PATIENT INFORMATION LEAFLET

EFFERFLU C IMMUNE BOOSTER PLUS

Complementary medicine – Discipline-specific – Combination product

SCHEDULING STATUS:

S0

EFFERFLU C IMMUNE BOOSTER PLUS effervescent tablets

Active ingredients	**Amount per tablet**	**% NRV***
Ascorbic acid (Vitamin C)	1000,00 mg	1000
Echinacea purpurea (L.) Moench, (Purple coneflower) 50 mg [flowering aerial parts, extract standardised to 4 %, providing 2 mg polyphenols]	50,00 mg	No % NRV established
Vitamin D_3 providing vitamin D	8 mg 20 µg (800 IU)	133
Zinc citrate providing zinc (elemental)	16,129 mg 5 mg	36

*NRV - Nutrient Reference Value

Contains sugar (sugar alcohol - mannitol 350,00 mg) and sweetener (sucralose 16,00 mg).

Contains sodium (277,513 mg)

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

EFFERFLU C IMMUNE BOOSTER PLUS is available without a doctor's prescription, for you to

maintain your health. Nevertheless, you still need to use EFFERFLU C IMMUNE BOOSTER PLUS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share EFFERFLU C IMMUNE BOOSTER PLUS with any other person.
- Ask your pharmacist if you need more information or advice.

What is in this leaflet

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

1. What EFFERFLU C IMMUNE BOOSTER PLUS is and what it is used for

EFFERFLU C IMMUNE BOOSTER PLUS is uniquely formulated to assist in providing support of normal immune function and promoting physical well-being, with antioxidant properties.

2. What you need to know before you take EFFERFLU C IMMUNE BOOSTER PLUS

Do not take EFFERFLU C IMMUNE BOOSTER PLUS:

- if you are hypersensitive (allergic) to ascorbic acid, *Echinacea purpurea*, zinc, plants of the *Asteraceae (Compositae)* family, vitamin D or to any of the other ingredients of EFFERFLU C IMMUNE BOOSTER PLUS (see What EFFERFLU C IMMUNE BOOSTER PLUS contains)
- if you have kidney stones or high oxalate levels in your urine
- if you have a genetic blood disorder called thalassaemia major, or sickle cell disease

- if you have a hereditary disease associated with an excess of iron in the body
- if you have kidney problems
- if you have tuberculosis (TB)
- if you have collagenases (a rare skin disorder)
- if you have multiple sclerosis (MS), a disease of the nervous system
- if you have HIV/AIDS
- if you have an autoimmune disorder (a disease where the body's immune system attacks healthy cells)
- if you have leukosis (a severe blood disease)
- if you have diseases and/or conditions resulting in hypercalcaemia or hypercalciuria
- if you have vitamin D toxicity.

EFFERFLU C IMMUNE BOOSTER PLUS should not be given to children below 12 years of age.

Take special care with EFFERFLU C IMMUNE BOOSTER PLUS:

- if you have diabetes (too much sugar in your blood), since ascorbic acid may interfere with your blood sugar level readings
- if you take high doses of ascorbic acid (vitamin C) for a long time, you may develop a tolerance to vitamin C, as contained in EFFERFLU C IMMUNE BOOSTER PLUS, which could result in symptoms of deficiency when ascorbic acid (vitamin C) intake is reduced to the normal dose
- if you take EFFERFLU C IMMUNE BOOSTER PLUS for a long time, high doses of zinc can lead to copper deficiency with associated blood disorders
- if you have laboratory tests on your blood, faeces or urine, you should inform your healthcare provider that you are taking EFFERFLU C IMMUNE BOOSTER PLUS, as results could be affected.

Children and adolescents

EFFERFLU C IB PLUS is not suitable for children under the age of 12.

Other medicines and EFFERFLU C IMMUNE BOOSTER PLUS

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

Tell your healthcare provider if you are taking any of the following medicines:

- desferrioxamine (used as an antidote to treat iron overload or poisoning)
- indinavir (an antiretroviral used in treatment of HIV/AIDS)
- cyanocobalamin (vitamin B12)
- disulfiram (used to treat alcoholism)
- antacids (used to treat heartburn and indigestion)
- oral contraceptives ('the pill')
- warfarin (used to treat and prevent blood clots)
- immunosuppressant medicines (used to suppress or reduce the strength of the body's immune system) such as basiliximab, azathioprine, corticosteroids, ciclosporin, daclizumab, muromonab, mycophenolic acid, mycophenolate, mofetil, sirolimus and tacrolimus
- amiodarone (used to treat irregular heartbeat)
- methotrexate (used in the treatment of rheumatoid arthritis)
- ketoconazole (an antifungal medicine)
- copper containing medicines
- antibiotic medicines such as ciprofloxacin, other fluoroquinolones and tetracyclines
- thiazide diuretics (water tablets)
- phenytoin (used to prevent and control seizures)

- barbiturates (used to help you relax, help you sleep and control seizures)
- glucocorticoid steroids (used to treat allergies and asthma)
- cholestyramine (used to lower high cholesterol levels in the blood)
- rifampicin (antibiotic to treat tuberculosis)

Pregnancy, breastfeeding and fertility

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 EFFERFLU C IB PLUS.

Driving and using machines

EFFERFLU C IMMUNE BOOSTER PLUS may influence your ability to drive or use machines, as dizziness and drowsiness are side effects. Caution is advised on performing these tasks until you know how EFFERFLU C IMMUNE BOOSTER PLUS affects you.

EFFERFLU C IB PLUS contains sodium

This medicine contains 277,513 mg sodium (main component of cooking/table salt) in each effervescent tablet. This is equivalent to 13,88 % of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW TO TAKE EFFERFLU C IMMUNE BOOSTER PLUS

Always take EFFERFLU C IMMUNE BOOSTER PLUS exactly as instructed in this leaflet. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one tablet daily, dissolved in half to one glass of water, and consumed immediately.

It is recommended that EFFERFLU C IMMUNE BOOSTER PLUS be dissolved in cold water for a more pleasant taste.

If you take more EFFERFLU C IMMUNE BOOSTER PLUS than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdosage include nausea, vomiting, dehydration, thirst, constipation, muscle weakness, fatigue, irregular heartbeat, stomach cramps, diarrhoea, lack of coordination, dizziness, kidney stones and blood disorders.

If you forget to take a dose of EFFERFLU C IMMUNE BOOSTER PLUS

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the next intended one. Do not take a double dose to make up for the missed dose.

4. Possible side effects

EFFERFLU C IMMUNE BOOSTER PLUS can have side effects.

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

If any of the following happens, stop taking EFFERFLU C IMMUNE BOOSTER PLUS 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.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to EFFERFLU C IMMUNE BOOSTER PLUS. You may need urgent medical attention or hospitalisation.

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

- Stevens-Johnson syndrome (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters)
- impaired kidney function (symptoms may include fever, abdominal or lower back pain, nausea, vomiting, fatigue or muscle weakness).

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- inflammation of the oesophagus (heartburn, bloating and belching, acid reflux), intestinal obstruction (severe abdominal pain, nausea, vomiting, inability to pass wind or stool).

Side effects of unknown frequency:

- blood disorders which can only be detected by blood tests
- reduction in blood pressure (dizziness, fainting, blurred vision, nausea, lack of concentration)
- increased infection as a result of your immune system not working properly
- dizziness, drowsiness, headache
- shortness of breath, breathing difficulties
- abdominal pain, indigestion, nausea, vomiting, stomach cramps, diarrhoea, gastric irritation and

other gastrointestinal disturbances, flatulence, metallic taste in the mouth

- skin-related reactions, redness of the skin, rash, severe itching, hives
- mild increase in urination, kidney stones (symptoms include severe pain in the side and back, persistent need to urinate, pain on urination, pink, red or brown urine, nausea, vomiting, fever and chills)
- interference with laboratory tests for blood, urine and faeces

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8 or http://www.sahpra.org.za/documents/adverse-drug-reactions-and-quality-problem-reporting-form/. By reporting side effects, you can help provide more information on the safety of EFFERFLU C IMMUNE BOOSTER PLUS**.** You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store EFFERFLU C IMMUNE BOOSTER PLUS

Store all medicines out of reach of children.

Store at or below 30 °C in a cool, dry place.

Protect from light and moisture.

Store in the original container and keep lid of polypropylene container tightly closed when not in use.

Do not use after the expiry date stated on the tube and carton.

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 EFFERFLU C IMMUNE BOOSTER PLUS contains:

The active substances are:

Vitamin C (ascorbic acid) 1000 mg, zinc citrate 16,129 mg providing 5 mg elemental zinc, *Echinacea purpura* 50 mg and Vitamin D3 providing 800 IU vitamin D.

EFFERFLU C IMMUNE BOOSTER PLUS contains sugar (sugar alcohol - mannitol) and sweetener (sucralose).

The other ingredients are:

Red beet juice powder, riboflavin 5-phosphate sodium, citric acid anhydrous, sodium bicarbonate, Effer-Soda, tangerine flavour, orange flavour and PEG 6000.

What EFFERFLU C IMMUNE BOOSTER PLUS looks like and contents of the pack

EFFERFLU C IMMUNE BOOSTER PLUS effervescent tablets are speckled, light pink, smooth, cylindrical, bevelled edge tablets.

EFFERFLU C IMMUNE BOOSTER PLUS effervescent tablets are packed in polypropylene tubes of 20, 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.

Holder of Certificate of Registration

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Application number

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

MOZAMBIQUE:

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GHANA:

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KENYA:

10471