1. NAME OF THE MEDICINAL PRODUCT

M & B Vitamin C 500mg Chewable Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Vitamin C 500mg (1 x 120)

3. PHARMACEUTICAL FORM

Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Development of bone and teeth
- Promotion of wound healing
- Buildup of body immune system
- Treatment of Cold and Scurvy

4.2 Posology and method of administration

Posology

As a dietary supplement

Adults: Therapeutic use – at least 250mg daily in divided doses Maximum of 1000mg daily.

Elderly: As for other adults. As the dietary intake of vitamin C may be less in the elderly, they have greater risk of presenting with vitamin C deficiency.

4.3 Contraindications

- ✓ Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- ✓ This medicinal product increases gastrointestinal absorption of iron. It should not be used in patients with haemochromatosis or thalassaemia.
- ✓ This medicinal product should not be used in patients with a pre-disposition to oxalate-urolithiasis.
- ✓ Because of the presence of aspartame, this medicinal product is contraindicated in phenylketonuria.

4.4 Special warnings and precautions for use

- ✓ Patients with impaired renal function should be monitored because of the risk of the formation of calcium oxalate calculi.
- ✓ High intakes of vitamin C by patients with an erythrocytic glucose-6-phosphate dehydrogenasedeficiency may cause haemolysis. Therefore, exceeding the given dosing recommendations mustbe avoided in these patients.
- ✓ At vitamin C doses above 2 g/day, ascorbic acid can interfere with the following laboratory tests: measurement of blood and urinary levels of creatinine and glucose (monitoring of diabetes

using glucose oxidase test strips).

- ✓ This medicinal product contains sorbitol. Its use is not recommended in patients with fructose intolerance (a rare inherited disease).
- ✓ This medicinal product contains 38 mg of sodium per chewable tablet. This must be taken into account in patients on a strict low-sodium diet.
- ✓ Because of a mild stimulant effect, it is advisable not to take this medicinal product at the end of the day.
- ✓ If problems persist after 2 weeks of treatment, get worse, or if other symptoms occur investigations into the cause should be undertaken and the treatment re-assessed.

4.5 Interactions with other medicinal products and other forms of interaction

Precautions for use

Concomitant treatment with deferoxamine and high doses of vitamin C may lead to cardiac dysfunction.

Monitor cardiac function if this combination is used.

Other combinations to be cautious with

Potential for other medicinal products to affect vitamin C

Aspirin can lower plasma levels of vitamin C by increasing its urinary excretion.
Medicinal products that contain oestrogen, such as oral contraceptives (birth control pills) and hormone replacement therapy, can lower plasma concentrations of vitamin C.
Calcitonin increases the rate of vitamin C excretion.
Barbiturates (phenobarbital) may increase vitamin C excretion in the urine.

Potential for vitamin C to affect other medicinal products

At high doses (>1 g/day), vitamin C can decrease the effect of anticoagulants. More frequent monitoring of the INR and a possible dosage adjustment are recommended.
A reduction in indinavir blood levels has been reported following administration of high doses of vitamin C.
This should be taken into account in patients being treated with protease inhibitors.
High doses of vitamin C taken together with iron may cause an iron overload due to an enhanced iron reabsorption.

High doses of vitamin C may decrease the urinary excretion of paracetamol, which could increase paracetamol blood levels.
Vitamin C may impair the bioavailability of cyclosporine A, phenothiazines and warfarin, and therefore, may decrease the therapeutic effect of these medicinal products.
Prolonged use of high doses of vitamin C can influence the interaction between disulfiram and alcohol.

4.6 Fertility, pregnancy and lactation

Pregnancy

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development (see section 5.3).
Clinically, analysis of a large number of exposed pregnancies does not indicate any particular malformative or fetotoxic effect of vitamin C. However, no well-controlled studies with ascorbic acid during human pregnancy have been performed.
As a precautionary measure, it is preferable to avoid the use of Vitamin C 1000mg during pregnancy.

Breastfeeding

Ascorbic acid/metabolites have been identified in breastfed newborns of a treated mother. There is

Insufficient information on the effects of ascorbic acid in newborns. Therefore, Vitamin C should not be used during breast-feeding.

Fertility

According to the data available to date, vitamin C is not expected to have an effect on human fertility.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

High doses (above 1 g) can trigger digestive disorders (gastric burning, diarrhoea) or urinary disorders

(precipitation of urate, cystine and/or oxalate stones) in some subjects, and may cause haemolysis in

individuals with G6PD deficiency.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

4.9 Overdose

At vitamin C doses above 1 g/day, there is the possibility of:

- ✓ digestive disorders (gastric burning, diarrhoea),
- ✓ urinary disorders (oxalate, cystine and/or urate stones),
- ✓ haemolysis in individuals with G6PD deficiency.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: ascorbic acid (vitamin C), ATC code: A11GA01.

Vitamin C is essential to humans. Its components, ascorbic acid and dehydroascorbic acid, form an important redox system.
Ascorbic acid has special functions in this redox interrelationship, as an antioxidant and enzyme cofactor, which plays a crucial role in various hydroxylation reactions. There are several ascorbate-dependent mono and deoxygenations in various neurotransmitter and hormone formation processes,and ascorbate is also required for the hydroxylation of carnitine.
It has been suggested that carnitine deficiency is responsible for the early symptoms of scurvy. Vitamin C has certain biological functions that can influence energy production and thus physical performance. In addition to its role for synthesis of collagen and carnitine, which transports long-chain fatty acids into mitochondria, vitamin C is also needed for synthesis of catecholamines, epinephrine, and norepinephrine.
Ascorbic acid facilitates the transport and uptake of non-haem iron at the mucosa, the reduction of folic acid intermediates, and the synthesis of cortisol. Vitamin C is a potent antioxidant that serves to regenerate vitamin E from its oxidized product.

5.2 Pharmacokinetic properties

Absorption

Ascorbic acid is rapidly absorbed by sodium-dependent active transport from the intestine, although the proportion absorbed decrease with increasing doses.

Distribution

It is present in plasma and is extensively distributed to all cells of the body, with higher levels found in the adrenal glands, pituitary and retina, and lower levels in kidney and muscle tissue. Tissue vitamin C concentrations are higher than that of plasma but saturate before.

Metabolism

Ascorbic acid is readily oxidized to dehydroascorbic acid. Irreversible breakdown yields 2,3-diketogulonic acid (without biological action), which is then oxidised to oxalic and threonic acids.

Excretion

The main route of excretion of ascorbic acid is in urine, but a small percentage is excreted in the faeces. Absorbed excess doses are largely excreted unchanged in urine. The plasma half-life of ascorbic acid in humans is 16 days.

5.3 Preclinical safety data

There are no non-clinical data of relevance to the prescriber which are additional to those already included elsewhere in the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Rose Hip

Acerola Extract

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C in a dry place.

6.5 Nature and contents of container

HDPE container with screw cap

7. MARKETING AUTHORISATION HOLDER

May & Baker Nigeria Plc
1 May & Baker Avenue, off
Idiroko road Ota
Ogun State.

8. PRODUCT DRUG MANUFACTURER

May & Baker Nigeria Plc

9. MARKETING AUTHORISATION NUMBER

Not Applicable