SCHEDULING STATUS: Unscheduled

PROPRIETARY NAME (AND DOSAGE FORM):

ORANGO EFFERVESCENT TABLETS

COMPOSITION:
Each EFFERVESCENT TABLET contains:

INGREDIENT	LABEL CLAIM	% RDA*
BETACAROTENE (3 mg)	500 µg RE	50
VITAMIN B1	15 mg	1071
VITAMIN B2	15 mg	938
VITAMIN B6	10 mg	500
VITAMIN B12	10 µg	1000
PANTOTHENIC ACID	22,5 mg	375
VITAMIN C	500 mg	966
NICOTINAMIDE	24 mg	133
BIOTIN	150 µg	150
FOLIC ACID	200 µg	100
CALCIUM	120 mg	15
MAGNESIUM	100 mg	33,3
ZINC	7,5 mg	50
SELENIUM (As Amino Acid Chelate)	10,0 µg	Not Established
COPPER	1,0 mg	Not Established

*RDA = Recommended daily allowance for persons 4 years and older.

SUGAR FREE
Artificially sweetened with saccharin and cyclamate.

PHARMACOLOGICAL CLASSIFICATION:
A 22.1 Multivitamins and Multivitamins with Minerals.

PHARMACOLOGICAL ACTION:
Dietary Supplement.

INDICATIONS:
Orango Effervescent tablets are a supplement providing Vitamin C, the B group Vitamins, Betacarotene (Pro-vitamin A, Antioxidant) as well as the minerals Calcium, Magnesium, Selenium, Zinc and Copper.

CONTRA-INDICATIONS:
Renal impairment, dehydration and gastric lesions or disorders.

DOSAGE AND DIRECTIONS FOR USE:
Adults and children over 4 years of age: Take one tablet, dissolved in a glass of water, daily.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Ascorbic acid (Vitamin C): Large doses may cause diarrhoea and the formation of renal calcium oxalate calculi. Daily doses of 600 mg or more have a diuretic action. Tolerance may be induced in patients taking high doses.
Diarrhoea, nausea and bowel discomfort may occur. Concurrent administration with zinc might diminish the effect of penicillamine. Tetracyclines may form a chelate with zinc.
Special precautions:
Pyridoxine hydrochloride (Vitamin B6) reduces the effects of levodopa. Cyanocobalamin (Vitamin B12) can mask symptoms of subacute degeneration of the spinal cord.

SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
The treatment of overdosage is symptomatic and supportive.

CONDITIONS OF REGISTRATION:
None.

IDENTIFICATION:
Large (25 mm), round, biplane, effervescent tablets. The tablets are light-yellow to grey with small dark-red particles impregnated into the tablet. The tablets effervesce in water with a slight foam. The red Betacarotene particles float to the surface at first, dissolving slowly to form an orange juice flavoured drink.

PRESENTATION:
Polypropylene tubes with 10 tablets, capped with a tamper-evident cap, containing drying material.

STORAGE INSTRUCTIONS:
Keep in a cool, dry place, below 25 °C.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION/APPLICATION NUMBER:
To be allocated.

NAME AND ADDRESS OF THE APPLICANT:
Mirren (Pty) Ltd
18 Golden Drive
Morehill
Benoni
South Africa

DATE OF PUBLICATION:
10 August 2002

SKEDULERINGSTATUS: Ongeskeduleerd

EIENDOMSNAAM (EN DOSEERVORM):

ORANGO BRUISTABLETTE

SAMESTELLING:
Elke BRUISTABLET bevat:

BESTANDDEEL	PER TABLET	% ADT*
BETA-KAROTEEN (3 mg)	500 µg RE	50
VITAMIEN B1	15 mg	1071
VITAMIEN B2	15 mg	938
VITAMIEN B6	10 mg	500
VITAMIEN B12	10 µg	1000
PANTOTEENSUUR	22,5 mg	375
VITAMIEN C	500 mg	966
NIKOTINAMIED	24 mg	133
BIOTIEN	150 µg	150
FOLIENSUUR	200 µg	100
KALSIUM	120 mg	15
MAGNESIUM	100 mg	33,3
SINK	7,5 mg	50
SELEEN (As Aminosuur Chelaat)	10,0 µg	Nie Vasgestel
KOPER	1,0 mg	Nie Vasgestel

*ADT = Aanbevole daaglikse dieettoelaag vir persone 4 jaar en ouer.

SUIKERVRY
Kunsmatig versoet met sakkarien en siklamaat.

FARMAKOLOGIESE KLASSIFIKASIE:
A 22.1 Multivitamiene en Multivitamiene met Minerale.

FARMAKOLOGIESE WERKING:
Dieetaanvulling.

INDIKASIES:
Orango Bruistablette is ’n supplement wat Vitamien C, Vitamien B kompleks, Beta-karoteen (Pro-vitamien A, Anti-oksidant) sowel as die minerale Kalsium, Magnesium, Seleen, Sink en Koper bevat.

KONTRA-INDIKASIES:
Renale ontoereikendheid, dehidrasie, gastriese letsels en wantoestande.

DOSIS EN GEBRUIKSAANWYSINGS:
Volwassenes en kinders ouer as 4 jaar: Neem een tablet, opgelos in ’n glas water, daagliks.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Askorbiensuur (Vitamien C): Groot dosisse mag diarree en die vorming van renale kalsium oksalaat kristalle by sekere individue veroorsaak. Dosisse van 600 mg en meer per dag het ’n diuretiese effek. Toleransie mag geïnduseer word by individue wat groot dosisse oor ’n lang tydperk neem.
Diarree, naarheid en gastriese ongemak mag voorkom. Die werking van penisillamien word ingekort wanneer sink gelyktydig ingeneem word. Tetrasikliene vorm ook komplekse met sink.
Spesiale voorsorg:
Piridoksien (Vitamien B6) verminder die effek van Levodopa. Sianokobalamien (Vitamien B12) mag die simptome van sub-akute degenerasie van die spinale kolom maskeer.

SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Die behandeling van oordosering is simptomaties en ondersteunend.

VOORWAARDES VAN REGISTRASIE:
Geen.

IDENTIFIKASIE:
Orango is ’n groot (25 mm) ronde, bi-planêre bruistablet. Die tablet is liggeel tot grys met klein rooi spikkels in die tablet geimpregneer. Die bruising in water is effens skuimend en die rooi betakaroteen deeltjies dryf eers bo-op die oplossing en los dan stadig op tot ’n aangename oranje-rooi lemoendrankie.

AANBIEDING:
Polipropileenbuise met 10 tablette. Die buise is geseël met ’n prop wat met ’n peuter-ring omsluit is. Binne-in die prop is drogingsmateriaal ingesluit.

BERGINGSVOORSKRIFTE:
Bewaar in ’n koel, droë plek, onder 25 ºC.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER/ APPLIKASIENOMMER:
Moet nog toegeken word.

NAAM EN BESIGHEIDSADRES VAN APPLIKANT:
Mirren (Edms) Bpk
Goldenrylaan 18
Morehill
Benoni
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