

**SUMMARY OF PRODUCT CHARACTERISTICS**  
**(SmPC) TEMPLATE**

# **SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)**

## **DR. MEYER'S CALCIMAX SUSPENSION**

### **1. NAME OF THE MEDICINAL PRODUCT**

**DR. MEYER'S CALCIMAX SUSPENSION** (Calcium Carbonate BP (as Calcium) 150mg, Magnesium Hydroxide BP (as Magnesium) 25mg, Zinc Sulphate BP (as Zinc) 1.5mg, Vitamin D<sub>3</sub> 200 I.U. / 5ml)

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 5ml contains:

Calcium Carbonate BP (as Calcium)	150mg,
Magnesium Hydroxide BP (as Magnesium)	25mg,
Zinc Sulphate BP (as Zinc)	1.5mg,
Vitamin D <sub>3</sub>	200 I.U

#### **Excipients:**

Nipagin (Methyl Paraben)	10mg
Nipasol (Propyl Paraben)	1mg
Sodium CMC	25.00mg
Sucrose B.P	2.50gm
Sorbitol 70%	900.00mg
Liquid Glucose	900.00mg
Xanthan Gum	10.00mg
Glycerin	50.00 mg
Tween 80	50.00mg
Banana Flavor	0.0025ml
Strawberry Flavor	0.0025ml
Sodium Hydroxide	0.20mg
Purified Water B.P.	q.s

For Full list of excipients refer section 6.1

### **3. PHARMACOLOGICAL FORM**

Oral Suspension

White suspension with banana & Strawberry flavors presented in 100ml amber pet bottle with metallic screw cap packed in a carton with insert and measuring cup

### **4. CLINICAL PARTICULARS**

#### **4.1 Therapeutic Indications**

- Maintains strong bones and healthy teeth.
- Supports healthy functioning of nerves, muscle and heart rhythm
- Helps alleviate inaimnia
- Supports a healthy metabolism
- Supports an alkaline systemic pH

Calcimax is also used for the treatment and prevention of low calcium levels and resulting bone conditions including osteoporosis (weak bones due to low bone density), rickets (a condition in children involving softening of the bones), and oosteomalacia ( a softening of the bone involving pain). It also helps in the development of strong teeth.

#### **4.2 Posology and Method of administration**

Children (1 -10 years): 5ml to be taken 2 times daily or as directed by the physician.

Infants (Under 1 year): 2.5m1 to be taken 2 times daily or as directed by the physician.

#### **Method of administration**

Oral

#### **4.3 Contraindications**

Hypersensitivity to any of the ingredients.

#### **4.4 Special Warnings and Precautions for Use**

Some people may experience diarrhea. Individuals with kidney or thyroid disorders should consult a healthcare practitioner before use. Take this supplement two hours after bisphosphonates.

Keep out of reach of children.

Do not exceed recommended daily dose/amount.

Do not use this medicine for other health conditions.

#### **4.5 Interactions with other medications**

Interaction may take place with the following drugs: alendronate, ciprofloxacin, doxycycline, ofloxacin, oral contraceptives, tetracyclines, thiazide diuretics, verapamil. Depletion or interference may take place when the following medications are used: albuterol, aluminum hydroxide, bile acid sequestrants, cycloserine, indomethacin, isoniazid, losartan, mineral oil, neomycin, sulfamethoxazole, thyroid hormones, tobramycin, triamterene, trimethoprim, verapamil. Excess calcium can impair the absorption of the minerals iron and zinc.

#### **4.6 Pregnancy and lactation**

Epidemiological studies have shown no increase in the teratogenic hazard to the foetus if used in the dose recommended for usual vitamin and calcium supplementation. Although calcium and other vitamins are excreted in breast milk, the concentration is not sufficient to produce an adverse effect on the neonate when taken in recommended doses.

As with any other drug, if you are a pregnant or nursing baby, contact your healthcare professional before taking this drug.

#### **4.7 Effects on ability to drive and use machines**

The medication does not have any effect on ability to drive and use machines.

#### **4.8 Undesirable effects**

The following steps are recommended to minimise or prevent further absorption of the medication. Gastric lavage should be considered only within 1 hour of a life-threatening amount being ingested, if the airway can be protected adequately.

### **5. PHARMACOLOGICAL PROPERTIES**

Calcimax Suspension is an important source of additional calcium. To optimize its effectiveness, Calcimax suspension has been balanced with vitamin D, Zinc and Magnesium. Each of these nutrients not only enhances the absorption and utilization of calcium, but also contributes significantly to the growth and development in young children. For example tooth enamel is poorly formed if adequate Magnesium is not available with Calcium. Calcium, magnesium, and vitamin D work together in the body to enhance each other's overall absorption and utilization.

Vitamin D increases the absorption of calcium. Both calcium and magnesium are essential factors in the formation and maintenance of healthy bones, but they also play an important role in the contraction and relaxation of muscles, including the heart when calcium flows into the muscle tissue cells they contract. When calcium leaves, magnesium replaces it and the muscle relaxes. They also work together to normalize the muscle tone of blood vessels.

Calcium is a mineral that is an essential part of bones and teeth. The heart, nerves and blood-clotting systems also need calcium to work. The bones and teeth contain over 99 % of calcium in the human body. Calcium is also found in the blood, muscles, and other tissues. Calcium in the bones can be used as a reserve that can be released into the body as needed. Calcium is a major mineral in the body that is perhaps most well-known for its role in the formation and maintenance of strong, healthy bones and tooth enamel. Although the majority of calcium in the body is found stored in the bones and teeth, a small amount is also found in the bloodstream. Calcium in the blood has many important roles to play: it transports nutrients across cell membranes; produces hormones and enzymes involved in digestion and metabolism; is involved in nerve cell communication; promotes blood clotting and wound healing; and assists with muscle contractions. Calcium is an essential nutrient throughout the lifespan, but it is particularly important for growing children and adolescents to help establish adequate bone mass for maintaining strong bones throughout life.

Magnesium is a mineral that is present in relatively large amounts in the body. It is important in more than 300 chemical reactions that keep the body working properly. Magnesium is required for the proper growth and maintenance of bones. It is also required for the proper function of nerves, muscles and other parts of the body. Approximately half of the magnesium in the body is found in the bones and it is an essential nutrient to keep them strong and healthy. Magnesium also plays an important role in maintaining the function of nerves and regulating muscle relaxation. A deficiency in magnesium is associated with the occurrence of muscle spasms, tremors and convulsion. Low magnesium levels have also been associated with psychiatric problems such as depression and schizophrenia.

Zinc is essential for making the hormones that control growth. It also helps to heal the body quickly from wounds, keeps the skin healthy, preserves eyesight and might even improve memory. It is present in many hormones including the ones that help the immune system attack germs.

Vitamin D, is a fat soluble vitamin that regulates calcium and magnesium metabolism. It promotes intestinal absorption of calcium, mobilization of calcium from bone stores and retention of calcium by the kidneys. The D<sub>3</sub> form Cholecalciferol may be absorbed more rapidly and completely than commonly used D<sub>2</sub> (Ergocalciferol) since this form requires the presence of bile salts.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of Excipients**

Nipagin (Methyl Paraben)	10mg
Nipasol (Propyl Paraben)	1mg
Sodium CMC	25.00mg
Sucrose B.P	2.50gm
Sorbitol 70%	900.00mg
Liquid Glucose	900.00mg
Xanthan Gum	10.00mg
Glycerin	50.00 mg
Tween 80	50.00mg
Banana Flavor	0.0025ml
Strawberry Flavor	0.0025ml
Sodium Hydroxide	0.20mg
Purified Water B.P.	q.s

### **6.2 Incompatibilities**

None specific

### **6.3 Shelf-Life**

36 Months

### **6.4 Special Precautions for Storage**

Store below 30° C. Replace cap securely.

### **6.5 Nature and Contents of Container**

100 ml in Amber coloured pet bottles with metallic screw cap / measuring cup/ insert packed in a carton.

**6.6 Instructions for Handling**

None specific.

**7. Applicant / Manufacturer:**

**Adler Products Limited**

32, Oduyemi Street,

Anifowoshe, Ikeja,

Lagos State,

Nigeria.

**Vitabiotics Nigeria Limited**

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