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This information is intended for use by health professionals

1. Name of the medicinal product

Vitamin A+D Soft Capsule

2. Qualitative and quantitative composition

Each capsule contains: Vitamin A (as β-Carotene) 10,000 iu
, Vitamin D2 (Ergocalciferol) 3,000 iu

Excipients with known effect:

Soya Bean Oil up to 1050 mg, Ponceau 4R : 0.12 mg and Amaranth : 0.54 mg.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Brown and maroon, oblong soft gelatin capsule.

4. Clinical particulars

4.1 Therapeutic indications

1. As a therapeutic nutritional adjunct where the intake of vitamins and minerals is suboptimal, e.g. in the presence of organic disease such as malignancy and immune deficiency syndromes, such as AIDS.

2. As a therapeutic nutritional adjunct in conditions where the absorption of vitamins and minerals is suboptimal, e.g. malabsorption, inflammatory bowel disease and fistulae, short bowel syndrome and Crohn's disease, and where concurrent medication decreases vitamin and mineral absorption.

3. As a therapeutic nutritional adjunct in convalescence from illness, e.g. where anorexia or cachexia exists and following chemo- or radio-therapy.

4. As a therapeutic nutritional adjunct in convalescence from surgery, e.g. where nutritional intake continues to be inadequate.

5. As a therapeutic nutritional adjunct for patients on special or restricted diets, e.g. in renal diets and where several food groups are restricted in therapeutic weight reducing diets.

6. As a therapeutic nutritional adjunct where food intolerance exists, e.g. exclusion diets.

7. As an adjunct in synthetic diets, e.g. in phenylketonuria, galactosaemia and ketogenic diets.

4.2 Posology and method of administration

Adults and the Elderly

One capsule daily, preferably taken one hour after meals. Do not exceed the stated dose. The capsule should be swallowed whole with water.

Children under 12 years of age

Vitamin A+D Capsules are not recommended for this age group.

4.3 Contraindications

Hypercalcaemia, haemochromatosis and other iron storage disorders.

Hypersensitivity to the active substance(s) or to any of the excipients.

Vitamin A+D capsules contain soya bean oil. Patients allergic to peanut or soya should not take this medicine.

4.4 Special warnings and precautions for use

Whilst taking Vitamin A+D Capsules both protein and energy are also required to provide complete nutrition in the daily diet. No other vitamins, minerals or supplements with or without vitamin A should be taken with this preparation except under medical supervision.

Do not take Vitamin A+D Capsules on an empty stomach. Do not exceed the stated dose. Keep out of the reach of children. If symptoms persist, consult your doctor.

Important warning: Contains iron. Keep out of the reach and sight of children, as overdose may be fatal.

This medicine contains amaranth and ponceau 4R red which may cause allergic reactions.

Evidence from Randomised Control Trials suggests that high doses (20-30 mg/day) b-carotene intake may increase the risk of lung cancer in current smokers and those previously exposed to asbestos. This high-risk population should consider the potential risks and benefits of Vitamin A+D Capsules, which contain 4.5mg per recommended daily dose, before use.

Patients with thyroid disorders should seek medical advice before taking Vitamin A+D Capsules. An allowance should be made for vitamins or minerals obtained from other sources.

4.5 Interaction with other medicinal products and other forms of interaction

Folic acid can reduce the plasma concentration of phenytoin. Oral iron and zinc sulfate reduce the absorption of tetracyclines.

4.6 Pregnancy and lactation

Vitamin A+D Capsules may be administered during pregnancy and lactation at the recommendation of the physician.

4.7 Effects on ability to drive and use machines

None anticipated.

4.8 Undesirable effects

Undesirable effects are listed by MedDRA System Organ Classes.

Assessment of undesirable effects is based on the following frequency groupings:

Very common: ≥1/10

Common: ≥1/100 to <1/10

Uncommon: ≥1/1,000 to <1/100

Rare: ≥1/10,000 to <1/1,000

Very rare: <1/10,000

Not known: cannot be estimated from the available data

Immune system disorders	*Not known:* Hypersensitivity reaction (such as rash)
Gastrointestinal disorders	*Not known:* Gastrointestinal disturbances (such as nausea, vomiting and abdominal pain)

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

No cases of overdosage due to Vitamin A+D therapy have been reported. Any symptoms which may be observed due to the ingestion of large quantities of Vitamin A+D capsules will be due to the fat soluble vitamin content. If iron overdosage is suspected, symptoms may include nausea, vomiting, diarrhoea, abdominal pain, haematemesis, rectal bleeding, lethargy and circulatory collapse. Hyperglycaemia and metabolic acidosis may also occur. Treatment should be implemented immediately. In severe cases, after a latent phase, relapse may occur after 24 - 48 hours, manifest by hypotension coma and hepatocellular necrosis and renal failure.

Treatment

The following steps are recommended to minimise or prevent further absorption of the medication:

1. Administer an emetic.

2. Gastric lavage may be necessary to remove drug already released into the stomach. This should be undertaken using desferrioxamine solution (2 g/l). Desferrioxamine 5 g in 50 - 100 ml water should be introduced into the stomach following gastric emptying. Keep the patient under constant surveillance to detect possible aspiration of vomitus; maintain suction apparatus and standby emergency oxygen in case of need.

3. A drink of mannitol or sorbitol should be given to induce small bowel emptying.

4. Severe poisoning: in the presence of shock and/or coma with high serum iron levels (>142 µmol/l) immediate supportive measures plus i.v. infusion of desferrioxamine should be instituted. The recommended dose of desferrioxamine is 5 mg/kg/h by slow i.v. infusion up to a maximum of 80 mg/kg/24 hours. Warning: hypotension may occur if the infusion rate is too rapid.

5. Less severe poisoning: i.m. desferrioxamine 50 mg/kg up to a maximum dose of 4 g should be given.

6. Serum iron levels should be monitored throughout.

7. Any fluid or electrolyte imbalance should be corrected.

5. Pharmacological properties

5.1 Pharmacodynamic properties

The following account summarises the pharmacological effects of the vitamins and minerals in Vitamin A+D Capsules and describes the conditions caused by deficiency of these.

Vitamin A

Vitamin A plays an important role in the visual process. It is isomerised to the 11-cis isomer and subsequently bound to the opsin to form the photoreceptor for vision under subdued light. One of the earliest symptoms of deficiency is night blindness which may develop into the more serious condition xerophthalmia. Vitamin A also participates in the formation and maintenance of the integrity of epithelial tissues and mucous membranes. Deficiency may cause skin changes resulting in a dry rough skin with lowered resistance to minor skin infections. Deficiency of Vitamin A, usually accompanied by protein-energy malnutrition, is linked with a frequency of infection and with defective immunological defence mechanisms.

Vitamin D

Vitamin D is required for the absorption of calcium and phosphate from the gastro-intestinal tract and for their transport. Its involvement in the control of calcium metabolism and hence the normal calcification of bones is well documented. Deficiency of Vitamin D in children may result in the development of rickets.

5.2 Pharmacokinetic properties

The following account describes the absorption and fate of each of the active constituents of Vitamin A+D Capsules.

Vitamin A

Except when liver function is impaired, Vitamin A is readily absorbed. β-carotene (as in Vitamin A+D Capsules) is Provitamin A and is the biological precursor to Vitamin A. It is converted to Vitamin A (Retinol) in the liver; retinol is emulsified by bile salts and phospholipids and absorbed in a micellar form. Part is conjugated with glucuronic acid in the kidney and part is metabolised in the liver and kidney, leaving 30 to 50% of the dose for storage in the liver. It is bound to a globulin in the blood. Metabolites of Vitamin A are excreted in the faeces and the urine.

Vitamin D

The metabolism of ergocalciferol is similar to that of cholecalciferol. Cholecalciferol is absorbed from the gastro-intestinal tract into the circulation. In the liver, it is hydroxylated to 25-hydroxycholecalciferol, is subject to entero-hepatic circulation and is further hydroxylated to 1,25-dihydroxycholecalciferol in the renal tubule cells. Vitamin D metabolites are bound to specific plasma proteins.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6. Pharmaceutical particulars

6.1 List of excipients

Soya Bean Oil, Soya Lecithin, Hard Vegetable Fat, Yellow Beeswax, Purified Water, Maize Oil.

Gelatin, Glycerine, Ponceau 4R , Amaranth, Titanium Dioxide, Red Iron Oxide Paste, Vegetable Black Paste.

6.2 Incompatibilities

No major incompatibilities are known.

6.3 Shelf life

24 months, as packaged for sale.

6.4 Special precautions for storage

Store in a cool dry place at a temperature not exceeding 25°C.

Protect from light.

6.5 Nature and contents of container

The product is presented in press-thru blister packs, each blister strip containing 10 Vitamin A+D capsules. The blister strip is composed of PVC/PVdC with a printed aluminium foil lidding. The foil is printed (red on gold) with the name and Batch number of the product. The product is available in packs of 10x10per box,

Product may also be supplied in bulk packs as 500capsule per bottle or Tin.

6.6 Special precautions for disposal and other handling

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

7. Marketing authorisation holder

Ningbo Voice Biochemic Co., Ltd.

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