1.3.2.1 Proposed Patient Information Leaflet (Clean Copy)

PATIENT INFORMATION LEAFLET

FOR

VITAFORCE A 50 000 IU,

VITAFORCE A 100 000 IU AND

VITAFORCE A 200 000 IU capsules.

SCHEDULING STATUS:

The scheduling status of **Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce A 200 000 IU** is Schedule 3 S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

The name of your medicine is **Vitaforce A 50 000 IU/Vitaforce A 100 000 IU/Vitaforce A 200 000 IU**

The active ingredient in all three variants is; **Vitamin A Palmitate** supplying Vitamin A 50 000 IU, 100 000 IU and 200 000 IU.

The three variants exist in a soft gelatine capsule form

Read all of this leaflet carefully before you start taking/using/giving Vitaforce A 50 000 IU/Vitaforce A 100 000 IU/Vitaforce A 200 000 IU:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you or your child personally and you should not share your medicine with other people or children. It may harm them, even if their symptoms are the same as yours or that of the child it is prescribed for.

WHAT VITAFORCE A 50 000 IU, VITAFORCE A 100 000 IU AND VITAFORCE A 200 000 IU CONTAINS:

Each **Vitaforce A 50 000 IU** capsules contains the following:

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

The **Vitaforce A 50 000 IU** also contains other ingredients (inactive ingredients): arachis oil, gelatine, glycerine, iron oxide (colourant), soya bean oil, sunflower oil and titanium dioxide (colourant)

Each **Vitaforce A 100 000 IU** capsule contains the following:

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

The **Vitaforce A 100 000 IU** also contains other ingredients (inactive ingredients): arachis oil, gelatine, glycerine, iron oxide (colourant), soya bean oil, sunflower oil and titanium dioxide (colourant)

Each **Vitaforce A 200 000 IU** capsule contains the following:

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

The **Vitaforce A 200 000 IU** also contains other ingredients (inactive ingredients): arachis oil, gelatine, glycerine, iron oxide (colourant), soya bean oil and titanium dioxide (colourant).

WHAT VITAFORCE A 50 000 IU/VITAFORCE A 100 000 IU/VITAFORCE A 200 000 IU ARE USED FOR:

The three variants are vitamins used mostly in children for the following:

- 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.

BEFORE YOU TAKE VITAFORCE A 50 000 IU/VITAFORCE A 100 000 IU/VITAFORCE A 200 000 IU:

Do not take or give VITAFORCE A 50 000 IU/VITAFORCE A 100 000 IU/VITAFORCE A 200 000 IU if:

If you or the child is hypersensitive (allergic) to any vitamin A or any of the other ingredients If you or the child suffer from hypervitaminosis A (vitamin A toxicity)

If you or the child has renal failure or liver disease If you or the child is receiving measles vaccination If you are pregnant or breastfeeding.

Special care should be taken with VITAFORCE A 50 000 IU/VITAFORCE A 100 000 IU/VITAFORCE A 200 000 IU:

- 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 papilloedema 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).

Taking Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce 200 000 IU with food and drink:

Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce 200 000 IU can be taken with/without a meal.

Pregnancy and Breastfeeding

- Do not exceed the stated dose. Woman who are or might become pregnant should avoid taking daily supplements containing more than 5 000 i.u. vitamin A.
- **Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce 200 000 IU** must not be taken by women who are planning pregnancy, pregnant or breastfeeding.

Driving and using machinery:

No effect on the ability to drive and use of machines had been reported.

Important information about some of the ingredients of Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce 200 000 IU:

Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce 200 000 IU capsules are sugar-free.

Taking other medicines with Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce 200 000 IU capsules:

Always tell your healthcare provider if you are taking any other medicines (This includes complementary or traditional medicines).

Examples of medicines that may interact with **Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce 200 000 IU** capsules include:

- 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 may stimulate bone loss and counteract the effects of calcium supplementation and cause hypercalcaemia.
- Tetracycline: concurrent use has been reported to cause benign intracranial hypertension (pseudotumour cerebri).
- Oral contraceptives: concurrent use 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.

HOW TO TAKE VITAFORCE A 50 000 IU/VITAFORCE A 100 000 IU/VITAFORCE A 200 000 IU:

Do not share medicines prescribed for you with any other person.

Always take **Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce A 200 000 IU** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Snip or twist-off the tip of the capsule or pierce the capsule and squeeze the contents into the mouth, unless otherwise prescribed.

Vitamin 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

An additional dose should be given 1-4 weeks later. The recommended doses should not be exceeded.

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.

If you take more Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce A 200 000 IU than you should:

The administration of excessive amounts of Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce A 200 000 IU capsules may lead to toxicity. Serum Vitamin A levels are useful for the diagnosis of hypervitaminosis A

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce A 200 000 IU:

Do not take double dose to make up for forgotten individual doses. Continue taking the capsules as directed

Contact your healthcare provider for further advice.

POSSIBLE SIDE EFFECTS:

Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce A 200 000 IU capsules can have side effects

Stop taking Vitaforce A 50 000 IU, Vitaforce A 100 000 IU and Vitaforce A 200 000 IU immediately and check with your doctor immediately or go to the casualty department at your nearest hospital:

If you experience: 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.

Other side effects may occur. However check with your doctor if any of the following side effects continue or are bothersome:

Sedation, dizziness, nausea and vomiting, erythema, pruritis, desquamation and increased intracranial pressure (resulting in bulging fontanelle in infants).

Not all side effects reported for VITAFORCE A 50 000 IU/VITAFORCE A 100 000 IU/VITAFORCE A 200 000 IU are included in this leaflet. Should your general state of health worsens while taking any of the three variants, please consult your doctor, pharmacist or other healthcare provider for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING VITAFORCE A 50 000 IU/VITAFORCE A 100 000 IU/VITAFORCE A 200 000 IU:

Store at or below 25 °C

Store in a dry place, protected from light. Do not store in a bathroom.

Do not use after the expiry date stated on the label. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF VITAFORCE A 50 000 IU/VITAFORCE A 100 000 IU/VITAFORCE A 200 000 IU:

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.

IDENTIFICATION OF VITAFORCE A 50 000 IU/VITAFORCE A 100 000 IU/VITAFORCE A 200 000 IU:

Vitamin A 50 000 IU capsules:

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

Vitamin A 100 000 IU capsules:

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

Vitamin 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.

REGISTRATION NUMBER:

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.

NAME AND ADDRESS OF REGISTRATION HOLDER:

Biotech Laboratories (Pty) Ltd

Ground Floor, Block K West, Central Park

400 16th Road, Randjespark

Midrand 1685

011 848 3050

DATE OF PUBLICATION:

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