SCHEDULING STATUS: **S0**

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

COMPOSITION:

Each dropperful (1,0 ml) contains:

Vitamin A	1 500 IU
Vitamin D	400 IU
Vitamin E	5 IU
Vitamin C (ascorbic acid)	35 mg
Vitamin B_1 (thiaminehydrochloride)	0,5 mg
Vitamin B_2 (riboflavin)	0,6 mg
Vitamin B_3 (nicotinamide)	8 mg
Vitamin B_6 (pyridoxin hydrochloride)	0,4 mg
Vitamin B_{12} (cyanocobalamin)	1,50 µg
Iron	10 mg
Preserved with:	
Methylparaben	0,05 % m/v
Benzoic acid	0,1 % m/v
Sugar free	

PHARMACOLOGICAL CLASSIFICATION:

A 22.1 Multivitamins and multivitamins with minerals

PHARMACOLOGICAL ACTION:

VI-DAYLIN PLUS IRON contains vitamins and iron for infants and young children.

INDICATIONS:

VI-DAYLIN PLUS IRON is intended for use as a dietary supplement, where a deficiency of the relevant vitamins and minerals exist.

CONTRAINDICATIONS:

VI-DAYLIN PLUS IRON is contraindicated in patients who are hypersensitive to any of its ingredients.

WARNINGS:

Prolonged administration of doses in excess of those recommended may result in iron overload. In patients receiving oral iron therapy, additional parenteral administration of iron may result in an iron overloading and toxicity.

DOSAGE AND DIRECTIONS FOR USE:

DO NOT EXCEED THE DAILY DOSE WITHOUT CONSULTING A DOCTOR.

VI-DAYLIN PLUS IRON may be administered directly into the infant's mouth, given in the formula, or mixed with cereal or fruit juice.

Daily dose for infants and children under 4 years:

1, 0 ml orally or as prescribed by the doctor

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Hypervitaminosis A and D may occur with the intake of excesses of these fat soluble vitamins over a prolonged period.

Hypervitaminosis A is characterised by fatigue, irritability and loss of weight, vomiting and other gastrointestinal disturbances, low-grade fever, polyuria, hepatosplenomegaly, pruritus, loss of hair, cracking and bleeding lips, and dry skin with desquamation, hyperkeratosis and yellow pigmentation. Anaemia, headache and visual disturbances have also been reported.

Subcutaneous swelling, pains in bones and joints and tenderness over the long bones commonly occur; in children premature closure of the epiphyses of the long bones may result in arrested bone growth. Intracranial hypertension and papilloedema, mimicking brain tumours, have been reported, usually in children.

Side effects of iron ingestion include gastrointestinal discomfort, diarrhoea, vomiting and constipation. Side effects may be reduced by taking **VI-DAYLIN PLUS IRON** immediately after food. As a result of iron therapy, stools may become darkened or black in colour.

Large doses of vitamin C may cause diarrhoea and the formation of renal calcium oxalate calculi. Vitamin C should be given with care to patients with hyperoxaluria.

Cyanocobalamin should not be given before a diagnosis has been fully established because of the possibility of masking the symptoms of subacute degeneration of the spinal cord.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Acute vitamin A intoxication may occur with very high doses and is characterised by sedation, headache, irritability, papilloedema and generalised peeling of the skin.

Symptoms of vitamin D overdosage are anorexia, lassitude, nausea, vomiting, diarrhoea, loss of weight, polyuria, profuse sweating, headache, extreme thirst and vertigo; the calcium and phosphorus concentrations of serum and urine are increased and calcium may be deposited in many tissues including the arteries and kidneys, which may lead to hypertension and renal failure; the cholesterol concentrations of plasma may be increased.

Acute overdosage of iron may cause nausea and vomiting, and, in severe cases, cardiovascular collapse and death.

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

IDENTIFICATION:

VI-DAYLIN PLUS IRON is a dark, orange-brown, clear liquid with the odour of blended citrus and a characteristic, sweet-sour citrus taste.

PRESENTATION:

VI-DAYLIN PLUS IRON is supplied with a calibrated dropper, in bottles containing 30 and 50 ml.

STORAGE INSTRUCTIONS:

Store at or below 25 ºC and protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

X/22.1/40

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Tiger Consumer Brands

2 Purlin Street

Isando

Kempton

1600

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

August 1993

SKEDULERINGSTATUS: **S0**

EIENDOMSNAAM: **VI-DAYLIN PLUS IRON**
(EN DOSEERVORM) (**DRUPPELS)**

SAMESTELLING:

Elke druppervol (1,0 ml) bevat :

Vitamien A	1 500 IE
Vitamien D	400 IE
Vitamien E	5 IE
Vitamien C (askorbiensuur)	35 mg
Vitamien B_1 (tiamienhidrochloried)	0,5 mg
Vitamien B_2 (riboflavien)	0,6 mg
Vitamien B_3 (nikotienamied)	8 mg
Vitamien B_6 (piridoksienhidrochloried)	0,4 mg
Vitamien B_{12} (sianokobalamien)	1,50 µg
Yster	10 mg
Gepreserveer met:	
Metielparabeen	0,05 % m/v
Bensoësuur	0,1 % m/v
Suikervry	

FARMAKOLOGIESE KLASSIFIKASIE:

A 22.1 Multivitamiene en multivitamiene met minerale

FARMAKOLOGIESE WERKING:

VI-DAYLIN PLUS IRON bevat vitamiene en yster vir babas en jong kinders.

INDIKASIES:

VI-DAYLIN PLUS IRON is bedoel vir gebruik as 'n dieetaanvulling waar daar 'n tekort bestaan van die bepaalde vitamiene en minerale.

KONTRA-INDIKASIES:

VI-DAYLIN PLUS IRON is teenaangedui by pasiënte wat hipersensitief is vir enige van die bestanddele.

WAARSKUWINGS:

Langdurige toediening van dosisse groter as die aanbevole, mag tot ysteroorlading lei. By pasiënte wat orale ysterterapie ontvang, mag addisionele parenterale toediening van yster, ysteroorlading en -toksisiteit tot gevolg hê.

DOSIS EN GEBRUIKSAANWYSINGS:

MOENIE DIE DAAGLIKSE DOSIS OORSKRY SONDER OM 'N GENEESHEER TE RAADPLEEG NIE.

VI-DAYLIN PLUS IRON kan direk in die baba se mond toegedien word, in die formule gegee word, of gemeng word met babapap of vrugtesap.

Daaglikse dosis vir babas en kinders onder 4 jaar:

1,0 ml mondelik of soos deur die geneesheer voorgeskryf.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Hipervitaminose A en D mag voorkom na die inname van oormate van hierdie vetoplosbare vitamiene oor 'n langdurige tydperk.

Hipervitaminose A word gekenmerk deur moegheid, prikkelbaarheid en gewigsverlies, braking en maagdermkanaalversteurings, laegraadse koors, poliurie, hepatosplenomegalie, pruritus, haarverlies, gekraakte en bloeiende lippe, droë vel met afskilfering, hiperkeratose en geel pigmentering. Anemie, hoofpyn en sigversteurings is ook aangemeld.

Subkutane swelling, pyne in bene en gewrigte en teerheid oor die langbene kom algemeen voor; by kinders mag premature sluiting van die epifises van die langbene aanleiding gee tot vertraagde beengroei. Intrakraniale hipertensie en papiledeem, wat breintumore mag naboots, is aangemeld - gewoonlik by kinders.

Newe-effekte van ysterinname sluit in maagdermkanaalongemak, diaree, braking en hardlywigheid. Newe-effekte mag verminder word deur **VI-DAYLIN PLUS IRON** onmiddellik na voedselinname te neem. As gevolg van ysterterapie mag die stoelgange verdonker of swart van kleur word.

Groot dosisse vitamien C kan diaree en die vorming van renale kalsiumoksalaatkalkuli veroorsaak. Vitamien C moet met omsigtigheid toegedien word aan pasiënte met hiperoksalurie.

As gevolg van die moontlike nabootsing van die simptome van subakute degenerasie van die rugmurg , moet sianokobalamien nie toegedien word alvorens 'n diagnose volledig vasgestel is nie.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Akute vitamien A-vergiftiging kan voorkom teen baie hoë dosisse en word gekenmerk deur sedasie, hoofpyn, prikkelbaarheid, papiledeem en verspreide afskilfering van die vel.

Simptome van vitamien D-oordosering is anoreksie, matheid, naarheid, braking, diaree, gewigsverlies, poliurie, oormatige sweet, hoofpyn, uitermatige dors en duiseling; die kalsium- en fosforkonsentrasies van serum en urien is verhoog en kalsium mag neergeslaan word in baie weefsels, met inbegrip van die slagare en die niere, wat mag aanleiding gee tot hipertensie en nierversaking; die cholesterolkonsentrasies van plasma mag verhoog word.

Akute oordosering van yster mag naarheid en braking en, in ernstige gevalle, kardiovaskulêre ineenstorting en die dood veroorsaak.
Indien simptome van oordosering verskyn, moet die gebruik van die medisyne gestaak word. Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

VI-DAYLIN PLUS IRON is 'n donker, oranjebruin, helder vloeistof met die geur van versnyde sitrus en ’n kenmerkende, soetsuur sitrussmaak.

AANBIEDING:

VI-DAYLIN PLUS IRON word voorsien met 'n gekalibreerde druppertoediener in bottels wat 30 en 50 ml bevat.

BERGINGSINSTRUKSIES:

Bêre teen of benede 25 ºC en beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

X/22.1/0040

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:

Tiger Consumer Brands
2 Purlin Straat
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1600

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET

Augustus 1993