

EFFERFLU C IMMUNE BOOSTER

SCHEDULING STATUS ^[50]

1. NAME OF THE MEDICINE
EFFERFLU C IMMUNE BOOSTER (Orange flavour), effervescent tablets.
EFFERFLU C IMMUNE BOOSTER (Raspberry flavour), effervescent tablets.
EFFERFLU C IMMUNE BOOSTER (Blackcurrant flavour), effervescent tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each effervescent tablet contains ascorbic acid (vitamin C) 1000 mg, *Echinacea purpurea* 50 mg and zinc lactate trihydrate 22,71 mg equivalent zinc 5 mg.

EFFERFLU C IMMUNE BOOSTER contains sugar alcohol (sorbitol). **Orange** 339,00 mg, **Raspberry** 291,00 mg, **Blackcurrant** 281,00 mg). Contains sweetener (acesulfame potassium 30,00 mg). Contains sodium: 322,00 mg per tablet.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Effervescent tablets.
EFFERFLU C IMMUNE BOOSTER (**Orange flavour**) effervescent tablets are round and flat, pink coloured with light dots.
EFFERFLU C IMMUNE BOOSTER **Raspberry flavour**) effervescent tablets are round and flat, pink coloured with light dots.
EFFERFLU C IMMUNE BOOSTER (**Blackcurrant flavour**) effervescent tablets are round and flat, pink coloured with light dots.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

One tablet daily, dissolved in half to one glass of water. If you are required to take other medication, it should be taken a few hours before or after taking EFERFLU C IMMUNE BOOSTER.

Each effervescent tablet contains:

Active ingredient	Amount per tablet	RDA* for adults	Safer upper limit
Ascorbic acid	1 000 mg	50 - 100 mg	2 000 mg
<i>Echinacea purpurea</i> (L.) Moench (Purple coneflower) (dry extract) (flower aerial parts, extracted standardised to 4%, providing 2 mg polyphenols)	50,00 mg	—	—
Zinc**	5 mg	Female: 8 mg Male: 11 mg	40 mg

*RDA – Recommended dietary allowance.

**Zinc lactate trihydrate equivalent to 5 mg of zinc.

Pediatric population

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

Method of administration

Oral use.

EFFERFLU C IMMUNE BOOSTER should be taken with food.
EFFERFLU C IMMUNE BOOSTER mixture should be consumed immediately after dissolution in water.

It is recommended that EFERFLU C IMMUNE BOOSTER effervescent tablets be dissolved in cold water for a more pleasant taste.

4.3 Contraindications

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

EFFERFLU C IMMUNE BOOSTER is contraindicated in the following conditions:

- hypersensitivity to ascorbic acid, *Echinacea purpurea*, zinc, plant of the *Asteraceae* (Compositae) family or to any of the ingredients of EFERFLU C IMMUNE BOOSTER (see section 6.1)
- hyperoxaluria

- iron overload states (haemochromatosis, thalassaemia major, sickle cell disease, glucose-6-phosphate dehydrogenase deficiency)
- renal disorders
- tuberculosis
- collagenosis
- multiple sclerosis
- HIV/AIDS
- autoimmune disorders
- leukosis

4.4 Special warnings and precautions for use

consult a healthcare professional prior to use if you have a progressive system disease such as tuberculosis (TB), collagenosis, multiple sclerosis (MS), acquired immunodeficiency syndrome (AIDS) and/or human immunodeficiency virus (HIV) infection or an autoimmune disorder
consult a healthcare professional prior to use if you are taking medication to suppress the immune system.

Ascorbic acid:

- EFFERFLU C IMMUNE BOOSTER should be used with caution in diabetis mellitus because of possible interference with glucose determinations
- tolerance may be induced with prolonged use of large doses, resulting in symptoms of deficiency when intake is reduced to normal.
- ascorbic acid interferes with laboratory tests (e.g. examinations for acetaminophen (paracetamol), aspartate aminotransferase (AST) also called serum glutamic-oxaloacetic transaminase (SGOT), bilirubin, carbamazepine, creatine, glucose, lactate dehydrogenase (LDH), stool calcium, theophylline and uric acid). Falsely-elevated or false-negative test results may be obtained from plasma, faeces or urine samples.

Echinacea purpurea:

- there is a possible risk of severe hypersensitivity reactions in atopic patients.
- Atopic patients should consult their healthcare provider before using EFERFLU C IMMUNE BOOSTER.

Zinc:

- prolonged use of high doses of zinc supplements lead to copper deficiency with associated sideroblastic anaemia and neutropenia.

Information on excipients of EFERFLU C IMMUNE BOOSTER

Sorbitol

EFFERFLU C IMMUNE BOOSTER contains sugar alcohol (sorbitol). **Orange** 339,00 mg, **Raspberry** 291,00 mg, **Blackcurrant** 281,00 mg). Patients with hereditary fructose intolerance (HF) should not take/be given EFERFLU C IMMUNE BOOSTER.

The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account.

The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

Sodium:

Effertlu Immune Booster contains 322,00 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 16,1 % of the recommended maximum daily dietary intake of sodium for an adult.

4.5 Interaction with other medicines and other forms of interaction

Ascorbic acid:

- ascorbic acid should not be given for the first month after starting treatment with desferrioxamine due to increased iron toxicity and cardiac function should be monitored during combined use
- ascorbic acid may reduce the efficacy of indinavir, zynanocobalamin and disulfiram
- concurrent use of ascorbic acid and antacids may lead to aluminium toxicity
- large doses of ascorbic acid may increase serum ethinyllestradiol concentration in women taking oral contraceptives
- may interact with warfarin.

Echinacea purpurea

- may decrease efficacy of basiliximab, azathioprine, corticosteroids, ciclosporin, amiloridone, methotrexate, ketoncazoole, dacizumab, muronornab, mycophenolic acid, mycophenolate mofetil, sirolimus and tacrolimus.

Zinc:

- zinc may reduce the absorption of copper, ciprofloxacin and other fluoroquinolones, iron, penicillamine and tetracyclines.

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of EFERFLU C IMMUNE BOOSTER has not been established in pregnancy.

Breastfeeding

The safety of EFERFLU C IMMUNE BOOSTER has not been established in breastfeeding.

Fertility

There is no data on fertility with EFERFLU C IMMUNE BOOSTER.

4.7 Effects on ability to drive and use machines

EFFERFLU C IMMUNE BOOSTER may influence the ability to drive or use machines, as dizziness and drowsiness are side effects.
Caution should be advised to patients on performing these tasks until it is known how EFERFLU C IMMUNE BOOSTER affects them.

4.8 Undesirable effects

a. Tabulated list of adverse effects

The frequencies of adverse events are ranked according to the following: Frequent (> 1/100 to < 1/10); Less frequent = Infrequent (> 1/1 000 to < 1/100); Rare (> 1/10 000 to < 1/1 000); Very rare (<1/10 000). Frequency not known – cannot be estimated from the available data.

Ascorbic acid:

System Organ Class	Frequency	Side effects
Blood and lymphatic system disorders	<i>Frequency unknown</i>	Haemolysis in patients with glucose-6-phosphate dehydrogenase deficiency
Gastrointestinal disorders	<i>Less frequent</i> <i>Frequency unknown</i>	Oesophagitis, intestinal obstruction Nausea, stomach cramps, diarrhoea and other gastrointestinal disturbances
Renal and urinary disorders	<i>Frequency unknown</i>	Renal impairment, hyperoxaluria, formation of renal calcium oxalate calculi, mild increase in urination
Investigations	<i>Frequency unknown</i>	Interference with laboratory tests involving oxidation and reduction reactions

Echinacea purpurea:

System Organ Class	Frequency	Side effects
Blood and lymphatic system disorders	<i>Frequency unknown</i>	Reduction in blood pressure
Immune system disorders	<i>Frequency unknown</i>	Hypersensitivity reactions including anaphylaxis, rash, itching, swelling of the face, urticaria, angioedema, Stevens-Johnson syndrome, Quincke oedema, bronchospasm with airway obstruction
Nervous system disorders	<i>Frequency unknown</i>	Dizziness, headache
Respiratory, thoracic and mediastinal disorders	<i>Frequency unknown</i>	Asthma, breathing difficulties
Gastrointestinal disorders	<i>Frequency unknown</i>	Gastrointestinal disorders
Skin and subcutaneous tissue disorders	<i>Frequency unknown</i>	Skin-related reactions, erythema, exanthema, pruritis

Zinc:

System Organ Class	Frequency	Side effects
Blood and lymphatic system disorders	<i>Frequency unknown</i>	Copper deficiency with associated sideroblastic anaemia and neutropenia, iron deficiency, reduction in serum high-density lipoprotein (HDL) levels
Immune system disorders	<i>Frequency unknown</i>	Immune system depression
Nervous system disorders	<i>Frequency unknown</i>	Headache, drowsiness
Gastrointestinal disorders	<i>Frequency unknown</i>	Abdominal pain, dyspepsia, nausea, vomiting, diarrhoea, gastric irritation, gastritis, gastric erosion, metallic taste in the mouth

Reporting of suspected adverse reactions

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://sahprm.org.za/cati/complaints/>.
By reporting side effects, you can help provide more information on the safety of EFERFLU C IMMUNE BOOSTER.

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

4.9 Overdose

Signs and symptoms:

Ascorbic acid:

Excessive doses may cause nausea, stomach cramps, diarrhoea, nephrolithiasis, and haemolysis in patients deficient in glucose-6-dehydrogenase.

Echinacea purpurea:

Case of overdose has been reported.

Zinc:

Overdosage may cause vomiting, dehydration, muscle incoordination, dizziness and abdominal pain.

Management of overdose:

Treatment for zinc overdosage consists of giving milk or alkali carbonates and activated charcoal. The use of emetics or gastric lavage should be avoided.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: D33.7 Combination Product

Pharmacodynamic properties:

Ascorbic acid:

Ascorbic acid has a beneficial effect on the body's immune system and is required for many vital functions of the human body. Ascorbic acid has proven antioxidant properties, and in high doses (up to 1 g daily) may reduce the severity and duration of the common cold.

Echinacea Purpurea:

Echinacea is a herb primarily directed toward the immune system. This herb has demonstrated antibacterial, anti-inflammatory, antiseptic and immune system enhancing properties.
The immunostimulant effect is brought about by three mechanisms: activation of phagocytosis and stimulation of fibroblasts; increase respiratory activity and increase mobility of the leukocytes. The pharmacological activity of *Echinacea spp.* has been attributed to five component fractions in addition to the essential oil, namely the alkylamides, caffeic acid derivatives, polyalkynes, polyalkenes, and polysaccharides.

Zinc:

Zinc is thought to have antibacterial properties and assists in maintaining the integrity of both cellular and subcellular membranes. Zinc deficiency may result in an impaired immune response.

5.2 Pharmacokinetic properties

Ascorbic acid:

Ascorbic acid is readily absorbed from the gastrointestinal tract and is widely distributed in the body tissue. Plasma concentrations of ascorbic acid rise as the dose ingested is increased until a plateau is reached with doses of about 90 - 150 mg daily.
Ascorbic acid is reversibly oxidised to ascorbate-2-sulfate, which is inactive, and oxalic acid which are excreted unchanged in the urine. Ascorbic acid in excess of the body's need is rapidly eliminated unchanged in the urine. Ascorbic acid crosses the placenta and is distributed into breast milk. It is removed by haemodialysis.

Echinacea purpurea:

Pharmacokinetic data is limited and mostly focused on alkalimides. Studies suggest that alkalimides of *Echinacea* are easily transported from the intestine and may contribute to *in vivo* effects of *Echinacea*, and that alkalimides of *Echinacea* are metabolised by cytochrome P450.

Zinc:

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 - 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.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acesulfame potassium

Citric acid anhydrous

Silica

L-leucine

Polyorbate 20

Red beet powder

Simethicone emulsion

Sodium carbonate anhydrous

Sodium hydrogen carbonate

Sorbitol

Orange flavour:

Riboflavin sodium phosphate

Raspberry flavour:

Raspberry flavour

Blackcurrant flavour:

Blackcurrant flavour

Blue colour (E133)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

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.

6.5 Nature and contents of container

EFFERFLU C IMMUNE BOOSTER effervescent tablets are packed in polypropylene tubes of 20's, closed with a polypropylene stopper equipped with a silica gel drying agent. The polypropylene tube is inserted into a cardboard carton with an information leaflet.

6.6 Special precautions for disposal

No special requirements.

APPLICANT:

Pharma Dynamics (Pty) Ltd

1st Floor Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, 7945

Cape Town, South Africa

Tel: +27 21 707 7000

or 0860-PHARMA (742 762)

MANUFACTURER:

Pharma Trento S.p.A

Frazione Riviera

Via Provina 2

38123, Trento, Italy

This leaflet was last revised in

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BOTSWANA:

BWN2100515 (Orange flavour)

ZAMRA-FNS-25-07 (Blackcurrant flavour)

BWN2500002 (Blackcurrant flavour)

Category of distribution: S0

GHANA:

DA/SD/233-050499 (Orange, Blackcurrant, Raspberry flavour)

KENYA:

10465 (Orange flavour)

10470 (Raspberry flavour)

10467 (Blackcurrant flavour)

MOZAMBIQUE:

S8919 (Orange flavour)

Category of distribution: Nutritional supplement

ZAMBIA:

ZAMRA-FNS-25-20 (Orange flavour)

ZAMRA-FNS-25-08 (Raspberry flavour)

ZAMRA-FNS-25-07 (Blackcurrant flavour)

Category of distribution: General Sale

ZIMBABWE APPROVAL NUMBER:

CM0526 (Orange flavour)

CM0527 (Raspberry flavour)

CM0528 (Blackcurrant flavour)

Category of distribution: Pharmacy complimentary medicines

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use, therefore THERAPEUTIC CLAIMS NOT CONSIDERED APPROVED.

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS ^[50]

EFFERFLU C IMMUNE BOOSTER (Orange flavour), effervescent tablets
EFFERFLU C IMMUNE BOOSTER (Raspberry flavour), effervescent tablets
EFFERFLU C IMMUNE BOOSTER (Blackcurrant flavour), effervescent tablets

Ascorbic acid (vitamin C) 1000 mg, *Echinacea purpurea* 50 mg and zinc lactate trihydrate equivalent zinc 5 mg
EFFERFLU C IMMUNE BOOSTER (Orange flavour) (sorbitol): Orange 339,00 mg, Raspberry 291,00 mg, Blackcurrant 281,00 mg
Contains sweetener (acesulfame potassium 30,00 mg)
Contains sodium: 322,00 mg per tablet

Read all of this leaflet carefully because it contains important information for you
EFFERFLU C IMMUNE BOOSTER is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use EFERFLU C IMMUNE BOOSTER carefully to get the best results from it.

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

What is in this leaflet

- What EFERFLU C IMMUNE BOOSTER is and what it is used for
- What you need to know before you take EFERFLU C IMMUNE BOOSTER
- How to take EFERFLU C IMMUNE BOOSTER
- Possible side effects
- How to store EFERFLU C IMMUNE BOOSTER
- Contents of the pack and other information

1. What EFERFLU C IMMUNE BOOSTER is and what it is used for
EFFERFLU C IMMUNE BOOSTER is uniquely formulated to assist in providing support of normal immune function and promoting physical well-being.

2. What you need to know before you take EFERFLU C IMMUNE BOOSTER:

- Do not take EFERFLU C IMMUNE BOOSTER:
 - if you are hypersensitive (allergic) to ascorbic acid, *Echinacea purpurea*, zinc, plants of the Asteraceae (Compositae) family or to any of the other ingredients of EFERFLU C IMMUNE BOOSTER (see section 6)
 - if you have kidney stones or high oxalate levels in your urine
 - if you have a hereditary disease associated with an excess of iron in the blood
 - if you have kidney problems
 - if you have tuberculosis (TB)
 - if you have collagenosis (a rare skin disorder)
 - if you have multiple sclerosis (MS), a disease of the nervous system
 - if you have human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (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)

Warnings and precautions

Take special care with EFERFLU C IMMUNE BOOSTER:

- if you have progressive system disease such as tuberculosis (TB), collagenosis symptoms such as skin rash, fatigue, muscle weakness and aches, joint pain, and fever and some collagen vascular diseases may cause kidney failure, multiple sclerosis (MS) infections, include numbness and tingling, loss of balance and dizziness, fatigue, stiffness or spasms, tremor, pain and bladder problems, AIDS and/or HIV infection or an autoimmune disorder consult your healthcare professional prior to use
- if you are taking medication to suppress the immune system consult a healthcare professional
- if you have diabetes (sugar in the blood) your blood sugar, 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 EFERFLU C IMMUNE BOOSTER, which could result in symptoms of deficiency when ascorbic acid (vitamin C) intake is reduced to the normal dose
- if you take EFERFLU C IMMUNE BOOSTER 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 EFERFLU C IMMUNE BOOSTER, as results could be affected
- if you have a tendency for hypersensitivity