Summary of Product Characteristics

Nat B Fizzy

1. Name of the medicinal product:

Nat B Fizzy

2. Qualitative and quantitative composition:

Each effervescent tablet contains

Vitamin B1 (as Thiamine Mononitrate)	15	mg
Vitamin B2 (as Riboflavin Sodium Phosphate)	15	mg
Vitamin B3 (as Nicotinamide)	50	mg
Vitamin B5 (as Calcium D-pantothenate)	23	mg
Vitamin B6 (as Pyridoxine Hydrochloride)	10	mg
Vitamin B12 (as Cyanocobalamin)	0.01	mg
Biotin	0.15	mg
Vitamin C (as Ascorbic Acid)	1000	mg
Calcium (as Calcium Carbonate)	100	mg
Magnesium (as Magnesium Hydroxide)	100	mg

For a full list of excipients, see section 6.1.

3. Pharmaceutical Form:

Effervescent tablet

Light yellow, round effervescent tablet, flat and plain on both sides.

4. Clinical Particulars:

4.1 Therapeutic indications:

- Physical and neurological (nervous system) nourishment.
- Fatigue, convalescence or post-surgery.
- Treatment of vitamin Bs, vitamin C, calcium and magnesium deficiencies.

4.2 Posology and method of administration:

One effervescent tablet dissolved in a glass of water after breakfast or other meal. Once daily or as directed by a physician.

Mode of Administration:

Oral administration.

4.3 Contraindications:

- Hypersensitivity or intolerance to any component of the product.
- Ascorbic acid should not be given to patients with hyperoxaluria.

4.4 Special warning and precautions for use:

- Increased intake of ascorbic acid over a prolonged period may result in increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly.

- Interference with serological testing
  - Ascorbic acid may interfere with tests and assays for urinary glucose, giving false-negative results with methods utilising glucose oxidase with indicator (e.g. Labstix, Testape) and false- positive results with neocuproin methods.
  - Estimation of uric acid by phosphotungstate or uricase with copper reduction and measurement of creatinine in non-deproteinised serum may also be affected.
  - High doses of ascorbic acid may give false-negative readings in faecal occult blood tests.

4.5 Interaction with other medicinal products and other forms of interaction:

Ascorbic acid increases the renal excretion of amphetamine. The plasma concentration of ascorbate is decreased by smoking and oral contraceptives.

Ascorbic acid increases the absorption of iron.

Concomitant administration of aspirin and ascorbic acid may interfere with absorption of ascorbic acid. Renal excretion of salicylate is not affected and does not lead to reduced anti-inflammatory effects of aspirin.

Concomitant administration of aluminium-containing antacids may increase urinary aluminium elimination. Concurrent administration of antacids and ascorbic acid is not recommended, especially in patients with renal insufficiency.

Co-administration with amygdalin (a complementary medicine) can cause cyanide toxicity.

Concurrent administration of ascorbic acid with desferrioxamine enhances urinary iron excretion. Cases of cardiomyopathy and congestive heart failure have been reported in patients with idiopathic haemochromatosis and thalassaemias receiving desferrioxamine who were subsequently given ascorbic acid. Ascorbic acid should be used with caution in these patients and cardiac function monitored.

Ascorbic acid may interfere with biochemical determinations of creatinine, uric acid and glucose in samples of blood and urine.

Pyridoxine may increase the peripheral metabolism of levodopa, reducing therapeutic efficacy of the latter drug. Therefore, patients with Parkinson's disease who are receiving treatment with plain levodopa should not take vitamin B6 in doses which greatly exceed the daily requirement. This does not apply when levodopa is combined with a peripheral decarboxylase inhibitor.

4.6 Fertility, pregnancy & lactation:

Should consult the physician before taking Nat B Fizzy.

4.7 Effects on ability to drive and use machine:

Nat B Fizzy has no influence on ability to drive and use machines.

4.8 Undesirable effects:

Nervous system disorders: headache.

Vascular disorders: flushing

Gastrointestinal disturbances: nausea, vomiting and stomach cramps.

Large doses of ascorbic acid may cause diarrhoea.

Skin and subcutaneous tissue disorders: redness of skin.

Renal and urinary disorders: Patients known to be at risk of hyperoxaluria should not ingest ascorbic acid doses exceeding 1gm daily as there may be increased urinary oxalate excretion. However, such risk has not been demonstrated in normal, non-hyper oxaluric individuals.

Increased intake of ascorbic acid over a prolonged period may result in increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly. Doses of more than 600mg daily have a diuretic effect.

Ascorbic acid has been implicated in precipitating haemolytic anaemia in certain individuals deficient of glucose-6-phosphate dehydrogenase.

4.9 Overdose and Treatment:

No case of overdosage has been reported.

5. Pharmacological Properties:

5.1 Pharmacodynamic Properties:

Ascorbic acid, coupled with dehydroascorbic acid to which it is reversibly oxidised, has a variety of functions in cellular oxidation processes. Ascorbic acid is required in several important hydroxylations, including the conversion of proline to hydroxyproline (and thus in collagen formation e.g. for intercellular substances and during wound healing); the formation of the neurotransmitters 5-hydroxytryptamine from tryptophan and noradrenaline from dopamine, and the biosynthesis of carnatine from lysine and methionine. Ascorbic acid appears to have an important role in metal ion metabolism, including the gastrointestinal absorption of iron and its transport between plasma and storage organs. There is evidence that ascorbic acid is required for normal leucocyte functions and that it participates in the detoxification of numerous foreign substances by the hepatic microsomal system. Deficiency of ascorbic acid leads to scurvy, which may be manifested by weakness, fatigue, dyspnoea, aching bones, perifollicular hyperkeratoses, petechia and ecchymosis, swelling and bleeding of the gums, hypochromic anaemia and other haematopoietic disorders, together with reduced residence to infections and impaired would healing.

Vitamin Bs are a group of water-soluble factors more or less closely associated in their natural occurrence. It is known that nearly every vitamin Bs forms part of a co-enzyme essential for the metabolism of protein, carbohydrate or fatty acid.

Magnesium is essential to the body as a constituent of skeletal structures and in maintaining cell integrity and fluid balance. It is utilised in many of the functions in which calcium is concerned but often exerts the opposite effect. Some enzymes require the magnesium ion as a co-factor.

Calcium is an essential body electrolyte. It is involved in the maintenance of normal muscle and nerve function and essential for normal cardiac function and the clotting

of blood. Calcium is mainly found in the bones and teeth. Deficiency of calcium leads to rickets, osteomalacia in children and osteoporosis in the elderly.

5.2 Pharmacokinetic Properties:

Ascorbic acid is well absorbed from the gastro-intestinal tract, and is widely distributed to all tissues. Body stores of ascorbic acid normally are about 1.5g. The concentration is higher in leucocytes and platelets than in erythrocytes and plasma. Ascorbic acid additional to the body's needs, generally amounts above 200mg daily, is rapidly eliminated; unmetabolised ascorbic acid and its inactive metabolic products are chiefly excreted in the urine. The amount of ascorbic acid excreted unchanged in the urine is dose-dependent and may be accompanied by mild diuresis.

Nicotinamide is readily absorbed from the GI tract following oral administration and is widely distributed in the body tissues. Small amounts of nicotinamide are excreted unchanged in urine following therapeutic doses, however, the amount excreted unchanged is increased with larger doses.

Pyridoxine is absorbed from the GI tract and is converted to the active form pyridoxal phosphate. It is excreted in the urine as 4-pyridoxic acid.

Riboflavine is absorbed from the GI tract and in the circulation is bound to plasma proteins. Although widely distributed, little is stored in the body, and amounts in excess of requirements are excreted in the urine.

Thiamine is absorbed from the GI tract and is widely distributed to most body tissues. It is not stored to any appreciable extent in the body and amounts in excess of requirements are excreted in the urine as unchanged thiamine or metabolites.

A third of ingested calcium is absorbed from the small intestine. Absorption of calcium decreases with age.

Magnesium salts are poorly absorbed from the gastro-intestinal tract; however, sufficient magnesium will normally be absorbed to replace deficiency states. Magnesium is excreted in both the urine and the faeces but excretion is reduced in deficiency states.

5.3 Preclinical Safety Data:

Not applicable.

6. Pharmaceutical Particulars:

6.1 List of excipients:

Anhydrous citric acid, Sodium bicarbonate, Polyethylene glycol, Sodium benzoate, Anhydrous sodium carbonate, Sorbitol, Copovidone, Sodium saccharin, Aspartame, Orange flavour.

6.2 Incompatibilities:

Not applicable.

6.3 Shelf life:

Two years from manufacture date.

6.4 Special precautions for storage:

Store below 30°C in a dry place, away from direct sunlight.

6.5 Nature and contents of container:

Tube of 10 effervescent tablets and packed in unit carton.

6.6 Special precautions for disposal and other handling:

No special requirements for disposal. Any unused product should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder:

MEGA LIFESCIENCES PUBLIC COMPANY LIMITED
Samutprakarn, Thailand

8. Marketing Authorization Numbers:

-

9. Date of first authorization / renewal of the authorization:

-

10. Date of revision of the text:

-

Note:
Read the instructions carefully before use.
Do not use the product after the expiry date.
Do not use the product if there are any significant changes in appearance of the tablet.
Keep out of reach of children