SUMMARY OF PRODUCT CHARACTERISITICS

1. Name of the Finished Pharmaceutical Product

1.1 Proprietary Name: PRENATAL SOFT GELATIN CAPSULES

1.2. Strength (composition):

Each softgel capsule contains:

Vitamin A 4,000.00 IU

Vitamin D3 400.00 IU

Vitamin B1 (Thiamine Mononitrate) 2.00 mg

Vitamin B2 (Riboflavin) 2.00 mg

Nicotinamide 10.00 mg

Vitamin B6 (Pyridoxine Hydrochloride) 2.00 mg

Calcium Pantothenate 2.00 mg

Folic Acid 0.25 mg

Vitamin C (Ascorbic Acid) 37.50 mg

Vitamin B12 2.00 mcg

Calcium (as Calcium Carbonate) 100.00 mg

Vitamin E 1.00 IU

Iron (as Ferrous Sulphate) 20.00 mg

Copper (as Copper Sulphate) 0.50 mg

Iodine (as Potassium Iodide) 0.05 mg

Magnesium (as Magnesium Sulphate) 1.00 mg

Manganese (as Manganese Sulphate) 0.10 mg

Potassium (as Potassium Sulphate) 1.00 mg

Zinc (as Zinc Sulphat) 0.15 mg

‘For full list of excipients, see section 6.1

1.3. Pharmaceutical dosage form: Soft gelatin capsule

2. Qualitative and quantitative compositions:

2.1. Qualitative Declaration:

2.2. Quantitative Declaration

Name of ingredient	Function	*Quality standard*	Label claim	Overages /capsule)	Quantity/ capsule
Active ingredient:					
Vitamin A Palmitate 1.0 mIU/g 4,000 IU	Active Ingredient	EP Current Edition	4, 000.00 I.U	800.00 IU	4,800.00 IU
Vitamin D3 1.0 mIU/g 400IU	Active Ingredient	EP Current Edition	400.00 I.U	80.00 IU	480.00 IU
Vitamin B1 (Thiamine mononitrate)	Active Ingredient	EP Current Edition	2.00 mg	0.80 mg	2.60 mg
Vitamin B2 (Riboflavin)	Active Ingredient	EP Current Edition	2.00 mg	0.60 mg	2.20 mg
Vitamin B6 (Pyridoxine HCl)	Active Ingredient	EP Current Edition	2.00 mg	0.20 mg	2.20 mg
Vitamin B12 0.1% WS	Active Ingredient	In-house	0.002 mg	0.20 mg	3.00 mg
Vitamin C (Ascorbic acid)	Active Ingredient	EP Current Edition	37.50 mg	18.75 mg	56.25 mg
Calcium pantothenate	Active Ingredient	EP Current Edition	2.00 mg	1.00 mg	3.00 mg
Nicotinamide	Active Ingredient	EP Current Edition	10.00 mg	1.00 mg	11.00 mg
Folic acid	Active Ingredient	EP Current Edition	0.25 mg	0.025 mg	0.275 mg
Vitamin E	Active Ingredient	EP Current Edition	1.00 I.U	0.02 IU	1.02 IU
Ferrous sulphate dried	Active Ingredient	BP Current Edition	20.00 mg	-------	20.00 mg
Copper sulfate anhydrous	Active Ingredient	EP Current Edition	0.50mg	-------	68.00 mg
Magnesium sulphate dried powder	Active Ingredient	USP Current Edition	0.10 mg	-------	0.308 mg
Manganese sulphate monohydrate	Active Ingredient	USP Current Edition	1.00 mg	-------	6.876 mg
Potassium iodide	Active Ingredient	EP Current Edition	0.05mg	-------	1.2557 mg
Potassium sulphate	Active Ingredient	EP Current Edition	1.00 mg	-------	2.23 mg
Zinc sulphate monohydrate	Active Ingredient	USP Current Edition	0.15 mg	-------	0.412 mg
Calcium Carbonate	Active Ingredient	EP Current Edition	100.00 mg	-------	250.00 mg
Inactive ingredient					
Aerosil 200	Suspending	EP Current	-------	-------	4.10 mg

Name of ingredient	Function	*Quality standard*	Label claim	Overages /capsule)	Quantity/ capsule
	agent	Edition			
Vanillin	Flavour enhancer	EP Current Edition	-------	-------	0.60 mg
Lecithim LV	Emulsifying agent	In-house	-------	-------	3.20 mg
Beewax White	Suspending agent	EP Current Edition	-------	-------	39.60 mg
Soyabean Oil	Diluent	EP Current Edition	-------	-------	356.53 mg
Capsule shell:					
Gelatin	Capsule shell	EP Current Edition/ In-house	-------	-------	224.21 mg
Glycerin	Plasticizer	EP Current Edition	-------	-------	114.82 mg
Purified water	Solvent	EP Current Edition	-------	-------	33.53 mg
Brilliant Blue	Coloring agent	In House	-------	-------	0.03 mg
Carmoisine	Coloring agent	In House	-------	-------	0.35 mg
Iron Oxide Red	Coloring agent	USP Current Edition	-------	-------	2.32 mg
Iron Oxide Black	Coloring agent	USP Current Edition	-------	-------	0.87 mg
Vanillin	Flavour enhancer	EP Current Edition	-------	-------	0.87 mg

3. Description:
16 minim, oblong shaped, opaque maroon, soft gelatin capsule

4. Clinical particulars:

4.1. Therapeutic indications:

A supplement to improve overall nutritional health during pregnancy and lactating period. Prenatal provides optimum levels of 19 essential nutrients including Zinc and Folic acid which are important for pregnancy.

4.2. Posology and method of administration:

One capsule daily after meal or as directed by the physician.

4.3. Contra-indications:

Not applicable.

4.4. Special warning and precautions for use:

Not applicable.

4.5. Interaction with other drugs, other forms of interactions:

Not applicable.

4.6. Use in pregnancy and lactation:

Not applicable.

4.7. Effects on ability to drive and operate machine:

Not applicable.

4.8. Undesirable effects:

Not applicable.

4.9. Overdoses:

Not applicable.

5. Pharmacological properties:

5.1. Pharmaco-kinetic properties:

5.2. Pharmaco-dynamic properties:

(Since it is a combination of multivitamin and minerals, it is difficult to define specifically the pharmaco-kinetic & pharmaco-dynamic properties of the individual ingredients.)

5.3. Pre-clinical safety data:

Not applicable.

6. Pharmaceutical particulars:

6.1. List of excipients:

Soybean oil, white beeswax, aerosil 200, lecithin, vanillin, gelatin, glycerin, purified water, iron oxide red, iron oxide black, carmoisine, brilliant blue.

6.2. Incompatibilities:

No.

6.3. Shelf-life:

Two years from manufacturing date.

6.4. Special precautions for storage:

Store below 30°C in a dry place, away from direct sunlight.

6.5. Nature and contents of container:

White round plastic bottle containing 30 capsules.

6.6 Special precaution for disposal and other handling

No special requirements.

7.0 Marketing authorization holder

MEGA LIFESCIENCES Public Company Limited
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8.0 Marketing authorization number: N/A

9.0 Date of first authorization/renewal of authorization: N/A

10. Date of revision of the text: November 2021