PATIENT INFORMATION LEAFLET

DAILYBOOST

Complementary Medicine – Health Supplement

SCHEDULING STATUS:

S0

DAILYBOOST effervescent tablets

Active ingredient	Amount per tablet	% NRV
Ascorbic acid (vitamin C)	550 mg	550
Calcium carbonate providing calcium (elemental)	500,9 mg 200 mg	15
Magnesium sulphate Magnesium carbonate providing magnesium (elemental)	199,7 mg 86,7 mg 50 mg	12
Potassium chloride providing potassium (elemental)	76,3 mg 40 mg	--
Niacinamide (vitamin B3)	15 mg	91
Vitamin E – 50 % providing Vitamin E (elemental - α-tochopherols)	21,8 mg 9,81 mg (11 IU)	65
Iron (amino acid chelate) – 10 % providing iron (elemental)	50 mg 5 mg	28
Zinc citrate trihydrate providing zinc (elemental)	16,1 mg 5 mg	45
Calcium-D-pantothenate providing pantothenic acid (vitamin B5)	4,8 mg 4,36 mg	87
Pyridoxine hydrochloride providing pyridoxine (vitamin B6)	2,6 mg 2,14 mg	126

Riboflavin-5-phosphate sodium providing riboflavin (vitamin B2)	1,8 mg 1,31 mg	101
Thiamine hydrochloride providing thiamine (vitamin B1)	1,6 mg 1,22 mg	102
Manganese sulphate monohydrate providing manganese (elemental)	3,1 mg 1 mg	43
Vitamin A palmitate providing vitamin A (retinol)	8,3 mg 623 µg (2076 IU)	69
Copper sulphate providing copper (elemental)	1,3 mg 0,5 mg	56
Folic acid	290 µg	73
Biotin (vitamin H)	218 µg	727
Potassium iodide providing iodine (elemental)	132 µg 100 µg	67
Chromium polynicotinate providing chromium (elemental)	333 µg 40 µg	114
Cholecalciferol (vitamin D3) providing vitamin D	8 mg 20 µg (800 IU)	133
Vitamin B12 – 0,1 % providing cyanocobalamin (vitamin B12)	728 µg 0,73 µg	30

Each effervescent tablet contains sugar, mannitol (690,46 mg) and sweetener, sucralose (15 mg)

Contains sodium: 231,85 mg per effervescent tablet.

PATIENT INFORMATION LEAFLET

DAILYBOOST

Read all of this leaflet carefully because it contains important information for you

DAILYBOOST is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use DAILYBOOST carefully to get the best results from it.

- Keep this leaflet. You may need to read it again
- Do not share DAILYBOOST with any other person
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What DAILYBOOST is and what it is used for
2. What you need to know before you take DAILYBOOST
3. How to take DAILYBOOST
4. Possible side effects
5. How to store DAILYBOOST
6. Contents of the pack and other information

1. What DAILYBOOST is and what it is used for

DAILYBOOST is a multivitamin and mineral supplement intended to

- boost healthy mind and body
- boost an active lifestyle
- increase energy.

2. What you need to know before you take DAILYBOOST

Do not take DAILYBOOST

- if you are hypersensitive (allergic) to any of the ingredients of DAILYBOOST (listed in section 6)
- if you are pregnant

- if you have eye diseases called Leber's disease or tobacco amblyopia
- if you have elevated chloride ions in your blood
- if you have severe liver disease
- if you have above normal calcium levels in your blood
- if you are under the age of 14 years.

Warnings and precautions

Take special care

- if you have problems with your kidneys, adrenal glands or liver
- if you have constant diarrhoea and irritation in your stomach, or a stomach ulcer
- if you have any heart problems or disease
- if you are severely dehydrated or have severe tissue damage (as with severe burns)
- if you are taking another multivitamin and mineral supplement. Do not take more than the recommended dosage
- if you are undergoing blood and urine tests, as DAILYBOOST may interfere with the results
- if you have Wilson's disease (a disease where excess copper builds up in the body) as the condition may worsen
- if you are taking iron-containing medicines (orally or via infusions) treatment for conditions related to iron storage or iron-absorption e.g. haemochromatosis (causes too much iron absorption) and haemoglobinopathies (blood disorder), or if you have inflammation in your intestines, narrowing of the intestines or have small bulging pouches in the lining of your intestines
- if you have been diagnosed with a type of anaemia (megaloblastic anaemia) as you may experience untoward nervous system symptoms
- if you have problems with your thyroid, especially if you are older than 45 years and diagnosed with

goitre, as the condition may worsen

- if you are prone to develop gout and if you drink large amounts of alcohol
- if you have diabetes, as your blood sugar levels may increase.

Children and adolescents

DAILYBOOST is not suitable for children under the age of 14.

Other medicines and DAILYBOOST

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Taking DAILYBOOST with the following medicine is not recommended:

- tetracyclines (antibiotic used to treat infections) as the effect of the antibiotic may be lowered. An interval of at least 2 - 3 hours should be allowed between taking DAILYBOOST and tetracyclines
- bisphosphonates e.g. risedronate, alendronate (medicine which prevents the loss of bone density and used to treat osteoporosis and similar bone diseases)
- desferrioxamine (used to treat iron overload) as it may worsen iron toxicity, particularly to the heart
- medicines used to treat high cholesterol levels called statins (e.g. simvastatin, rosuvastatin) as muscle breakdown may occur, which may lead to kidney problems and pain or weakness in the muscles
- dimercaprol (treatment for acute poisoning by arsenic, mercury, gold and lead).

The absorption and/or effect of certain vitamins or minerals may be lowered when DAILYBOOST is taken together with certain medicine. These include:

- cholestyramine, colestipol (treatment for bile condition)

- orlistat (treatment for obesity)
- omeprazole (treats heartburn and stomach ulcers)
- aminosalicylic acid (antibiotic used to treat tuberculosis) and rifampicin and isoniazid (treatment for tuberculosis)
- colchicine (treats gout attacks)
- iron supplements
- penicillamine (medicine used to treat Wilson's disease)
- medicine which contains phosphorus
- aspirin (used to treat pain, fever and inflammation)
- lithium (treatment for bipolar disorder)
- amiodarone (treats heart problems)
- cortisone medicine (treatment for inflammation)
- other substances which contain magnesium and calcium (e.g. antacids, other mineral supplements, carbonates and bicarbonates, oxalates or phosphates).

The effect of DAILYBOOST may be increased when taken with the following medicine:

- mexiletine (to treat heart conditions)
- neomycin, ciprofloxacin, enoxacin, pipemidic acid (antibiotics used to treat infections)
- fluvoxamine (treatment for depression)
- terbinafine (treatment for fungal infections)
- H_2-antagonists e.g. cimetidine, ranitidine (treatment for acid reflux and stomach ulcers)
- methoxsalen (used to treat the skin diseases, psoriasis and eczema)
- the "pill" (oral contraceptives) and hormone replacement therapy
- phenytoin (treats epilepsy)

- other substances which contain vitamin C and citric acid.

The effect of certain medicine or substances may be reduced when taken together with DAILYBOOST. These include:

- levodopa and entacapone (treatment for Parkinson's disease)
- altretamine (cancer treatment)
- warfarin (treatment for blood clots)
- insulin or oral hypoglycaemics (diabetes medication)
- fluphenazine (treatment for bipolar disorder)
- phenobarbitone and phenytoin (treats epilepsy)
- fluoroquinolones (antibiotics used to treat infections e.g. ciprofloxacin, moxifloxacin)
- cefdinir (antibiotic used to treat infections)
- methyldopa (lowers high blood pressure)
- mycophenolate mofetil (lowers the immune system response)
- penicillamine (used to treat Wilson's disease)
- copper supplements
- levothyroxine (treatment for thyroid problems).

DAILYBOOST should be used with caution if you are taking other medicine which may increase your potassium levels i.e. some diuretics ("water pills" e.g. amiloride, spironolactone), ACE inhibitors e.g. enalapril, lisinopril (treatment for high blood pressure and heart failure), ciclosporins (immunosuppressants) and other medicine containing potassium.

Taking DAILYBOOST with antimuscarinics (e.g. atropine, ipratropium bromide) may slow down stomach

emptying and elevate the risk of untoward stomach and intestinal disturbances.

Acitretin (treatment for psoriasis), isotretinoin (treats acne and other skin conditions) and tretinoin (treats acne and other skin conditions) - additional vitamin A supplements - taken together with DAILYBOOST, may lead to vitamin A toxicity.

Taking DAILYBOOST and calcium or phosphate containing products and “water pills” e.g. hydrochlorothiazide and indapamide, may cause a condition where there is too much calcium in your blood.

Taking DAILYBOOST with food and drink

Take one effervescent tablet dissolved in a half to full glass of cold water, with or directly after meals. Do not take on an empty stomach.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice, before taking DAILYBOOST.

Driving and using machinery

It is unlikely that DAILYBOOST may interfere with your daily activities, but it is not always possible to predict to what extent. Thus, ensure that you do not engage in the above activities until you are aware of the measure to which DAILYBOOST affects you.

DAILYBOOST contains sodium

DAILYBOOST contains 231,85 mg sodium (main component of cooking/table salt) in each effervescent tablet. This is equivalent to 11,6 % of the recommended maximum daily dietary intake of 2 g of sodium for an adult.

3. How to take DAILYBOOST

Always take DAILYBOOST exactly as instructed in this leaflet. You should check with your doctor, pharmacist or healthcare provider if you are unsure.

Take 1 effervescent tablet daily. Dissolve the effervescent tablet in a half to full glass of cold water. Then drink the contents of the whole glass. Do not take more than the recommended dosage. Take DAILYBOOST with or directly after meals.

If you take more DAILYBOOST than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. In the event of overdose the following symptoms may occur: lack of appetite, lack of energy, nausea and vomiting, constipation, diarrhoea, heartburn, excessive urination, frequent urination during the night, sweating, headache, thirst, excessive sleepiness, a feeling of losing balance (dizziness), bleeding gums, sore mouth, confusion, abdominal pain, blurred vision, muscle weakness, tingling sensations, slow heartbeat and a weak pulse.

If you forget to take a dose of DAILYBOOST

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

DAILYBOOST can have side effects.

Not all side effects reported for DAILYBOOST are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking DAILYBOOST, please consult your healthcare provider for advice.

If any of the following happens, stop taking DAILYBOOST and tell your doctor immediately, or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction or hypersensitivity to DAILYBOOST. You may need urgent medical attention or hospitalisation. Discontinue use.

Tell your doctor immediately, or go to the casualty department at your nearest hospital if you notice any of the following:

- experiencing symptoms of a heart attack (symptoms include crushing chest pain, feeling clammy and sweaty, arms may feel heavy, dizziness), abnormal heartbeat
- difficulty breathing, shortness of breath
- kidney stones (painful when urinating), urinating less than normal, swelling in your legs, ankles and feet
- liver infection and toxicity, liver failure, jaundice (yellowish or greenish pigmentation of the skin and eyes, paler faeces and dark urine)
- problems with your thyroid – overactive thyroid and thyroid related problems, including hives, swelling, bruising, fever, joint pain, swollen lymph nodes and a high white blood cell count

- increased thirst and urination, stomach pain, nausea, bone pain, muscle weakness, confusion and fatigue (this may be due to high levels of calcium in the blood).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- stomach and intestine disturbances including stomach pain, indigestion, nausea, vomiting, stomach irritation, stomach inflammation and watery diarrhoea (if medicine is taken on an empty stomach).

Less frequent side effects:

- constipation, farting
- skin reactions, blister-like sores
- kidney failure
- vomiting, fatigue and a water-electrolyte imbalance, which is due to a condition called milk-alkali syndrome
- muscle weakness, cramps or pain due to a condition called alkalosis
- hardening of tissue due to accumulation of calcium (as diagnosed by your doctor).

Side effects of unknown frequency:

- laboratory test results showing abnormal blood counts (including low white- and red blood cell count, low platelet count, high levels of calcium, low phosphate levels, abnormal levels of potassium and magnesium), also abnormal urine, faeces or liver function test results
- reduced glucose tolerance and high levels of sugar in the blood
- high levels of uric acid
- depression, sleeplessness, feeling confused

- weakness, numbness and pain from nerve damage, rise in pressure around your brain
- irritated, swollen eyes and eyelids, abnormal tearing, blurry and dimness of vision, dry eyes, eye problems
- flushing, which can be accompanied by tingling, itching, headache, dizziness, rapid heartbeat, shortness of breath, sweating, chills or swelling
- a sensation of heat, faintness, pounding in the head, low blood pressure, dizziness, chills
- cough
- black stools/faeces, stomach ulcer, heartburn, cramps, lack of appetite
- hives, blister-like eruptions, dry skin, itching, more pigments on skin, rash, tingling, yellowing, dryness of sensitive skin, dry hair, itchy scalp and hair loss, cracking and bleeding lips
- pain or weakness in the muscles, paralysis, pain in the joints
- bright yellow urine, gout, more night-time urination
- impotence
- fever, metallic taste, more salivation, burning or pain in the mouth, common cold like symptoms, swelling and inflammation in the throat, headache, irritability, build-up of fluid in the body causing swelling.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you develop any side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the online complaints portal, found under: https://sahpracm.org.za/catd/complaints/.

By reporting side effects, you can help provide more information on the safety of DAILYBOOST.

Additionally, please send a mail to pharmacovigilance@pharmadynamics.co.za

5. How to store DAILYBOOST

Store all medicines out of reach of children.

Store at or below 30 °C.

Store in the original package/container.

Keep the container tightly closed.

Do not use after the expiry date stated on the packaging.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DAILYBOOST contains

Active ingredients:

D-biotin, calcium, chromium, copper, folic acid, iron, magnesium, manganese, potassium, vitamin A, B1, B2, B3, B5, B6, B12, C, D3, E, and zinc.

Other ingredients:

citric acid, mannitol, orange flavour, PEG 6000, sodium bicarbonate, sodium carbonate, sucralose, sunset yellow colourant.

What DAILYBOOST looks like and contents of the pack

DAILYBOOST are speckled, orange, smooth, cylindrical, bevelled edge effervescent tablets.

DAILYBOOST effervescent tablets are packed in 2 x polypropylene tubes of 15 tablets, closed with a polyethylene stopper equipped with a silica gel drying agent. The polypropylene tube is inserted into a cardboard carton with an information leaflet.

Colour of solution: Orange solution with white precipitate

Applicant

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: + 27 21 707 7000

or 0860-PHARMA (742 762)

Manufacturer

Technikon Laboratories (Pty) Ltd

1073 Anvil Road

Robertville

Florida

1709, South Africa

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This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

KENYA:

10468

ZAMBIA:

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