

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Abidec Multivitamin Oral Drops Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Abidec Multivitamin Drops contains 1333 IU retinol (as vitamin A palmitate), 400 IU ergocalciferol, 0.4 mg thiamine hydrochloride, 0.8 mg riboflavin sodium phosphate, 0.8 mg pyridoxine hydrochloride, 8 mg nicotinamide, and 40 mg ascorbic acid in each 0.6 ml dose.

Excipient(s) with known effect

Contains sucrose 45 mg per 0.6 ml dose and arachis oil (peanut oil)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral drops, solution

A clear yellow/brown solution with a characteristic odour and taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Abidec Multivitamin Drops is indicated for the prevention of vitamin deficiencies and for the maintenance of normal growth and health during the early years of infancy and childhood; multivitamin supplement.

4.2 Posology and method of administration

Posology

Adults and children over 12 years:

Not appropriate.

Children aged 1 to 12 years: Oral.

One 0.6ml dose taken daily.

Maximum daily dose: 0.6ml.

Children under 1 year:

Oral.

One 0.3ml dose taken daily.

Maximum daily dose: 0.3ml.

The Elderly:

Not appropriate.

Hepatic/renal dysfunction:

Normal dosage is appropriate.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Vitamin A palmitate contains refined peanut oil (Arachis oil) and should not be taken by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and allergy to soya, patients with soya allergy should also avoid Abidec Multivitamin Drops.

4.4 Special warnings and precautions for use

When prescribing Abidec Multivitamin Drops, as with all multivitamin preparations, allowance should be made for vitamins obtained from other sources.

While children are taking Abidec Multivitamin Drops no other vitamin supplement containing vitamins A and D should be taken unless under medical supervision.

This multivitamin supplement should not be given to babies who are receiving more than 500mls of formula milk per day to avoid exceeding the safe upper limit of Vitamin A.

Excessive dosage of vitamin A and D may lead to hypervitaminoses. Due allowance should always be made for intake of these vitamins from other sources.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. May be harmful to the teeth.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interactions

None.

4.6 Fertility, pregnancy and lactation

Not indicated in this age group.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Vitamin A palmitate

Adverse effects are extremely rare at daily doses of less than 9mg. (16363.6 IU).

Ergocalciferol (Vitamin D₂)

The only known adverse effects of vitamin D occur when excessive doses are taken. Adverse effects are not anticipated at the quantity present in Abidec Multivitamin Drops.

Ascorbic Acid (C), Nicotinamide, Pyridoxine (B₆), Riboflavin (B₂) & Thiamine (B₁)

These water soluble vitamins are generally non toxic compounds with a wide margin of safety, the excess amounts being rapidly excreted in the urine. Adverse effects are not anticipated at the quantities present in Abidec Multivitamin Drops.

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 HPRA Pharmacovigilance; Website: www.hpra.ie.

4.9 Overdose

Symptoms and signs

Abidec Multivitamin Drops contains levels of vitamins which present little risk of overdose.

Vitamin A palmitate

Acute administration of high doses of vitamin A can cause headache, nausea, vomiting and irritability. In infants acute toxicity can lead to transient hydrocephalus. All these effects disappear within 24 hours of taking retinol.

Ergocalciferol (Vitamin D₂)

Excessive doses of vitamin D, 60 000 units per day, can result in hypercalcaemia and hypercalciuria. Adverse effects of hypercalcaemia may include muscle weakness, apathy, headache, anorexia, nausea and vomiting, hypertension and cardiac arrhythmias.

Thiamine hydrochloride (Vitamin B₁)

When taken orally, thiamine is non-toxic. If large doses are ingested they are not stored by the body but excreted unchanged by the kidneys.

Riboflavin (Vitamin B₂)

Riboflavin has been found to be practically non-toxic.

Pyridoxine hydrochloride (Vitamin B₆)

Acute doses less than 500mg per day appear to be safe. Excessive doses may lower serum folate concentrations. Sensory neuropathy has been described with chronic dosing of 200mg daily.

Nicotinamide

A single large overdose of nicotinamide is unlikely to have serious ill effects, through transient abnormalities of liver function might occur.

Ascorbic acid (Vitamin C)

Ascorbic acid is not stored to a great extent by the body, any excess amounts are eliminated in the urine. Ascorbic acid is thought to become toxic at chronic doses in excess of 6g.

Treatment

Treatment should be supportive and symptomatic.

5 PHARMACOLOGICAL PROPERTIES**5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Multivitamins, plain, ATC code: A11BA

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.

5.2 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.

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 cholecalciferol which is then further metabolised in the kidney to the active form 1, 25-dihydroxycholecalciferol and other hydroxylated metabolites. Ergocalciferol and its 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 coenzymes: flavin mononucleotide (FMN) and flavin adenine dinucleotide (FAD). Riboflavin is not stored in body tissue 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 its active co-enzyme from 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 coenzyme 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.

Pharmacokinetics in Renal Impairment

There have been no specific studies of Abidec Multivitamin Drops in renal impairment.

Pharmacokinetics in the Elderly

Not appropriate.

5.3 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 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 active ingredients.

Fertility

Not appropriate.

6 PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Sodium hydroxide
Sucrose
Refined peanut oil (a carrier for Vitamin A palmitate)
Polysorbate 60
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

18 months.

Once opened: use within 4 weeks.

6.4 Special precautions for storage

Do not store above 25°C. Keep the bottle in the outer carton to protect from light.

6.5 Nature and contents of container

Abidec Multivitamin Drops are presented in an amber Type III glass bottle, with a tamper-evident Polypropylene cap or ROPP aluminium cap containing a PET/Aluminium/Polyethylene/Expanded Polyethylene laminated wad.

One or two 25ml bottles enclosed in a printed cardboard carton with one polyethylene/polystyrene syringe graduated at 0.3 ml and 0.6 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Wash and dry syringe thoroughly after use (not in a steam steriliser).

Make sure no water is left inside.

Reseal the bottle with original cap after each use.

Store syringe in a clean dry place. The syringe is for use with this product only.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Chefaro Ireland DAC
The Sharp Building
Hogan Place
Dublin 2
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1186/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 September 2000

Date of last renewal: 01 September 2010

10 DATE OF REVISION OF THE TEXT

March 2021