

**PROFESSIONAL INFORMATION**
**Complementary Medicine: Combination Product (Western Herbal/Health Supplement)**

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

**SCHEDULING STATUS:** S0

**1. NAME OF THE MEDICINE**  
**BIOGEN IMMUNO BOOST EFFERVESCENT (effervescent tablets)**
**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

<i>Echinacea purpurea</i> (L.) Moench (Echinacea) [aerial parts, as 12,5 mg of a 4:1 extract]	50 mg
Ascorbic Acid (Vitamin C)	1 000 mg
Zinc	25 mg
Niacinamide (Vitamin B <sub>3</sub> )	20 mg
Pantothenic Acid (Vitamin B <sub>5</sub> )	15 mg
Pyridoxine (Vitamin B <sub>6</sub> )	2 mg
Riboflavin (Vitamin B <sub>2</sub> )	2 mg
Cyanocobalamin (Vitamin B <sub>12</sub> )	3 µg

Contains sugar: 400 mg sorbitol and 200 mg isomalt per effervescent tablet.  
 Contains sweetener: 20 mg (Naartjie); 21 mg (Cherry & Raspberry); 24 mg (Orange) sucralose per effervescent tablet.

For a full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**

Effervescent tablets  
 White to off-white, flat round bevelled-edged effervescent tablets with a citrus/orange/cherry/raspberry flavour.

**4. CLINICAL PARTICULARS**
**4.1 Therapeutic indications**

Echinacea is known to boost the immune system to assist the body with fighting off bacterial and viral infections. Vitamin C and B-Vitamins are essential vitamins for the maintenance of good health. Vitamin C and zinc contribute to the normal function of the immune system.

BIOGEN IMMUNO BOOST EFFERVESCENT is indicated in adults and children 14 years and older.

**4.2 Posology and method of administration**

*Adults and children over 14 years old:*  
 Take 1 tablet daily, dissolved in a glass of water.  
 Do not swallow the effervescent tablet whole.  
 Do not exceed the recommended daily dosage.

**Additional information on special populations:**
**Elderly:**

No specific studies have been performed in the elderly, but according to clinical experience dosage adjustment is not required when treating otherwise healthy, elderly patients.

**Children and adolescents:**

BIOGEN IMMUNO BOOST EFFERVESCENT is not recommended for use in children and adolescents below the age of 14 years due to the risk of severe allergic reactions.

**4.3 Contraindications:**

BIOGEN IMMUNO BOOST EFFERVESCENT must not be used:  
 In patients who are pregnant or breastfeeding.  
 In patients that are allergic or sensitive any of the ingredients, specifically for those who are allergic to the Asteraceae/Compositae plant family. Members of this family include ragweed, chrysanthemums, marigolds, daisies and many other herbs.  
 Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

**4.4 Special warnings and precautions for use**

- Echinacea appears to stimulate immune function, and theoretically might exacerbate autoimmune diseases by stimulating the disease activity. Individuals with an autoimmune disorder and/or individuals taking immunosuppressants should use with caution.
- Large amounts of vitamin C can cause haemolysis in individuals with glucose-6-phosphate dehydrogenase (G6PD) deficiency, and can increase the risk of oxalate stone formation in people with a history of oxalate kidney stones. The daily recommended dosage should not be exceeded.
- Individuals with atopy may be more likely to experience an allergic reaction when taking Echinacea.
- Large doses of zinc can lower blood sugar in people with diabetes. Patients with diabetes should monitor blood glucose levels closely, and dose adjustments to diabetes medications might be necessary.

**4.5 Interaction with other medicines and other forms of interaction**

- Care should be exercised when BIOGEN IMMUNO BOOST is co-administered with immunosuppressant medicines (e.g. azathioprine, basiliximab, cyclosporine, daclizumab, muromonab-CD3, mycophenolate, tacrolimus, sirolimus, prednisone, and corticosteroids) as Echinacea may interfere with immunosuppressant therapy (see section 4.4 Special warnings and precautions for use).
- Concomitant use of medicines predominantly metabolised by cytochrome P450 1A2 (CYP1A2) (e.g. caffeine, acetaminophen, amitriptyline, clopidogrel, clozapine, diazepam, estradiol, olanzapine, ondansetron, propranolol, ropinirole, tacrine, theophylline, cerapamil and warfarin) must be carefully monitored. Inhibition of this isoenzyme by Echinacea may increase plasma concentrations of these medicines.
- Patients taking medications metabolized by CYP3A4 (e.g. lovastatin, clarithromycin, cyclosporine, diltiazem, estrogens, indinavir, triazolam) should be closely monitored as Echinacea appears to induce hepatic CYP3A4 and inhibit intestinal CYP3A4.
- Concomitant use of etoposide and Echinacea has been associated with more severe thrombocytopenia than the use of etoposide alone, which suggests the inhibition of etoposide metabolism.
- Concomitant use of BIOGEN IMMUNO BOOST EFFERVESCENT and other zinc-containing medicines may result high zinc levels in the body.
- Zinc may decrease cephalixin levels by chelating with cephalixin in the gut and preventing its absorption. To avoid this interaction, advise patients to take zinc sulphate 3 hours after taking cephalixin.

**4.6 Fertility, pregnancy and lactation**

Safety in fertility, pregnancy and lactation has not been established as there is insufficient reliable data available.

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

No studies on the effects on the ability to drive or use machinery have been performed. Patients should exercise caution before driving or use of machinery until they are reasonably certain BIOGEN IMMUNO BOOST does not adversely affect their performance.

**4.8 Undesirable effects**
**Gastrointestinal:**

*Frequent:* nausea, abdominal pain, diarrhoea, heartburn, constipation, vomiting, unpleasant taste, dry mouth, burning, tingling or numbness of the tongue.

**Immunologic:**

*Frequent:* allergic reactions, itching, urticaria, rash, runny nose, dyspnea, bronchospasm, acute asthma, angioedema, and anaphylaxis which may result in death.

**Musculoskeletal:**

*Frequent:* joint and muscle pain

**Neurologic/CNS:**

*Frequent:* headache and dizziness.  
*Less frequent:* drowsiness and aggressiveness.

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>

**4.9 Overdose**

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity. In addition, overdose has resulted in symptoms including gastrointestinal tract corrosion, acute renal tubular necrosis, interstitial nephritis, central nervous system symptoms, formation of renal calcium oxalate calculi, induced vitamin C tolerance and haemolysis.

Treatment of overdose is symptomatic and supportive.

**5. PHARMACOLOGICAL PROPERTIES**
**5.1 Pharmacodynamic properties**

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***Echinacea purpurea* (L.) Moench** is known to boost the immune system to assist the body with fighting off bacterial and viral infections.

**Riboflavin** plays a role in energy-generating reactions involving carbohydrates, fatty acids and amino acids.

**Niacinamide** is a precursor of co-enzymes NAD and NADP involved in carbohydrate and amino acid degradation as well as lipid and steroid biosynthesis and the electron transport chain.

**Pantothenic acid** is a component of coenzyme-A and acyl-carrier protein involved in energy metabolism and the synthesis of fatty acids, cholesterol, steroid hormones and the neurotransmitter acetylcholine.

**Pyridoxine** serves as a co-enzyme for multiple enzymes involved in the synthesis and breakdown of amino acids. It assists in glycogenesis and synthesis of various neurotransmitters and porphyrin precursors of haem.

**Cyanocobalamin** is required for nucleoprotein and myelin synthesis, cell reproduction, normal growth, and the maintenance of normal erythropoiesis.

**Ascorbic acid** and **zinc** contribute to the normal function of the immune system.

**5.2 Pharmacokinetic properties**

***Echinacea purpurea* (L.) Moench** has limited clinical pharmacokinetic data. A metabolite thereof (Dodeca-2E,4E,8Z,10E/Z-tetraenoic acid) was reported to be detectable in blood one hour after oral administration.

**Riboflavin** is readily absorbed from the gastrointestinal tract and widely distributed to body tissues. Little is stored in the body and is excreted in urine, partly as metabolites. Riboflavin crosses the placenta and is distributed into breast milk.

**Niacinamide** is readily absorbed from the GI tract following oral administration and widely distributed into body tissues and breast milk. It is metabolized in the liver to N-methylniacinamide, other N-methylated derivatives, and nicotinic acid (the glycine conjugate of niacin) and excreted in urine.

**Pantothenic acid** is readily absorbed from the GI tract following oral administration and widely distributed into body tissues, mainly as coenzyme A. About 70 % of an oral dose of pantothenic acid is excreted unchanged in urine and about 30 % in faeces.

**Pyridoxine** is readily absorbed from the GI tract following oral administration and stored mainly in the liver with lesser amounts in muscle and brain. It crosses the placenta and is excreted into breast milk. In erythrocytes, pyridoxine is converted to pyridoxal phosphate and is phosphorylated to pyridoxine phosphate in the liver. The biologic half-life of pyridoxine appears to be 15–20 days. In the liver, pyridoxal is oxidized to 4-pyridoxic acid which is excreted in urine.

**Cyanocobalamin** is irregularly absorbed from the distal small intestine following oral administration. It is protein-bound and this bond must be split by proteolysis and gastric acid before absorption. It is distributed into the liver, bone marrow, and other tissues, including the placenta and breast milk. Healthy individuals receiving only dietary vitamin B<sub>12</sub>, about 3–8 µg of the vitamin is secreted into the GI tract daily, mainly via bile, with about 1 µg being reabsorbed and less than 0,25 µg of the vitamin is usually excreted in urine.

**Ascorbic acid** is readily absorbed from the gastrointestinal tract and is widely distributed in the body tissues. Concentrations are higher in leucocytes and platelets than in erythrocytes and plasma. It is reversibly oxidised to dehydroascorbic acid; and metabolised to an inactive ascorbate-2-sulfate and oxalic acid which are excreted in the urine. Excess ascorbic acid (exceeding 100 mg daily) is rapidly eliminated unchanged in the urine. Ascorbic acid crosses the placenta and is distributed into breast milk.

Absorption of **zinc** from the gastrointestinal tract is incomplete, and is reduced in the presence of some dietary constituents such as phytates. Bioavailability of dietary zinc varies widely between different sources, but is about 20 % to 30 %. Zinc is distributed throughout the body with the highest concentrations found in muscle, bone, skin, eye, and prostatic fluids. It is primarily excreted in the faeces, and regulation of faecal losses is important in zinc homeostasis. Small amounts are lost in urine and perspiration.

**6. PHARMACEUTICAL PARTICULARS**
**6.1 List of excipients**

Sodium Bicarbonate, Citric Acid Anhydrous, Isomalt, Sorbitol, Tartaric Acid, Sucralose, Polyethylene glycol, Polyvinylpyrrolidone, Flavour and Colour.

Contains sugar: 400 mg sorbitol and 200 mg isomalt per effervescent tablet.  
 Contains sweetener: 20 mg (Naartjie); 21 mg (Cherry & Raspberry); 24 mg (Orange) sucralose per effervescent tablet.

**6.2 Incompatibilities**

Not applicable

**6.3 Shelf Life**

24 Months

**6.4 Special precautions for storage**

Protect from moisture and store at or below 25 °C.  
 Keep effervescent tablets in original container until required for use.  
 KEEP OUT OF REACH OF CHILDREN.

**6.5 Nature and contents of container**

Ten white to off-white, flat round effervescent tablets with a naartjie/orange/cherry/raspberry flavour, packed in a white polypropylene tube, with desiccant containing white lid.  
 Tubes are packed into an outer cardboard carton in pack sizes of either 10 or 20 effervescent tablets.

**6.6 Special precautions for disposal**

No special requirements.

**7. HOLDER OF CERTIFICATE OF REGISTRATION**

Biogen  
 23 Stag Road, Glen Austin, South Africa  
 info@biogen.co.za  
 www.biogen.co.za  
 Tel: 0860 347243

**8. REGISTRATION NUMBER**

Will be allocated by SAHPRA upon registration.

**9. DATE OF FIRST AUTHORISATION**

Will be allocated by SAHPRA upon registration.

<b>JOB:</b> BPS_ImmunoBoostEffervescent_10's & 20's (Cherry)	<b>SIZE:</b> 210mm x 395mm
<b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>	
<b>COLOURS:</b>	<b>FINISHING:</b>
<input checked="" type="checkbox"/> K <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot	<input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss
<input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot	<input type="checkbox"/> Spot UV <input type="checkbox"/> Doming <input type="checkbox"/> Embossing