PROFESSIONAL INFORMATION

EFFERFLU C IMMUNE BOOSTER RANGE

SCHEDULING STATUS

S0

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 EFFERFLU 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*
Echinacea purpurea (L.) Moench, (Purple coneflower) (dry extract) [flowering aerial parts, extract 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.*

Paediatric poulation

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 EFFERFLU 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 EFFERFLU 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 supress the immune system

Ascorbic acid:

- EFFERFLU C IMMUNE BOOSTER should be used with caution in diabetes 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), AST (SGOT), bilirubin, carbamazepine, creatine, glucose, LDH, stool guaiac, 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 EFFERFLU 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 EFFERFLU C IMMUNE BOOSTER

EFFERFLU C IMMUNE BOOSTER contains sugar alcohol (sorbitol: **Orange** 339,00 mg, **Raspberry**

291,00 mg, **Blackcurrant** 281,00 mg) and may have a laxative effect.

Patients with the rare hereditary condition of sorbitol intolerance should not take EFFERFLU 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:

Efferflu 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, cyanocobalamine and disulfiram
- concurrent use of ascorbic acid and antacids may lead to aluminium toxicity
- large doses of ascorbic acid may increase serum ethinylestradiol concentration in women taking oral contraceptives
- may interact with warfarin.

Echinacea purpurea

- may decrease efficacy of basiliximab, azathioprine, corticosteroids, ciclosporin, amiodarone,

methotrexate, ketoconazole, daclizumab, muromonab, mycophenolic acid, mycophenelate 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 EFFERFLU C IMMUNE BOOSTER has not been established in pregnancy.

Breastfeeding

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

Fertility

There is no data on fertility with EFFERFLU 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 EFFERFLU 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	Frequency unknown	Haemolysis in patients with glucose-6-phosphate dehydrogenase deficiency
Gastrointestinal disorders	Less frequent Frequency unknown	Oesophagitis, intestinal obstruction Nausea, stomach cramps, diarrhoea and other gastrointestinal disturbances
Renal and urinary disorders	Frequency unknown	Renal impairment, hyperoxaluria, formation of renal calcium oxalate calculi, mild increase in urination
Investigations	Frequency unknown	Interference with laboratory tests involving oxidation and reduction reactions

Echinacea purpurea:

System Organ Class	Frequency	Side effects
Blood and lymphatic system disorders	Frequency unknown	Reduction in blood pressure

Immune system disorders	Frequency unknown	Hypersensitivity reactions including anaphylaxis, rash, itching, swelling of the face, urticaria, angioedema, Stevens-Johnson syndrome, Quincke oedema, bronchospasm with airway obstruction
Nervous system disorders	Frequency unknown	Dizziness, headache
Respiratory, thoracic and mediastinal disorders	Frequency unknown	Asthma, breathing difficulties
Gastrointestinal disorders	Frequency unknown	Gastrointestinal disorders
Skin and subcutaneous tissue disorders	Frequency unknown	Skin-related reactions, erythema, exanthema, pruitus

Zinc:

System Organ Class	**Frequency**	**Side effects**
Blood and lymphatic system disorders	Frequency unknown	Copper deficiency with associated sideroblastic anaemia and neutropenia, iron deficiency, reduction in serum HDL levels

Immune system disorders	Frequency unknown	Immune system depression
Nervous system disorders	Frequency unknown	Headache, drowsiness
Gastrointestinal disorders	Frequency unknown	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://sahpracm.org.za/catd/complaints/.

By reporting side effects, you can help provide more information on the safety of EFFERFLU 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:

No 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's action is 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; increasing 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 to 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 alkamides. Studies suggest that alkamides of *Echinacea* are easily transported from the intestine and may contribute to in vivo effects of *Echinacea*, and that alkamides 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 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.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acesulfame potassium

Citric acid anhydrous

Silica

L-leucine

Polysorbate 20

Red beets powder

Simethicone emulsion

Sodium carbonate anhydrous

Sodium hydrogen carbonate

Sorbitol

Orange flavour:

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, Cape Town

7945, South Africa

Tel.: +27 21 707 7000

or 0860-PHARMA (742 762)

MANUFACTURER:

Pharma Trento S.p.A

Friazione Ravina, Via Provina,2

38123

Trento, Italy

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BOTSWANA:

BWN2100515 (Orange flavour)

BWN2500001 (Raspberry flavour)

BWN2500002 (Blackcurrant flavour)

Category of distribution: S0

GHA:

FDASD.233-050499 (Orange, Blackcurrant, Raspberry flavour)

KEN:

10465 (Orange flavour)

10470 (Raspberry flavour)

10467 (Blackcurrant flavour)

MOZ:

S89/19 (Orange flavour)

Category of distribution: Nutritional supplement

ZAM:

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.