1.3.1.1 PROFESSIONAL INFORMATION (English)

SCHEDULING STATUS:

S3

1. NAME OF THE MEDICINE (and dosage form):

Vitaforce A 50 000 IU (soft gelatine capsule)

Vitaforce A 100 000 IU (soft gelatine capsule)

Vitaforce A 200 000 IU (soft gelatine capsule)

2. QUALITATIVE AND QUANTITIVE COMPOSITION:

Vitaforce A 50 000 IU

Each capsule contains:

Vitamin A (Palmitate)	50 000 IU
Equivalent to Retinol	15 mg
Natural Vitamin E (Antioxidant)	0, 03 IU

For the full list of excipients, see section 6.1

Sugar free

Vitaforce A 100 000 IU

Each capsule contains:

Vitamin A (Palmitate)	100 000 IU
Equivalent to Retinol	30 mg
Natural Vitamin E (Antioxidant)	0, 02 IU

For the full list of excipients, see section 6.1

Sugar free

Vitaforce A 200 000 IU

Each capsule contains:

Vitamin A (Palmitate)	200 000 IU
Equivalent to Retinol	60 mg

For the full list of excipients, see section 6.1

Sugar free

3. PHARMACEUTICAL FORM

Vitaforce A 50 000 IU capsules:

Opaque off-white snip/twist off tip soft gelatine capsule containing a clear yellow oily liquid.

Vitaforce A 100 000 IU capsules:

Opaque greyish-blue snip/twist-off tip soft gelatine capsule containing a clear yellow to brown oily liquid.

Vitaforce A 200 000 IU capsules:

Opaque dark pink to orange snip/twist-off tip soft gelatine capsule containing a clear yellow to brown oily liquid.

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

To decrease the risk of measles related complications and death in pre-school children with malnutrition and/or vitamin deficiency

Vitamin A deficiency states e.g. night-blindness (nyctalopia) and xerophthalmia.

To decrease the risk and severity of respiratory infections and diarrhoea in pre-school children with malnutrition and/or vitamin A deficiency.

4.2 POSOLOGY AND METHOD ADMINISTRATION

POSOLOGY

Snip or twist-off the tip of the capsule or pierce the capsule and squeeze the contents into the

mouth, unless otherwise prescribed.

Vitaforce A 50 000 IU

Prevention of xerophthalmia:

≥ 1 year of age: Oral administration of 200 000 IU vitamin A every 4 to 6 months

< 1 year of age: Oral administration of 100 000 IU vitamin A every 4 to 6 months. Treatment of xerophthalmia: upon diagnosis of xerophthalmia:

≥ 1 year of age: Oral administration of 200 000 IU vitamin A daily for 2 days

< 1 year of age: Oral administration of 100 000 IU vitamin A daily for 2 days An additional dose should be given 1-2 weeks later.

Measles: upon diagnosis of measles:

≥ 1 year of age: Oral administration of 200 000 IU vitamin A daily for 2 days

< 1 year of age: Oral administration of 100 000 IU vitamin A daily for 2 days

Vitaforce A 100 000 IU:

To prevent Vitamin A deficiency:

For mothers:

The contents of two capsules to be taken once orally within two weeks of giving birth. For infants 6-11 months of age:

The contents of one capsule to be taken once orally. For children 12 months or older:

The contents of two capsules to be taken once orally every 6 months. In the case of measles and xerophthalmia:

A second dose to be taken on the next day.

In the case of xerophthalmia or measles with eye signs of severe vitamin A deficiency: A third dose to be taken once after 2 weeks.

Vitaforce A 200 000 IU:

To prevent Vitamin A deficiency:

For mothers:

The contents of one capsule to be taken once orally by the mother within two weeks of giving birth.

For children 12 months or older:

The contents of one capsule to be taken once orally every 6 months. In the case of measles and xerophthalmia:

A second dose to be taken on the next day.

In the case of xerophthalmia or measles with eye signs of severe vitamin A deficiency: A third dose to be taken once after 2 weeks.

METHOD OF ADMINISTRATION

For oral administration

4.3 CONTRAINDICATIONS

Hypersensitivity to any of the ingredients including excipients Hypervitaminosis A

Renal failure

Liver disease (see SPECIAL WARNING AND PRECAUTIONS FOR USE)

Pregnancy and lactation (see FERTILITY, PREGNANCY and LACTATION).

4.4 SPECIAL WARNING AND PRECAUTIONS FOR USE

The administration of excessive amounts of vitamin A substances over long periods can lead to toxicity, known as hypervitaminosis A. This is characterised by fatigue, irritability, anorexia and loss of weight, vomiting and other gastro-intestinal disturbances, low-grade fever hepatosplenomegaly, skin changes (yellowing, dryness, sensitivity to sunlight) alopecia, dry hair, cracking and bleeding lips, anaemia, headache, hypercalcaemia, subcutaneous swelling, nocturia and pains in bones and joints, menstrual disturbances and elevated blood lipids. Subperiosteal new bone growth and cortical thickenings, especially of the small bones of the hands and feet and the long bones have been reported in children. Symptoms of chronic toxicity may also include raised intracranial pressure and papilledema mimicking brain tumours, tinnitus, visual disturbances which may be severe, and painful swelling over the long bones. Symptoms usually clear on withdrawal of vitamin A, but in children premature closure of the epiphysis of the long bones may result in arrested bone

growth.

Acute vitamin A intoxication may occur with very high doses and is characterised by sedation, dizziness, nausea and vomiting, erythema, pruritis, desquamation and increased intracranial pressure (resulting in bulging fontanelle in infants).

Absorption of vitamin A from the gastrointestinal tract may be reduced by the presence of neomycin, cholestyramine, or liquid paraffin. There is an increased risk of hypervitaminosis A if vitamin A is co- administered with synthetic retinoids such as acitretin, isotretinoin and tretinoin.

Do not exceed the stated dose. Woman who are or might become pregnant should avoid taking daily supplements containing more than 5 000 IU vitamin A.

Ability to perform tasks that require judgement, motor or cognitive skills: No effect on the ability to drive and use of machines has been reported.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORM OF INTERACTIONS

Absorption of Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce A 200 000 IU capsules from the gastrointestinal tract may be reduced in the presence of neomycin, cholestyramine, colestipol, orlistat or liquid paraffin.

There is an increased risk of hypervitaminosis A, if Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce A 200 000 IU capsules are co-administered with synthetic retinoids such as acretin, isotretinoin, etretinate and tretinoin.

Calcium supplements: concurrent use of Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce A 200 000 IU capsules may stimulate bone loss and counteract the effects of calcium supplementation and cause hypercalcaemia.

Tetracycline: concurrent use with Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce A 200 000 IU capsules daily has been reported to cause benign intracranial hypertension (pseudotumour cerebri).

Oral contraceptives: concurrent use with Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce A 200 000 IU capsules may increase vitamin A concentrations.

The following laboratory values may be altered with administration of Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce A 200 000 IU capsules:

Serum urea, creatinine, calcium, cholesterol and triglyceride concentrations may be increased in chronic vitamin A toxicity. Erythrocyte counts and leukocyte counts may be decreased by high doses of vitamin A.

4.6 FERTILITY, PREGNANCY AND LACTATION

Women who are or might become pregnant should avoid taking daily supplements containing more than 5000 IU vitamin A per daily dose without consulting a medical practitioner because of the risk of teratogenicity.

Pregnancy: Problems in humans have not been documented with intake of normal daily recommended amounts. Vitamin A crosses the placenta to only a limited extent. Foetal abnormalities (including urinary tract malformations), growth retardation, and early epiphyseal closure have been reported in children whose mothers took excessive amounts during pregnancy. Daily amounts from supplements exceeding 5000 IU are not recommended because of potential fetotoxicity. (See CONTRA-INDICATIONS).

Breast-feeding: Vitamin A is distributed into breast milk; however, problems in humans have not been documented with intake of normal daily recommended amounts.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

VITAFORCE A 50 000 IU, VITAFORCE100 00 IU and VITAFORCE 200 00 IU have no known effect on an individual's ability to drive or operate machinery.

4.8 UNDESIRABLE EFFECTS

ACUTE EFFECTS: Acute vitamin A intoxication may occur with very high doses of Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce A 200 000 IU capsules. Acute toxicity is characterised by:

Central and peripheral nervous system: dizziness, headache, increased intracranial pressure (pseudotumour cerebri), resulting in bulging fontanelle in infants.

Gastrointestinal system: nausea, vomiting, diarrhoea, bleeding from gums, sore mouth.

Psychiatric disorder: sedation, irritability, confusion or unusual excitement.

Skin and appendages: erythema pruritus, desquamation (especially on the lips and palms)

Vision disorders: double vision

Enhanced susceptibility to the effects of vitamin A maybe seen in children and in patients with liver disease.

Gastrointestinal absorption of vitamin A may be impaired in cholestatic jaundice and fat-malabsorption conditions.

CHRONIC EFFECTS: The administration of excessive amounts of Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce A 200 000 IU capsules over long periods can lead to toxicity.

Hypervitaminosis A is characterised by:

Body as a whole, general disorders: Fatigue, low-grade fever, generalised feeling of weakness or discomfort, subcutaneous swelling

Cardiovascular disorders: Portal hypertension

Central and peripheral nervous system: Headache, raised intracranial pressure and papilloedema mimicking brain tumours, convulsions

Gastrointestinal system: Vomiting, stomach pain

Hearing and vestibular disorders: Tinnitus

Liver and biliary system: Hepatosplenomegaly, hepatotoxicity

Metabolic and nutrition disorders: Loss of weight, hypercalcaemia

Musculo-skeletal system disorders: Pains in bones and joints, painful swelling over the long bones, premature closure of the epiphyses of the long bones in children which may result in arrested bone growth

Psychiatric disorders: Irritability, anorexia

Red blood cell disorders: Anaemia, haemolysis

Reproductive disorders: Hypomenorrhoea

Skin and appendages: Skin changes (yellowing, dryness, sensitivity to sunlight), alopecia, dry hair, cracking and bleeding lips

Urinary system disorders: Nocturia

Vision disorders: Visual disturbances which may be severe

Symptoms of chronic toxicity are slowly reversible on withdrawal of vitamin A but may persist for several weeks.

4.9 OVERDOSE

Signs and symptoms:

The administration of excessive amounts of Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce A 200 000 IU may lead to toxicity. Serum Vitamin A levels are useful for the diagnosis of hypervitaminosis A (see SPECIAL WARNING AND PRECAUTIONS FOR USE))

Treatment:

Treatment consists of the withdrawal of Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce A 200 000 IU, and should be symptomatic and supportive. Some signs and symptoms disappear within 1 week, while others may persist for several weeks to months.

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES PHARMACOTHERAPEUTIC GROUP:

A 22.2 Vitamins. Others.

Vitamin A is necessary for growth and differentiation of epithelial tissue and is required for growth of bone, reproduction, embryonic development and plays an essential role in the function of the retina. Together with certain carotenoids, vitamin A appears to enhance the function of the immune system. One IU of vitamin A is equivalent to 0, 3 microgram of all-trans-retinol or 0, 6 microgram of beta-carotene.

5.2 PHARMACOKINETIC PROPERTIES

Vitamin A is a fat-soluble vitamin and is readily absorbed from the gastrointestinal tract.

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.

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Vitaforce A 50 000 IU

Arachis oil Gelatine Glycerine

Iron oxide (colourant) Soya bean oil Sunflower oil Titanium dioxide

Vitaforce A 100 000 IU

Arachis oil Gelatine Glycerine

Iron oxide (colourant) Soya bean oil Sunflower oil

Titanium dioxide (colourant)

Vitaforce A 200 000 IU

Arachis oil Gelatine Glycerine

Iron oxide (colourant) Soya bean oil Sunflower oil

Titanium dioxide

6.2 INCOMPATIBILITIES

None

6.3 SHELF LIFE

36 Months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store at or below 25 °C. Store in a dry place protected from light. KEEP OUT OF REACH OF CHILDREN.

6.5 NATURE AND CONTENTS OF CONTAINER

Vitamin A 50 000 IU capsules:

White opaque round plastic bottle containing 50 or 200 soft gelatine capsules. Vitamin A 100 000 IU capsules:

White opaque round plastic bottle containing 50 or 250 soft gelatine capsules. Vitamin A 200 000 IU capsules:

White opaque round plastic bottle containing 50 or 250 soft gelatine capsules.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biotech Laboratories (Pty) Ltd

Ground Floor, Block K West, Central Park

400 16th Road, Randjespark

Midrand 1685

011 848 3050

8. REGISTRATION NUMBER(S)

Vitamin A 50 000 IU capsules:

36/22.1.4/0361

Vitamin A 100 000 IU capsules:

36/22.1.4/0362.

Vitamin A 200 000 IU capsules:

36/22.1.4/0363.

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF AUTHORISATION

Vitamin A 50 000 IU capsules:

11 February 2005

Vitamin A 100 000 IU capsules:

06 June 2003

Vitamin A 200 000 IU capsules:

06 June 2003

10. DATE OF REVISED OF THE TEXT

30 October 2020