SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1.NAME OF FINISHED PHARMACEUTICAL PRODUCT:

FERTILION - F
(Myo-Inositol, D-Chiro-Inositol, Folic acid, Vitamin C and Selenium Capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

2.1 Qualitative Declaration:

S.No	Ingredients	Function
1	Inositol (Myo-Inositol)	Vitamin supplement
2	D-Chiro-Inositol	Vitamin supplement
3	Vitamin C (Ascorbic acid)	Vitamin supplement
4	Para amino benzoic acid	Vitamin supplement
5	Vitamin B9 (Folic acid)	Vitamin supplement
6	L-Arginine	Amino acid
7	Vitamin B1 (Thiamine Mononitrate)	Vitamin supplement
8	Vitamin B6(Pyridoxine Hcl)	Vitamin supplement
9	Vitamin B_2(Riboflavin)	Vitamin supplement
10	Methylcobalamin	Vitamin supplement
11	Retinol	Vitamin supplement
12	Vitamin D3	Vitamin supplement
13	Vitamin E (dl alpha tocopheryl acetate)	Vitamin supplement
14	Magnesium	Mineral
15	Zinc	Mineral
16	Iron	Mineral
17	Copper	Mineral
18	Manganese	Mineral
19	Selenium	Mineral
20	Iodine	Mineral
21	Chromium	Mineral
22	Butylated Hydroxy anisole	Anti oxidant
23	Butylated Hydroxy toluene	Anti oxidant

24	Hydrogenated Vegetable oil	Suspending agent
25	Yellow Bees wax	Suspending agent
26	Lecithin	Emollient
27	Refined soya oil	Diluent

SHELL MATERIALS

S.No	Ingredients	Function
28	Gelatin	Gelling Agent
29	Glycerol	Plasticizer
30	Liquid Sorbitol (Non-Crystallizing)	Plasticizer
31	Methyl Hydroxy Benzoate	Preservative
32	Fumaric Acid	Acidity Regulator
33	Red oxide of iron	Colouring Agent
34	Black oxide of iron	Colouring Agent
35	Purified Water	Vehicle

2.2 Quantitative Declaration :

BATCH SIZE: 2, 50,000 capsules

S.No	Ingredients	Label claim mg/cap	Overage in %	Added mg/ cap	Added kg/ batch	Function
FILL MATERIALS						
1.	Inositol (Myo-Inositol)	200.00	---	200.000	50.000	Vitamin supplement
2.	D-Chiro-Inositol	10.00	---	10.000	2.500	Vitamin supplement
3.	Vitamin C (Ascorbic acid)	75.00	10	82.500	20.625	Vitamin supplement
4.	Para amino benzoic acid	12.50	---	12.500	3125.000	Vitamin supplement
5.	Vitamin B9 (Folic acid)	1.50	50	2.250	0.563	Vitamin supplement
6.	L-Arginine	10.00	---	10.000	2.500	Amino acid
7.	Vitamin B1 (Thiamine Mononitrate)	5.00	15	5.750	1.438	Vitamin supplement
8.	Vitamin B6(Pyridoxine Hcl)	5.00	10	5.500	1.375	Vitamin supplement

9.	Vitamin B_2(Riboflavin)	2.50	10	2.750	0.688	Vitamin supplement
10.	Methylcobalamin	500.0 mcg	50	0.750	187.500	Vitamin supplement
11.	Retinol	375.00mcg	10	0.808	0.202	Vitamin supplement
	as Vitamin A Palmitate	---				
12.	Vitamin D3	12.50mcg	30	0.01625	4.063	Vitamin supplement
13.	Vitamin E (dl alpha tocopheryl acetate)	12.50	5	13.125	3.281	Vitamin supplement
14.	Magnesium	25.00	---	41.450	10.363	Mineral
	as Magnesium oxide light	---				
15.	Zinc	10.00	---	---	6.863	Mineral
	as Zinc sulphate monohydrate	---		27.450		
16.	Iron	9.00	---	---	6.847	Mineral
	as Ferrous Fumarate	---		27.387		
17.	Copper	750.00 mcg	---	---	0.737	Mineral
	as Copper sulphate Pentahydrate	---		2.947		
18.	Manganese	1.50 mcg	---	---	0.0012	Mineral
	As Manganese sulphate monohydrate	---		0.00461		
19.	Selenium	100.00mcg	---	---	40.750	Mineral
	As Selenium a	---		0.1630		
20.	Iodine	50.00mcg	---	0.0654	16.350	Mineral
	as Potassium Iodide	---				
21.	Chromium	50.00mcg	---	0.4022	100.550	Mineral
	as Chromium Picolinate	---				
22.	Butylated Hydroxy anisole		---	0.080	20.000	Anti oxidant
23.	Butylated Hydroxy toluene		---	0.080	20.000	Anti oxidant
24.	Hydrogenated Vegetable oil		---	15.000	3.750	Suspending agent
25.	Yellow Bees wax		---	6.000	1.500	Suspending agent
26.	Lecithin		---	20.000	5.000	Emollient
27.	Refined soya oil		---	543.021	135.755	Diluent

SHELL MATERIALS[1]						
28.	Gelatin[2]	---	---	242.290	60.573	Gelling Agent
29.	Glycerol	---	---	90.154	22.539	Plasticizer
30.	Liquid Sorbitol (Non-Crystallizing)	---	---	28.173	7.043	Plasticizer
31.	Methyl Hydroxy Benzoate	---	---	0.789	0.197	Preservative
32.	Fumaric Acid	---	--	2.817	0.704	Acidity Regulator
33.	Red oxide of iron	---	---	1.257	0.314	Colouring Agent
34.	Black oxide of iron	---	---	3.519	0.880	Colouring Agent
35.	Purified Water	---	---	41.000	10.250	Vehicle

Abbreviation:

BP : British Pharmacopoeia

USP : United States Pharmacopoeia

IHS : In-House Specification

1Current 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 yellowish brown coloured oily mass

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Improves pregnancy rate and lower cancellation rate in women with Polycystic Ovary Syndrome .

Restores normal ovulatory activity and fertility in women with Polycystic Ovary Syndrome .

Lowers testosterone levels.

Improves insulin sensitivity.

Decreases luteinizing hormone .

Improves appetite balance .

4.2 Posology and method of administration

Dosage:

As directed by the Physician

Method of administration: Oral

4.3 Contraindications

Fertilion-F, 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:

Inositol

Inositol supplements seem to be well-tolerated by most people. However, mild side effects have been reported with doses of 12 grams per day or higher. These include nausea, gas, difficulty sleeping, headache, dizziness and tiredness. Up to 4 grams of inositol daily has been taken by pregnant women in studies without adverse effects, though more research is needed in this population. There are also not enough studies to determine the safety of the supplements while breastfeeding. However, breast milk seems to be naturally rich in inositol.

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 altertamine (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-F 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

Myo-Inositol

D-myo-Inositol is an insulin-sensitizing supplement that is useful in polycystic ovarian syndrome and other insulin resistant fertility concerns. Inositol has shown favorable results in improving nearly all aspects of PCOS, including insulin sensitivity, reproduction (restores ovulation and improves oocyte quality), hormonal imbalance, (improves androgens) and metabolic issues (inflammation, dyslipidemia, hypertension and weight loss). Insulin resistance and /or compensatory hyperinsulinemia have a central role in the pathogenesis of PCOS. Inositol-phosphogycan (IPG) is a mediator of insulin action. Inositol also serves as a precursor for the synthesis of phosphoinositides, which constitute the phosphatidylinositol signal transduction system involved in the regulation of various cellular functions including cell proliferation. Inositol, along with estradiol in human follicular fluid, also plays a role in follicular maturity and provides a marker of good quality oocytes.

The main functions are:

Inositol improves ovarian activity, insulin sensitivity and fertility in patients with PCOS. Inositol also decrease testosterone and is a marker of good egg quality.

D-chiro-Inositol

D-chiro –inositol helps improve insulin sensitivity, lower free and total testosterone , lower blood pressure and increase the frequency of ovulation

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 pregnanat women, pregnant women with PCOS need to get sufficient folic acid to prevent neutral tube defects.

Selenium:

Selenium improves insulin sensitivity and lipods in women with PCOS. So, th e rational use of nutitional 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.

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

Inositol

Inositol phosphates are synthesized from the parent molecule inositol, with daily dietary consumption of inositol. Once inositol reaches the cells of the intestinal tract, it is phosphorylated to create inositol hexaphosphate, 5,6 and then subsequently dephosphorylated to its lower forms (IP1-5), which play important roles in signal transduction

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

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 riboflavine is converted to flavine mononucleotide (FMN) and then to flavine adenine dinucleotide (FAD).

Iodine

Iodides are absorbed and stored in the thyroid gland as thyroglobulin. Iodides are excreted in the urine with smaller amounts appearing in the faeces, saliva and sweat.

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.	Butylated Hydroxy anisole
2.	Butylated Hydroxy toluene
3.	Hydrogenated Vegetable oil
4.	Yellow Bees wax
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