbital. Phenytoin and valproic acid appear to interfere with folate absorption

Pyridoxine

Pyridoxine in doses of 5 mg or more daily may appreciably reverse the effects of levodopa (Drugdex Evaluation, Pyridoxine).

Pyridoxine should not be co administered with altretamine as it alters the results of altretamine (Drugdex Evaluation, Pyridoxine).

Metabolism of Phenobarbital and phenytoin is increased if co administered with

Pyridoxine Co administration of pyridoxine with amiodarone might increase the chances of sunburn, blistering, or rashes on areas of skin exposed to sunlight

4.6 Pregnancy and lactation

If you are pregnant, may become pregnant, breastfeeding, or are undergoing treatment for cancer, consult your health care professional before using this product

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable effects

Ingredients present in Fertilion-M are generally well tolerated but mild side effects like nausea, headache etc might be observed.

4.9 OVERDOSE

No data available

5- PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties

Lycopene

Studies using human and animal cells have identified a gene, connexin 43, whose expression is upregulated by lycopene and which allows direct intercellular gap junctional communication (GJC). GJC is deficient in many human tumors and its restoration or upregulation is associated with decreased proliferation. The combination of low concentrations of lycopene with 1,25-dihydroxyvitamin D3 exhibits a synergistic effect on cell proliferation and differentiation and an additive effect on cell cycle progression in the HL-60 promyelocytic leukemia cell line, suggesting some interaction at a nuclear or subcellular level.

Ascorbic Acid:

Ascorbic Acid (vitamin C) is a water-soluble vitamin indicated for the prevention and treatment of scurvy, as ascorbic acid deficiency results in scurvy. Collagenous structures are primarily affected, and lesions develop in bones and blood vessels. Administration of ascorbic acid completely reverses the symptoms of ascorbic acid deficiency. Ascorbic acid is reversibly oxidized to dehydroascorbic acid in the body. These two forms of the vitamin are believed to be important in oxidation-reduction reactions.

Folic Acid:

Folic acid is helpful in regulating homocysteine levels, promoting ovarian and smooth functioning and improve PCOS symptoms. Folic acid may help treat ovulatory infertility-one of the major complications of PCOS. As with all pregnant women, pregnant women with PCOS need to get sufficient folic acid to prevent neural tube defects.

Selenium:

Selenium improves insulin sensitivity and lipids in women with PCOS. So, the rational use of nutritional supplements, combined with a healthy diet, will contribute substantially to health promotion and work in balance and synergism on protection and integration of the physiological functions of the body.

Vitamin E

Vitamin E deficiency has been linked to disorders such as cystic fibrosis where fat absorption is impaired. It is essential for the normal function of the muscular system and the blood.

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.

Selenium

Selenium is an essential trace element, deficiency of which has been reported in man. It is thought to be involved in the functioning of membranes and the synthesis of amino acids. Deficiency of selenium in the diet of experimental animals produces fatty liver followed by necrosis.

5.2 Pharmacokinetic Properties

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.

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.

Methylcobalamine

Evidence indicates methylcobalamin is utilized more efficiently than cyanocobalamin to increase levels of one of the coenzyme forms of vitamin B12. Experiments have demonstrated similar absorption of methylcobalamin following oral administration. The quantity of cobalamin detected following a small oral dose of methylcobalamin is similar to the amount following administration of cyanocobalamin; but significantly more cobalamin accumulates in liver tissue following administration of methylcobalamin. Human urinary excretion of methylcobalamin is about one third that of a similar dose of cyanocobalamin, indicating substantially greater tissue retention

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

Human pharmacokinetic studies indicate folic acid has very high bioavailability, with large oral doses of folic acid substantially raising plasma levels in healthy subjects in a time- and dose-dependent manner. Subsequent to high-dose oral administration of folic acid (ranging from 25-1,000 mg/day), red blood cell (RBC) folate levels remain elevated for periods in excess of 40 days following discontinuation of the supplement. Folic acid is poorly transported to the brain and rapidly cleared from the central nervous system. The primary methods of elimination of absorbed folic acid are fecal (through bile) and urinary

Selenium

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

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS:

6.1 List of Excipients

S.No	INGREDIENTS
1.	Light Magnesium Oxide
2.	Butylated Hydroxy anisole
3.	Butylated Hydroxy toluene
4.	Hydrogenated Vegetable oil
5.	Lecithin
6.	Refined soya oil
7.	Gelatin
8.	Glycerol
9.	Liquid Sorbitol (Non-Crystallizing)
10.	Methyl Hydroxy Benzoate
11.	Fumaric Acid
12.	Red oxide of iron
13.	Black oxide of iron
14.	Purified Water

6.2 Incompabilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 30 ° C .Protect from direct sunlight .Keep medicines out of reach of children

6.5 Nature and contents of container

30's Blister pack

7. Marketing authorization holder and manufacturing site address

Manufacturing site address

Old Survey No. 20/1, New survey No. 9/810

Vandalur – Kelambakkam Road,

Pudupakkam Village, Kancheepuram District – 603 103, Tamilnadu,India

8. Marketing authorization holder

9. Date of first registration/ renewal of the registration

10. Date of revision of the text –Nil