SCHEDULING STATUS: **S0**

PROPRIETARY NAME: **VI-DAYLIN®**
(AND DOSAGE FORM) **(DROPS)**

COMPOSITION:

Each 0,6 ml drops contain :	
Vitamin A	5 000 IU
Vitamin D (Viosterol)	400 IU
Vitamin C (ascorbic acid)	50 mg
Vitamin B_1 (thiamine)	1,5 mg
Vitamin B_2 (riboflavin)	1,2 mg
Nicotinamide B_3	10 mg
Vitamin B_6 (pyridoxine)	0,5 mg
Preserved with :	
Methylparaben	0,05 % m/v
Benzoic acid	0,10 % m/v

Antioxidant: butylated hydroxyanisole
Sugar free

PHARMACOLOGICAL CLASSIFICATION:
A 22.1.1 Vitamins for paediatric use

PHARMACOLOGICAL ACTION:
VI-DAYLIN drops provide vitamins for infants.

INDICATIONS:
VI-DAYLIN drops are intended for use as a dietary supplement.

CONTRAINDICATIONS:
VI-DAYLIN drops are contraindicated in patients hypersensitive to any of the ingredients. Not intended for patients where a specific vitamin deficiency exists.

WARNINGS:
Keep this product out of the reach of children. In cases of accidental overdose, call a doctor or seek medical advice immediately.

Women who are, or might, become pregnant should avoid taking daily supplements containing more than 5 000 IU vitamin A, without consulting a medical practitioner. The safe dosage may be exceeded when medicines and/or health products containing vitamin A are taken together with a high dietary intake of vitamin A.

DOSAGE AND DIRECTIONS FOR USE:

VI-DAYLIN drops will not curdle milk and may be added to infants' feeds or may be mixed with cereal or fruit juice, or may be taken as is.

Daily dosage for babies 1 to 12 months :

0,6 ml orally or as directed by the doctor.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Side effects:

Allergic reactions, including rash, pruritus, and anaphylaxis have been reported with vitamin use.

Components of these products have been associated with gastrointestinal effects such as heartburn, eructation, abdominal pain and cramps, diarrhoea, constipation, vomiting, nausea and anorexia.

Deterioration of acne vulgaris, or eruption of acneform exanthema, has been noted with several components.

Bright yellow urine discolouration has been reported with riboflavin usage.

Long-term administration of vitamin A >10 000 IU daily may cause chronic hypervitaminosis A. Symptoms of chronic intoxication are as follows : headache, vertigo, hyperkeratosis, changes in skin and mucous membranes, tenderness and pain in the bone and joints, fever, increased serum cholesterol and serum triglyceride concentration, intracranial hypertension, fatigue, hypercalcaemia, hyperglycaemia, increased alkaline phosphatase, hypoproteinaemia, hypoprothrombinaemia, low serum ascorbic acid, decreased protein content of the cerebrospinal fluid, elevated urinary hydroxyproline and hypercalciuria, polyuria, increased frequency of micturition, urinary incontinence, enuresis and acute renal failure due to tubular necrosis, papilloedema, dryness, haemorrhages and fissures of the lips, yellow to yellow-orange discolouration of the skin, decreased tolerance to sunlight, changes in pigmentation, hair loss and brittle nails, spider angiomas and oedema.

Prolonged moderate intake of vitamin A (20 000 IU per day), when taken over prolonged periods of time can cause significant hepatic injury, including cirrhosis. Total cumulative dose may be a critical factor.

Characteristic features of chronic vitamin D intoxication include hypercalcaemia and deposition of calcium salts in various tissues. Occasionally, mental disturbances, cerebellar ataxia, peripheral facial paresis, apathy, and lack of interest have been reported.

Precautions:

Caution should be used in patients with chronic liver disease and in patients with hyperlipidaemia.

Vitamin D should be used with caution in patients with hypercalcaemia.

Increased sensitivity to vitamin D is observed in patients with renal impairment and having an abnormal calcium/phosphorus ratio.

Drug interactions:

The effects of vitamin D may be reduced in patients taking barbiturates of anticonvulsants due to accelerated metabolism of vitamin D.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

High doses of individual components of this product have been associated with eczematous and exanthematous skin lesions, fatigue, and insomnia. In higher niacinamide doses, liver damage, gout and ulcer formation have been noted.

High doses of vitamin A can lead to haemolysis, anaemia, neutropaenia, leukocytosis, thrombocytopaenia, aplastic anaemia, increased sedimentation rate, and accelerated reabsorption of trabecular and cortical bone.

Initial symptoms of vitamin D overdose are usually comprised of weakness, lassitude, headache, nausea, vomiting and diarrhoea. Renal function can be impaired at an early stage with polyuria, polydipsia, nocturia, decreased urinary concentrating ability, and proteinuria.

If symptoms of overdosage arise, discontinue use of the medicine. Treatment is symptomatic and supportive.

IDENTIFICATION:

VI-DAYLIN drops are a yellow liquid with a characteristic citrus odour and flavour.

PRESENTATION:

VI-DAYLIN drops are supplied in 25 ml amber glass bottles, with calibrated dropper to allow for the measuring of exact dosage.

STORAGE INSTRUCTIONS:

Store at or below 25 °C in a cool place. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER:

H 2088 (Act 101/1965).

NAME AND BUSINESS ADDRESS OF APPLICANT:

Tiger Consumer Brands
2 Purlin Street
Isando
Kempton Park
1600

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

March 1975

SKEDULERINGSTATUS: **S0**

EIENDOMSNAAM: **VI-DAYLIN®**
(EN DOSEERVORM) **(DRUPPELS)**

SAMESTELLING:

Elke 0,6 ml druppels bevat:

Vitamien A	5 000 IE
Vitamien D (Viosterol)	400 IE
Vitamien C (askorbiensuur)	50 mg
Vitamien B_1 (tiamien)	1,5 mg
Vitamien B_2 (riboflavien)	1,2 mg
Nikotienamied	10 mg
Vitamien B_6 (piridoksien)	0,5 mg
Gepreserveer met :	
Metielparabeen	0,05 % m/v
Bensoësuur	0,10 % m/v

Antioksidant: gebutileerde hidroksianisool

Suikervry

FARMAKOLOGIESE KLASSIFIKASIE:

A 22.1.1 Vitamiene vir pediatriese gebruik

FARMAKOLOGIESE WERKING:

VI-DAYLIN druppels voorsien vitamiene vir babas

INDIKASIES:

VI-DAYLIN druppels word gebruik as 'n dieetaanvullin

KONTRA-INDIKASIES:

VI-DAYLIN druppels is teenaangedui by pasiënte wat hipersensitief is vir enige van die bestanddele. Nie vir gebruik by pasiënte met 'n spesifieke vitamientekort nie.

WAARSKUWING:

Hou hierdie produk buite die bereik van kinders. In geval van 'n toevallige oordosis, raadpleeg 'n geneesheer of kry onmiddellik mediese advies.

Vrouens wat swanger is, of swanger mag raak, behoort die inname van daaglikse aanvullings wat meer as 5 000 IE vitamien A bevat, sonder om 'n mediese praktisyn te raadpleeg, te vermy.

Die veilige dosis kan oorskry word wanneer medisynes en/of gesondheidsprodukte wat vitamien A bevat saam met 'n hoë dieetinname van vitamien A geneem word.

DOSIS EN GEBRUIKSAANWYSINGS:

VI-DAYLIN druppels sal melk nie laat skif nie en kan by babas se voedings gevoeg of met graankos of vrugtesap gemeng word. Dit kan ook skoon geneem word.

Daaglikse dosis vir babas van 1 tot 12 maande:

0,6 ml mondelings of soos deur die geneesheer voorgeskryf.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Newe-effekte:

Allergiese reaksies met inbegrip van veluitslag, gejeuk en anafilakse is met vitamiengebruik aangemeld.

Bestanddele van hierdie produkte is geassosieer met gastroïntestinale effekte soos sooibrand, oprisping, abdominale pyn en krampe, diaree, hardlywigheid, braking, naarheid en anoreksie.

Verslegting van acne vulgaris of die voorkoms van aknevormige huiduitslag is met verskeie bestanddele waargeneem.

Heldergeel verkleuring van die urien is met die gebruik van riboflavien aangemeld.

Langtermyn toediening van vitamien A >10 000 IE daagliks kan tot chroniese hipervitamienose A lei. Simptome van chroniese vergiftiging sluit die volgende in: hoofpyn, duiseling, hiperkeratose, veranderings in vel en slymvliese, teerheid en pyn in been en gewrigte, koors, verhoogde serumcholesterol- en serumtrigliseriedkonsentrasie, intrakraniale hipertensie, moegheid, hiperkalsemie, hiperglukemie, verhoogde alkaliese fosfatase, hipoproteïnemie, hipoprotrombinemie, lae serumaskorbiensuur, verlaagde proteïeninhoud van serebrospinale vloeistof, verhoogde urinêre hidroksiprolien en hiperkalsiurie, poliurie, verhoogde frekwensie van urinering, urinêre beheerverlies, enurese en akute nierversaking weens tubulêre nekrose, papiledeem, droogheid, bloeding en barsies van die lippe, geel tot geel-oranje verkleuring van die vel, laer toleransie vir sonlig, veranderings in pigmentasie, haarverlies en bros naels, spinangiome en edeem.

Langdurige, matige inname van vitamien A (20 000 IE per dag) oor lang periodes kan tot aansienlike lewerbeskadiging, met inbegrip van sirrose, lei. Totale kumulatiewe dosis kan 'n kritieke faktor wees.

Kenmerkende eienskappe van chroniese vitamien D vergiftiging sluit in hiperkalsemie en die afsetting van kalsiumsoute in verskeie weefsels. Soms is geestesversteurings, serebellêre ataksie, perifere deelsverlamming van die gesig, apatie en gebrek aan belangstelling ook aangemeld.

Voorsorgmaatreëls:
Omsigtigheid moet aan die dag gelê word by pasiënte met chroniese lewersiekte en by pasiënte met hiperlipidemie.

Vitamien D moet ook met omsigtigheid gebruik word by pasiënte met hiperkalsemie.

Verhoogde sensitiwiteit vir vitamien D is waargeneem by pasiënte met nieraantasting en wat 'n abnormale kalsium/fosfor verhouding toon.

Geneesmiddelwisselwerking:
Die effekte van vitamien D kan verminder word by pasiënte wat barbiturate of stuipmiddels neem weens versnelde metabolisme van vitamien D.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Hoë dosisse van individuele bestanddele van hierdie produk is geassosieer met eksemateuse en eksanteemvelletsels, moegheid en slaaploosheid. Lewerskade, jig en ulkusvorming is by hoër dosisse niasienamied waargeneem.

Hoë dosisse vitamien A kan lei tot hemolise, anemie, neutropenie, witseltoename, trombositopenie, aplastiese anemie, verhoogde besinkingsnelheid, asook versnelde herabsorpsie van balk- en kortikale been.

Aanvanklike simptome van vitamien D-oordosis sluit gewoonlik swakheid, matheid, hoofpyn, naarheid, braking en diaree in. Nierfunksie kan op 'n vroeë stadium aangetas word met simptome soos poliurie, oordorstigheid, nokturie, verminderde urinêre konsentrasievermoë en proteïenurie.

Staak gebruik van die medisyne indien simptome van oordosering waargeneem word.
Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

VI-DAYLIN druppels is 'n geel vloeistof met 'n kenmerkende sitrusgeur en -smaak.

AANBIEDING:

VI-DAYLIN druppels word verskaf in 25 ml amberkleurige glasbottels met 'n gekalibreerde pipet om die afmeet van 'n presiese dosis te vergemaklik.

BERGINGSAANWYSINGS:

Bêre teen of onder 25 ºC op 'n koel plek. Beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS.

VERWYSINGSNOMMER:

H 2088 (Wet 101/1965)

NAAM EN BESIGHEIDSADRES VAN DIE APPLIKANT:

Tiger Consumer Brands
2 Purlin Street
Isando
Kempton Park
1600

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:

Maart1975