SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<TRADE NAME> <STRENGTH> Oral Drops

<REGARDING THE APPROVAL>

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

<REGARDING THE APPROVAL>

Each 0.6 ml contains

Vitamin A plamitate <STRENGTH>

Ergocalciferol (Vitamin D2) <STRENGTH>

Thiamine hydrochloride (Vitamin B1) <STRENGTH>

Riboflavin (Vitamin B2) <STRENGTH>

Pyridoxine hydrochloride (Vitamin B6) <STRENGTH>

Ascorbic acid (Vitamin C) <STRENGTH>

Nicotinamide <STRENGTH>

Excipient with known effect:

<REGARDING THE APPROVAL>

For the full list of excipients, see section 6.1.

1. PHARMACEUTICAL FORM

Oral Drops

<REGARDING THE APPROVAL>

1. CLINICAL PARTICULARS
   1. Therapeutic indications

As a supplement for the prevention of vitamin deficiency states. As an aid to the maintenance of normal health and growth in infants and young children.

* 1. Posology and method of administration

Method of administration

To be administered by oral route.

*Dose:*

Infants from 6 weeks to one year : 0.3 ml daily (7 drops).

Older children, adults and elderly: 0.6 ml daily (14 drops) or as directed by the physician.

<REGARDING THE APPROVAL>

* 1. Contraindications

Hypersensitivity to any of the active substances or any of the excipients.

Contraindicated in hypercalcaemia.

Contraindicated in women who are (or may become) pregnant (see 4.6).

* 1. Special warnings and precautions for use

When multivitamin preparations are prescribed allowance must be made for vitamins from other sources.

No other preparations contain vitamin A should be taken with this preparation except under medical supervision.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Label will state:

Do not exceed the stated dose.

Keep out of the Reach and Sight of children.

Contains Sodium methylhydroxybenzoate (E219). May cause allergic reactions (possibly delayed). <REGARDING THE APPROVAL>

Contains Sucrose: If you have been told by doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. <REGARDING THE APPROVAL>

* 1. Interaction with other medicinal products and other forms of interaction

**Vitamin A**

Neomycin: Absorption of Vitamin a possibly reduced by neomycin

Retinoids: Risk of hypervitaminosis A when vitamin A given with retinoids

**Vitamin D:**

Barbiturates, carbamazepine, phenytoin, primidone: Vitamin D requirements possibly increased when given with either of the listed medications.

Diuretics thiazide: Increased risk of hypercalacaemia when vitamin D given with thiazide and related diuretics.

* 1. Fertility, pregnancy and lactation

In view of evidence suggesting that high levels of Vitamin A may cause birth defects, women who are (or may become) pregnant are advised not to take Vitamin A supplements (including tablets and fish-liver oil drops), except on the advice of a doctor or an antenatal clinic ( see section 4.3).

Vitamin D is secreted in breast milk and may cause hypercalcaemia in infants.

* 1. Effects on ability to drive and use machines

None known.

* 1. Undesirable effects

No undesirable effects due to the administration of Boston Multivitamins Oral Drops have been reported, and none can be expected if the dosage schedule is adhered to.

Excessive dose of Vitamins A and D can lead to hypervitaminosis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Health Product Vigilance Center; HPVC

* 1. Overdose

Symptoms of Vitamin overdosage may include anorexia, nausea, vomiting, rough dry skin, polyuria, thirst, loss of hair, painful bones and joints, as well as raised plasma and urine calcium and phosphate concentration.

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

Pharmacotherapeutic group: Multivitamins ATC Code: A11A multivitamins combinations.

**Vitamin A palmitate**

Vitamin A plays an essential role in the function of the retina, the growth and function of epithelial tissue, bone growth, reproduction and embryonic development.

**Ergocalciferol (Vitamin D2)**

Vitamin D is a regulator of both calcium and phosphate homeostasis.

**Thiamine hydrochloride (Vitamin B1)**

Vitamin B1 is essential for proper carbohydrate metabolism and plays an essential role in the decarboxylation of alpha keto acids.

**Riboflavin (Vitamin B2)**

Riboflavin is essential for the utilisation of energy from food. It is a component of co-enzymes which play an essential role in oxidative/ reductive metabolic reactions. Riboflavin is also necessary for the functioning of pyridoxine and nicotinic acid.

**Pyridoxine hydrochloride (Vitamin B6)**

Vitamin B6 is a constituent of the co-enzymes, pyridoxal pyrophosphate and pyridoxamine phosphate, both of which play an important role in protein metabolism.

**Nicotinamide**

Nicotinamide is an essential component of co-enzymes responsible for proper tissue respiration.

**Ascorbic acid (Vitamin C)**

Ascorbic acid is a water soluble vitamin and a powerful antioxidant. It is a cofactor in numerous biological processes, such as the metabolism of folic acid, amino acid oxidation and the absorption and transport of iron. It is also required for the formation, maintenance and repair of intercellular cement material. Ascorbic acid is important in the defence against infection, the normal functioning of T-lymphocytes and for the effective phagocytic activity of leucocytes. It also protects cells against oxidation damage to essential molecules.

* 1. Pharmacokinetic properties

**Absorption**

Vitamins A, B1, B2, B6, C, D2 and nicotinamide are well absorbed from the gastro-intestinal tract.

**Distribution**

The vitamins present in Abidec Multivitamin Drops are widely distributed to all tissues in the body.

**Metabolism and elimination**

**Vitamin A palmitate**

Vitamin A palmitate is hydrolysed in the intestinal lumen to retinol which is then absorbed. Retinol circulates in the blood bound to retinol binding protein which protects it from glomerular filtration. The complex circulates to target tissues where the vitamin is released, permeates the cell and binds intracellularly to cellular retinol binding protein. Of the absorbed retinol 20 - 50 % is either conjugated or oxidised to various products and excreted over a matter of days in the urine and faeces, while the remainder is stored. This stored retinol is gradually metabolised by the liver and peripheral tissues.

**Ergocalciferol (Vitamin D2)**

Vitamin D circulates in the blood associated with vitamin D binding protein. It is stored in fat deposits. Ergocalciferol is hydroxylated in the liver and gut to 25-hydroxy colecalciferol which is then further metabolised in the kidney to the active form 1,25-dihydroxycolecalciferol and other hydroxylated metabolites. Ergocalciferol and it’s metabolites are excreted largely in bile with eventual elimination in the faeces, with only small amounts of some of the metabolites appearing in the urine.

**Thiamine hydrochloride (Vitamin B1)**

Thiamine has a plasma half life of 24 hours and is not stored to any great extent in the body. Excess ingested thiamine is excreted in the urine as either the free vitamin or as the metabolite, pyrimidine.

**Riboflavin (Vitamin B2)**

Following absorption riboflavin is converted into the co-enzymes: flavin mononucleotide (FMN) and flavin adenine dinucleotide (FAD). Riboflavin is not stored in body tissues to any great extent and amounts in excess of the body’s requirements are excreted in the urine largely unchanged.

**Pyridoxine hydrochloride (Vitamin B6)**

The half life of pyridoxine ranges from 15 - 20 days. Once absorbed vitamin B6 is converted to it’s active co-enzyme form pyridoxal 5-phosphate. Muscle is the major storage site for pyridoxal 5-phosphate. It is degraded in the liver to 4-pyridoxic acid which is eliminated by the kidneys.

**Nicotinamide**

Nicotinamide is readily taken up into tissues and utilised for the synthesis of the co-enzyme forms nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP). Nicotinamide is degraded in the liver and other organs to a number of products that are excreted in the urine, the major metabolites being n-methyl-2-pyridone-5-carboxamide and n-methylnicotinamide.

**Ascorbic acid (Vitamin C)**

Ascorbic acid reaches a maximum plasma concentration 4 hours following oral administration after which there is rapid urinary excretion. Following oral administration 60 % of the dose is excreted in 24 hours either as ascorbic acid or its metabolite dihydroascorbic acid.

* 1. Preclinical safety data

**Mutagenicity**

There is insufficient information to determine the mutagenic potential of the active ingredients. However very large doses of vitamin C are claimed to be mutagenic.

**Carcinogenicity**

There is insufficient information to determine the carcinogenic potential of the active ingredients.

**Teratogenicity**

High doses of vitamin D are known to be teratogenic in experimental animals, but direct evidence for this is lacking in humans. The teratogenicity of vitamin A in animals is well known, both high and low levels of the vitamin result in defects. But the significance of this for humans is in dispute. Synthetic versions of vitamin A (Isotretinoin and Etretinate) have been shown to be powerful teratogens. There is insufficient information to determine the teratogenic potential of the other active ingredients.

**Fertility**

Not appropriate.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<REGARDING THE APPROVAL>

* 1. Incompatibilities

None known.

* 1. Shelf life

<REGARDING THE APPROVAL>

* 1. Special precautions for storage

<REGARDING THE APPROVAL>

* 1. Nature and contents of container

<REGARDING THE APPROVAL>

* 1. Special precautions for disposal

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION HOLDER

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION NUMBER(S)

<REGARDING THE APPROVAL>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<REGARDING THE APPROVAL>

1. DATE OF REVISION OF THE TEXT1

<REGARDING THE APPROVAL>