SCHEDULING STATUS: **S0**

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

COMPOSITION:

Each 5 ml contains:

Vitamin A	3 000 IU
Vitamin D (Viosterol)	400 IU
Vitamin C (ascorbic acid)	50 mg
Vitamin B_1 (thiamine hydrochloride)	1,5 mg
Vitamin B_2 (riboflavin)	1,2 mg
Nicotinamide	10 mg
Vitamin B_6 (pyridoxine hydrochloride)	1,0 mg

Preserved with:	
Methylparaben	0,03 % m/v
Benzoic acid	0,10 % m/v

Contains sugar:	
Sucrose	779 mg
Liquid glucose	5 263 mg

PHARMACOLOGICAL CLASSIFICATION:

A 22. 1. Vitamins

PHARMACOLOGICAL ACTION:

VI-DAYLIN SYRUP provides vitamins.

INDICATIONS:

VI-DAYLIN SYRUP is for use as a dietary supplement.

CONTRAINDICATIONS:

VI-DAYLIN SYRUP is 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 SYRUP 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 5 years :

One medicine measureful (5 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 and 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.

Caution should be exercised when using this product in patients with pre-existing thyroid disease.

Drug interactions:

With concomitant use of alcohol, toxic delirium and lactic acidosis have been noted.

The effects of vitamin D may be reduced in patients taking barbiturates or 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 re-absorption 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 SYRUP is a yellow liquid with a characteristic citrus odour and flavour.

PRESENTATION:

VI-DAYLIN SYRUP is supplied in 150 ml amber glass bottles.

STORAGE INSTRUCTIONS:

Store in a cool place (below 25 °C).
Protect from light.
KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER:

H 2604 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

Tiger Consumer Brands
2 Purlin Street
Isando
Kempton Park
1600

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

April 1993

SKEDULERINGSTATUS: **S0**

EIENDOMSNAAM: **VI-DAYLIN® SYRUP**

(EN DOSEERVORM) **(STROOP)**

SAMESTELLING:

Elke 5 ml bevat:

Vitamien A	3 000 IE
Vitamien D (Viosterol)	400 IE
Vitamien C (askorbiensuur)	50 mg
Vitamien B_1 (tiamienhidrochloried)	1,5 mg
Vitamien B_2 (riboflavien)	1,2 mg
Nikotienamied	10 mg
Vitamien B_6 (piridoksienhidrochloried)	1,0 mg

Gepreserveer met:	
Metielparabeen	0,03 % m/v
Bensoësuur	0,10 % m/v

Bevat suiker:	
Sukrose	779 mg
Vloeibare glukose	5 263 mg

FARMAKOLOGIESE KLASSIFIKASIE:

A 22.1 Vitamiene

FARMAKOLOGIESE WERKING:

VI-DAYLIN SYRUP voorsien vitamiene.

INDIKASIES:

VI-DAYLIN SYRUP is vir gebruik as 'n dieetaanvulling.

KONTRA-INDIKASIES:

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

WAARSKUWINGS:

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 SYRUP 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 5 jaar :

Een medisynemaat (5 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 hipervitaminose 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, hipoproteïenemie, hipoprotrombinemie, lae serumaskorbiensuur, verlaagde proteïeninhoud van die 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.

Omsigtigheid moet aan die dag gelê word by pasiënte met voorafgaande tireoïedsiekte.

Geneesmiddelwisselwerking:

Toksiese delirium en melkasidose is met die meegaande gebruik van alkohol waargeneem.
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 eksanteem-velletsels, 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 trabekel- 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 SYRUP is 'n geel vloeistof met 'n kenmerkende sitrusgeur- en smaak.

AANBIEDING:

VI-DAYLIN SYRUP word verskaf in 150 ml amberkleurige glasbottels.

BERGINGSAANWYSINGS:

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

VERWYSINGSNOMMER:

H2604 (Wet 101/1965)

NAAM EN BESIGHEIDSADRES VAN DIE APPLIKANT:

Tiger Consumer Brands
2 Purlin Straat
Isando
Kempton Park
1600

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET

April 1973