

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product : EUROVIT DROPS ((Multivitamin Drops)

2. Qualitative and Quantitative composition:

Composition:

Each 0.6 ml contains:

Vitamin A (As Palmitate) BP1500 IU
 Colecalciferol (Vitamin D3) BP.....400.00 IU
 Thiamine Hydrochloride (Vitamin B1).....0.50 mg
 Riboflavin (Vitamin B2) BP0.60 mg
 Pyridoxine Hydrochloride (Vitamin B6) BP.....0.60 mg
 Ascorbic Acid (Vitamin C) BP.....30.00 mg
 Nicotinamide (Vitamin B3) BP6.0 mg
 Flavored syrup baseq.s
 Appropriate Overages of Vitamins added

Sr.No.	Raw Materials	Specifica- tion	Label claim / 0.6 ml	% Overages	Quantity in /0.6 ml(mg)	Reason for Adding
Active Ingredients						
1	Vitamin A (As Palmitate)	BP	1500 IU	50%	1.238	Active
2	Thiamine Hydrochloride (Vitamin B1)	BP	0.5 mg	70%	0.85	Active
3	Riboflavin (Vitamin B2)	BP	0.6 mg	10%	0.66	Active
4	Pyridoxine Hydrochloride (Vitamin B6)	BP	0.6 mg	30%	0.78	Active
5	Ascorbic Acid (Vitamin C)	BP	30 mg	30%	39.0	Active
6	Colecalciferol (Vitamin D3)	BP	400 IU	100%	0.02	Active
7	Nicotinamide (Vitamin B3)	BP	6 mg	5%	6.30	Active
Excipients						
8	Sodium Methyl Paraben	BP	--	Nil	1.2	Preservative
9	Sodium Propyl Paraben	BP	--	Nil	0.36	Preservative
10	Sodium Benzoate	BP	--	Nil	1.8	Preservative
11	Sodium Hydroxide	BP	--	Nil	6.6	Buffering agent
12	Di Sodium Hydrogen Phosphate (Anhydrous)	BP	--	Nil	0.42	Chelating Agent
13	Glycerin	BP	--	Nil	300.0	Preservative
14	Thio Urea	BP	--	Nil	0.6	Antioxidant
15	Acrysol K-140 / Cresmer RH 40	BP	--	Nil	36.0	Solubilizer

16	Enisweet	In-house	--	Nil	0.3	Sweetner
17	Colour Caramel	In-house	--	Nil	0.024 ml	Colouring agent
18	Orange Juicy M- 7031 Flavour	In-house	--	Nil	0.0024	Flavour
19	Purified Water	BP	--	Nil	q.s.	Vehicle

BP: British Pharmacopoeia; q.s.: Quantity Sufficient

3. Pharmaceutical Form: Oral Drops

4. Clinical Particulars:

4.1 Therapeutic Indications

Eurovit 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:

Adults and children over 12 years:

Not appropriate.

Children aged 1 to 12 years:

Oral. One 0.6 ml dose taken daily.

Maximum daily dose: 0.6 ml

Children under 1 year:

Oral. One 0.3 ml dose taken daily.

Maximum daily dose: 0.3 ml

The Elderly:

Not appropriate

Hepatic/renal dysfunction

Normal dosage is appropriate.

Method of Administration

For oral administration.

4.3 Contraindications

Contraindicated in patients known to be hypersensitive to any of its components and in patients with hypervitaminosis.

4.4 Special warnings and precautions for use

When prescribing Eurovit Drops, as with all multi-vitamin preparations, allowance should be made for vitamins obtained from other sources.

While children are taking Eurovit 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.

4.5 Interaction with other medicinal products and other forms of interaction:

None.

4.6 Pregnancy and Lactation:

Not indicated.

4.7 Effects on the ability to drive and use machines

None known.

4.8 Undesirable effects:

Vitamin A palmitate

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

Colecalciferol (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 Eurovit 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 Eurovit Drops

4.9 Overdose

Symptoms and signs

EUROVIT DROPS contains levels of vitamins which present little risk in 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.

Colecalciferol (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 200 mg daily.

Nicotinamide

A single large overdose of nicotinamide is unlikely to have serious ill effects, though 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 6 g.

Treatment

Treatment should be supportive and symptomatic.

5. Pharmacological Particulars:

5.1 Pharmacodynamic properties

(i) Pharmaco-therapeutic group: Combination of Vitamins

(ii) ATC code: A11JA

Mechanism of action:

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.

Colecalciferol (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 Eurovit 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.

Colecalciferol (Vitamin D₂)

Vitamin D circulates in the blood associated with vitamin D binding protein. It is stored in fat deposits. Colecalciferol 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. Colecalciferol 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 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 its 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.

Pharmacokinetics in Renal Impairment

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

Pharmacokinetics in the Elderly

Not appropriate.

5.3 Pre-clinical Safety:

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.

6. Pharmaceutical Particulars:

List of Excipients:

Sodium Methyl Paraben	BP
Sodium Propyl Paraben	BP
Sodium Benzoate	BP
Sodium Hydroxide	BP
Di Sodium Hydrogen Phosphate (Anhydrous)	BP
Glycerin	BP
Thio Urea	BP
Acrysol K-140 / Cresmer RH 40	BP
Enisweet	In-house
Colour Caramel	In-house
Orange Juicy M- 7031 Flavour	In-house
Purified Water	BP

6.2 Incompatibilities: None known.

6.3 Shelf Life: 24 months.

6.4 Special Precautions for storage:

Store below 30°C in a dry place. Protect from light.

6.5 Nature and contents of container:

30 ml in Amber colour Glass bottle packed in a Primary Carton along with the Dropper & Pack Insert.

6.6 Special precautions for disposal and other handling:

None

7. Marketing Authorization Holder:

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