IRISH MEDICINES BOARD ACT 1995, as amended

Medicinal Products (Control of Placing on the Market) Regulations, 2007, as amended

PA0256/005/001
Case No: 2049567

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Vitabiotics Limited

1 Beresford Avenue, **Wembley**, **Middlesex HA0 1NU**, **England**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Pregnacare 30 Capsules

the particulars of which are set out in the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **11/01/2007**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pregnacare 30 Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Betacarotene	4.2	mg
Vitamin D (as Colecalciferol) (100 IU)	2.5	micrograms
Vitamin E (as D-α-tocopherol Acid Succinate)	20	mg
Viamin B_1 (as Thiamine Mononitrate)	3	mg
Vitamin B_2 Riboflavin	2	mg
Vitamin B_6 Pyridoxine hydrochloride	10	mg
Vitamin B_{12} (as Cyanocobalamin)	6	micrograms
Vitamin K (as Phytomenadione)	200	micrograms
Folic Acid	400	micrograms
Niacin (as Nicotinamide)	20	mg
Vitamin C Ascorbic Acid	70	mg
Iron (as Ferrous Fumarate)	20	mg
Zinc (as Zinc Sulphate Monohydrate)	15	mg
Magnesium (as Magnesium Oxide)	150	mg
Iodine (as Potassium Iodide)	140	micrograms
Copper (as Copper Sulphate Monohydrate)	1	mg

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard
Dark brown, size 0, hard gelatin capsules.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Prevention and treatment of vitamin and mineral deficiencies.

4.2 Posology and method of administration

Adults: Only one capsule per day with your main meal, with a full glass of water or a cold drink. Not to be chewed.

Children: Not recommended.

4.3 Contraindications

Hypersensitivity to any of the constituents.

Ascorbic acid should not be given to patients with hyperoxaluria, reduced renal function or a deficiency of glucose 6-

phosphate dehydrogenase.

Vitamin C increases the absorption of iron and supplements should therefore not be used by people with a tendency to iron accumulation diseases.

4.4 Special warnings and precautions for use

This product contains beta-carotene. Women should not smoke during pregnancy or while taking this product. Prolonged excessive ingestion of vitamin D can lead to hypervitaminosis states which may occur if foods high in this vitamin, (for example liver), are ingested in association with the recommended doses of this product.

4.5 Interaction with other medicinal products and other forms of interaction

If preparations including vitamin C and deferoxamine (an iron binding remedy) are taken at the same time excretion of the iron complex is enhanced. Ascorbic acid should be avoided during the first two weeks of deferoxamine treatment as impaired cardiac function has been encountered during combined therapy. Larger doses of vitamin C can interfere with the control of anticoagulation.

Pyridoxine may increase the peripheral metabolism of levodopa, reducing therapeutic efficacy in patients with Parkinson’s disease.

Salazosulfapyridine can reduce the absorption of folic acid. Most anti-epileptic drugs can reduce the plasma concentration of folic acid.

4.6 Pregnancy and lactation

Iron containing products, if required, should be used during pregnancy after the first thirteen weeks.

Vitamin D given during the last trimester of pregnancy may cause hypercalcaemia in infants.

It is advised that if possible women receiving vitamin D do not breast feed their infants as this may lead to the development of hypercalcaemia in the infant.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

The intake of iron might cause constipation or diarrhoea, epigastric pain, nausea, or vomiting. The undesirable effects are dose dependent.

Ascorbic Acid may cause haemolytic anaemia in certain individuals with a deficiency of glucose-6-phosphate dehydrogenase. Yellow colouration of urine is normal on recommended dosage. Increased intake of ascorbic acid over a prolonged period may result in an increase in renal clearance of ascorbic acid and deficiency may result if it is withdrawn rapidly.

4.9 Overdose

Iron
The symptoms are nausea, vomiting, abdominal pain, diarrhoea, haematemesis; coma and hepatocellular necrosis occur later. Mortality is reduced with intensive and specific therapy. The effective antidote if desferrioxamine, with chelates iron. The stomach should be emptied at once, preferably by inducing vomiting as this as the quickest. Gastric lavage in hospital should be followed as soon as possible using desferrioxamine mesylate solution 2g in 1 litre of water. A solution of 10 g of desferrioxamine mesylate in 50 ml water should be left in the stomach. Absorbed iron can also be

chelated by an intramuscular injection of 2g of desferrioxamine mesylate in 10ml of water.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

None stated.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule shell compositon

Gelatin
Titanium dioxide (E171)
Red iron oxide (E172)
Black iron oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Blister strips composed of PVC/aluminium foil with 20µm H/T foil 112 mm.

Each carton contains 30 capsules in 2 blister strips of 15 capsules each.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Vitabiotics Ltd.
1 Beresford Avenue
Wembley
Middlesex HAO 1NU
England

8 MARKETING AUTHORISATION NUMBER

PA 256/5/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 January 2002

Date of last renewal: 11 January 2007

10 DATE OF REVISION OF THE TEXT

August 2010