SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dalivit Drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.6 ml contains:

Vitamin A Palmitate	BP	5,000 units
Ergocalciferol (Vitamin D_2)	Ph Eur	400 units
Thiamine hydrochloride (Vitamin B1)	BP	1 mg
Riboflavin (Vitamin B2)	BP	400 micrograms
Pyridoxine hydrochloride (Vitamin B6)	BP	500 micrograms
Ascorbic acid (Vitamin C)	BP	50 mg
Nicotinamide	BP	5 mg

Excipient(s):

This product contains Sucrose.
This product also contains E219 Sodium Methylhydroxybenzoate.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Drops, Emulsion (Oral Drops)
Yellowish orange coloured liquid, slightly viscous.

4 CLINICAL PARTICULARS

4.1 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.

4.2 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.

4.3 Contraindications

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

Contra-indicated in hypercalcaemia.

Contra-indicated in women who are (or may become) pregnant (see 4.6).

4.4 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).
- 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.

4.5 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.

4.6 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.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

No undesirable effects due to the administration of Dalivit 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

4.9 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Multivitamins

ATC Code: A11A multivitamins combinations

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Polysorbate 80
Sodium hydroxide
Sodium methyl hydroxybenzoate (E219)
Deionized water

6.2 Incompatibilities

None known.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store in dry place below 25°C. Protect from light.

6.5 Nature and contents of container

Pack size 25ml 2 bottles per carton
Pack size 25ml 1 bottle per carton
Pack size l0ml 1 bottle per carton
Pack size 50ml 1 bottle per carton

6.6 Special precautions for disposal and other handling

This medicine must not be used after the date (Exp) printed on the back. Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Boston Healthcare Limited

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Calder Park

Wakefield

West Yorkshire WF2 7BJ

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 39974/0001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13/03/2007

10 DATE OF REVISION OF THE TEXT

15/07/2015