# GOVERNMENT NOTICE

## DEPARTMENT OF HEALTH

**No. R. 837** **28 October 2014**

### MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965)

The Medicines Control Council, hereby by virtue of its vested powers by Section 14(2) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) ("the Act"), and by resolution approved by the Minister of Health, determines that, with effect from the date of publication of this notice, all oral preparations which-

(1) contain a vitamin(s) or an elemental mineral(s) (including salts or derivatives thereof), excluding foodstuffs as defined in the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) which contain a vitamin(s) or an elemental mineral(s) either as such or in combination with any other pharmacologically active ingredient(s) (including trace elements), whether medicinal claims are made or not; and

(2) exceed per recommended total daily dose any of the respective doses stated in this notice or, in the absence of a dosage schedule, exceed per oral dosage unit of any particular dosage form any of the respective doses stated in this notice;

shall be subject to registration as Category A medicines as defined in Regulation 25(1) of the General Regulations promulgated under the Act, and more particularly, as Category A medicines falling under Pharmacological Classifications 22, 22.1, 22.1.1, 22.1.2, 22.1.3, 22.1.4, 22.1.5 and Pharmacological Classification 32 as defined in Regulation 25(2) of the said Regulations for vitamin and mineral oral preparations respectively.

It is hereby further notified that, under Section 14(2)(b) of the Act, the above-mentioned resolution shall relate to preparations that are available for sale in the Republic on or before the date on which the notice comes into operation and shall also relate to preparations that become available after the said date.

| ***Vitamin/ Mineral*** *(Including all existing isomers, salts and analogues)* | ***Dose*** |
|---|---|
| VITAMIN A | 5000 I.U (Dosage is based on the all-trans isomer of retinol equivalent $C_{20}H_{30}O$- molecular mass = 286,5- expressed in international units and 0,3 µg of the all-trans isomer of retinol equivalent to 1 I.U. Vitamin A activity). |
| VITAMIN $B_1$ (THIAMINE) | 100 mg (Dosage is based on the thiamine hydrochloride equivalent $C_{12}H_{17}ClN_4OS$, HCl- molecular mass = 337,3). |
| VITAMIN $B_2$ (RIBOFLAVIN) | 100 mg (Dosage is based on the riboflavin equivalent $C_{17}H_{20}N_4O_6$- molecular mass = 376,4). |
| VITAMIN $B_3$ (NIACIN) | 35 mg (Dosage is based on niacinamide equivalent $C_6H_6N_2O_3$- molecular mass = 122,1). |
| NICOTINAMIDE | 500 mg |
| VITAMIN $B_5$ (PANTOTHENIC ACID) | 200 mg (Dosage is based on the D-pantothenic acid equivalent $C_9H_{17}NO_{15}$- molecular mass = 219,2). |
| VITAMIN $B_6$ (PYRIDOXINE) | 100 mg (Dosage is based on the pyridoxine hydrochloride equivalent $C_8H_{11}NO_3HCL$- molecular mass = 205,6). |
| VITAMIN $B_{12}$ (CYANOCOBALAMIN) | 100 *µg* (Dosage is based on the cyanocobalamin equivalent $C_{63}H_{88}CoN_{14}O_{14}P$- molecular mass = 1355,4). |
| VITAMIN C (ASCORBIC ACID) | 1000 mg (Dosage is based on the L-ascorbic acid equivalent $C_6H_8O_6$- molecular mass = 176,1). |

VITAMIN D (CHOLECALCIFEROL)..... 1000 I.U.

(Dosage is based on either cholecalciferol equivalent $C_{27}H_{44}O$- molecular mass = 384,6- expressed in international units (I.U.) or the ergocalciferol equivalent $C_{28}H_{44}O$- molecular mass = 396,7- expressed in international unit (I.U.). 0,025 µg Vitamin D is equivalent to 1 international unit).

VITAMIN E..... 400 I.U.

(Dosage is based on the dl-alphatocopheryl acetate equivalent $C_{31}H_{52}O_3$- molecular mass = 472,8). 1 mg dl-alphatocopheryl acetate is equivalent to 1 international unit).

VITAMIN K..... 120 *µg*

(Except when used in infant milk feeds or formulae in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectant Act, 1972 (Act 54 of 1972).

VITAMIN H (BIOTIN)..... 500 *µg*.

FOLIC ACID..... 400 *µg*.

(Dosage is based on the pteroylmonoglutamic acid equivalent $C_{19}H_{19}N_7O_6$- molecular mass = 441,4).

BORON..... 3 mg.

CALCIUM..... 1300 mg.

CHROMIUM..... 50 *µg*.

COPPER..... 4 mg.

IODINE..... 150 *µg*

IRON..... 24 mg.

MAGNESIUM..... 250 mg.

MANGANESE..... 4 mg.

MOLYBDENUM..... 230 *µg*.

PHOSPHORUS..... 250 mg.

POTASSIUM..... 1500 mg.

SELENIUM..... 60 *µg*.

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|---|---|
| STRONTIUM | All levels |
| VANADIUM | 182 *µg* |
| ZINC | 25 mg. |

**MS M HELA**
**REGISTRAR OF MEDICINES**
**DATE:** 22/10/14