Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Femin-9 Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Pyridoxine Hydrochloride Ph. Eur.	75	mg
Ascorbic Acid Ph. Eur	60	mg
Alpha-Tocopheryl Acetate Ph. Eur.	30	IU
Iron (as dried ferrous sulphate Ph. Eur.)	12	mg
Zinc (as zinc sulphate monohydrate Ph. Eur.)	4	mg
Cyanocobalamin Ph. Eur.	2	micrograms
Folic Acid Ph. Eur.	300	micrograms
Iodine (as potassium iodide Ph. Eur.)	140	micrograms
Epanoil	100	mg

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsules, soft
6 minim oval, opaque black, soft gelatin capsules containing an oily, yellow liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For use in the management of symptoms associated with the premenstrual syndrome.

4.2 Posology and method of adminstration

Adults:
One capsule daily for 6 days pre-menses and for the first 2-3 days of menstruation.

Elderly:
Not applicable.

Children:
Not applicable.

Infants and Neonates:
Not applicable.

DO NOT EXCEED THE STATED DOSE.

Method of Administration

Orally.

4.3 Contraindications

i) Use in patients hypersensitive to any ingredient.
ii) Use in patients with undiagnosed anaemia.

4.4 Special warnings and special precautions for use

i) If there is no improvement the doctor should be consulted.
ii) If the patient is on any other medication or has another illness, the physician should confirm that use of the product is safe.

4.5 Interaction with other medicinal products and other forms of interaction

i) Pyridoxine reduces the effects of levodopa.
ii) Zinc may diminish the effect of penicillamine.

4.6 Pregnancy and lactation

i) The product will not be used during pregnancy.
ii) Use during lactation as for adult dose.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Not applicable.

4.9 Overdose

Symptoms of overdosage are unlikely following an acute intake. No data available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ascorbic Acid: Ascorbic Acid (Vitamin C) is an essential vitamin. Severe deficiency produces the classical syndrome of Vitamin C deficiency.

D-L-Alpha-Tocopheryl Acetate: DL-alpha Tocopheryl acetate (vitamin E) is an essential fat-soluble vitamin for the prevention of body tissue oxidation (antioxidant), and is involved in metabolic reaction.

Iron: Iron is an essential constituent of the body and is necessary for haemoglobin formation and for the oxidative processes of living tissue. Iron is important in the reduction of anaemia.

Zinc: Zinc is an essential nutritional element and is a constituent of many enzyme systems and it is an integral constituent of insulin.

Cyanocobalamin: Cyanocobalamin (Vitamin B12) is an essential vitamin, for which the average daily human requirement is between 2-3mcg, and which occurs only in animal products. Strict vegetarians can be Vitamin B12 deficient.

Vitamin B12 metabolites act as co-enzymes in nucleic acid synthesis, and are closely associated with folic acid

in several important metabolic pathways. Vitamin B12 deficiency can result in anaemia.

Folic Acid: Folic Acid is a vitamin.

Iodine: Iodine in the form of potassium iodide is utilised for the alleviation of iodine-deficiency.

Epanoil: Epanoil is a source of the polyunsaturated fatty acids eicosapentaenoic acid and docosahexaenoic acid which can act as precursors for eicosanoid bio-synthesis.

5.2 Pharmacokinetic properties

Pyridoxine: Pyridoxine is readily absorbed from the gastrointestinal tract following oral administration and is converted to pyridoxal phosphate. This is stored mainly in the liver where there is oxidation to 4-pyridoxic acid which is excreted in the urine.
Pyridoxal crosses the placenta and appears in breast milk.

Ascorbic Acid: Ascorbic acid is readily absorbed from the gastrointestinal tract and is widely distributed in the body tissues.

Ascorbic acid is reversibly oxidised to dehydroascorbic acid; some of which is metabolised to ascorbate-2-sulphate, which is inactive and oxalic acid, which is secreted in the urine.

Ascorbic acid in excess of the body's needs is also rapidly eliminated in the urine.

D-L-Alpha-Tocopheryl Acetate: D-L-alpha-tocopheryl acetate absorption from the gastrointestinal tract is dependent upon the presence of bile. It enters the bloodstream via the lymph and is widely distributed in all tissues, and is stored in adipose tissue.

Some Vitamin E is metabolised in the liver to glucuronides and tocopheronic acid and its gamma-lactone and is excreted in the urine. Most vitamin E is slowly excreted in bile. Vitamin E appears in breast milk, but is poorly transported across the placenta.

Iron: Iron is irregularly and incompletely absorbed from the gastrointestinal tract, the main sites of absorption being the duodenum and jejunum.

Iron absorption is usually increased in conditions of iron-deficiency or when given in a fasting state.

The absorption of iron may be reduced in certain disease states.

Zinc: Zinc is poorly absorbed from the gastrointestinal tract, and only a small proportion of dietary zinc is absorbed.

Zinc is distributed widely throughout the body and is excreted in the faeces with only traces appearing in the urine.

Cyanocobalamin: Vitamin B12 binds to intrinsic factor and is then actively absorbed from the gastrointestinal tract. Vitamin B12 is extensively bound to transcobalamins in the plasma, and is transported to all tissues. Vitamin B12 is stored in the liver, excreted in the bile and undergoes enterohepatic recycling. Some is excreted in the urine, most in the first 8 hours following intake. Vitamin B12 diffuses across the placenta and appears in the breast milk.

Folic Acid: Folic acid is absorbed mainly from the proximal part of the small intestine, and is widely distributed in the body tissues. The principal folic acid storage site is the liver. There is an enterohepatic circulation of folate, and about 4 to 5 micrograms are excreted in the urine daily. Folate is distributed into breast milk.

Iodine: Iodine is absorbed through the gastrointestinal tract as Iodide and is trapped by the thyroid gland.

Iodine is excreted mainly in the urine, with smaller amounts appearing in the faeces, saliva and sweat. Iodides readily cross the placenta and appear in breast milk.

Epanoil: Epanoil is a source of polyunsaturated fatty acids, eicosapentaenoic acid and docosahexaenoic acid.

Polyunsaturated fatty acids are readily absorbed in the small intestinal section of the gastrointestinal tract, and are widely distributed throughout the body in membrane phospholipids.

5.3 Preclinical safety data

There are no preclinical safety data of relevance which are additional to those already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

a) Fill Ingredients
Hydrogenated vegetable oil
Soya lecithin (E322)
Beeswax (E901)

b) Shell Ingredients
Gelatine
Glycerol
Black iron oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Three years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

White polypropylene tubs with blue polypropylene caps, with bore seals and containing 30 capsules.

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Seven Seas Limited
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HU9 5NJ
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 416/9/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th December 1992
Date of last renewal: 18th December 2002

10 DATE OF REVISION OF THE TEXT

June 2005