

PATIENT INFORMATION LEAFLET
EFFERFLU C IMMUNE BOOSTER JUNIOR

COMPLEMENTARY MEDICINE – DISCIPLINE SPECIFIC – COMBINATION PRODUCT

SCHEDULING STATUS:

S0

EFFERFLU C IMMUNE BOOSTER JUNIOR (berry flavour) effervescent tablets

Active ingredients	Amount per tablet	% NRV
Ascorbic acid (Vitamin C)	200,00 mg	200
Zinc citrate trihydrate providing zinc (elemental)	16,129 mg 5 mg	50
Selenium Aac (0,2 % selenium)	30,00 microgram	27
<i>Echinacea purpurea</i> extract	60,00 mg	No % NRV established

*NRV – Nutrient Reference value

Contains sugar (sugar alcohol - mannitol 800,00 mg) and sweetener (sucralose 16,00 mg)

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

EFFERFLU C IMMUNE BOOSTER JUNIOR is available without a doctor's prescription, for you to maintain your child's health. Nevertheless, EFFERFLU C IMMUNE BOOSTER JUNIOR still needs to be used 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 JUNIOR with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What EFFERFLU C IMMUNE BOOSTER JUNIOR is and what it is used for
2. What you need to know before you give EFFERFLU C IMMUNE BOOSTER JUNIOR to

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your child

3. How to use EFFERFLU C IMMUNE BOOSTER JUNIOR
4. Possible side effects
5. How to store EFFERFLU C IMMUNE BOOSTER JUNIOR
6. Contents of the pack and other information

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

EFFERFLU C IMMUNE BOOSTER JUNIOR contains ascorbic acid (vitamin C), zinc, echinacea and selenium.

EFFERFLU C IMMUNE BOOSTER JUNIOR is uniquely formulated to assist in providing support of normal immune function and promoting physical well-being in children aged 4 -14 years.

2. What you need to know before you give EFFERFLU C IMMUNE BOOSTER JUNIOR to your child

Do not use EFFERFLU C IMMUNE BOOSTER JUNIOR:

- if your child is hypersensitive (allergic) to ascorbic acid, zinc, echinacea and selenium or to any of the other ingredients of EFFERFLU C IMMUNE BOOSTER JUNIOR (see WHAT EFFERFLU C IMMUNE BOOSTER JUNIOR CONTAINS)
- if your child has kidney stones or high oxalate levels in his/her urine
- if your child has a genetic blood disorder called thalassaemia major, or sickle cell disease
- if your child has a hereditary disease associated with an excess of iron in the body or if his/her body does not have enough of an enzyme called glucose-6-phosphate dehydrogenase
- if your child has kidney problems
- if your child has a copper deficiency.

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EFFERFLU C IMMUNE BOOSTER JUNIOR should not be given to children younger than 4 years of age.

Warnings and precautions:

Take special care with EFFERFLU C IMMUNE BOOSTER JUNIOR:

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

Other medicines and EFFERFLU C IMMUNE BOOSTER JUNIOR

Always tell your healthcare provider if your child is taking any other medicine. (This includes complementary or traditional medicines.)

Tell your healthcare provider if your child is taking any of the following medicines:

- amygdalin (alternative cancer treatment)
- fluphenazine (used to treat symptoms of a mental/mood condition – schizophrenia)
- desferrioxamine (used as an antidote to treat iron overload or poisoning)

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- indinavir (an antiretroviral used in treatment of HIV/AIDS)
- penicillamine (used to treat rheumatoid arthritis)
- Calcium salts (used to treat calcium deficiency)
- iron (used to treat iron deficiency)
- phosphorus-containing medicines (used to treat phosphorus deficiency)
- antacids (used to treat heartburn and indigestion)
- warfarin (used to treat and prevent blood clots)
- aspirin (used for pain and fever)
- trientine (used in the treatment of Wilson's disease)
- copper containing medicines
- antibiotic medicines such as ciprofloxacin, cyclosporine, levofloxacin, moxifloxacin, norfloxacin, ofloxacin other fluoroquinolones and tetracyclines.

3. How to use EFFERFLU C IMMUNE BOOSTER JUNIOR

Do not share medicines with any other person.

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

Children from 4 years: One tablet daily, dissolved in half to one glass of cold water (see section 6). EFFERFLU C IMMUNE BOOSTER JUNIOR mixture should be consumed immediately after dissolution in water (see section 5). It is recommended to take a supplement at the same time every day for best results. To be taken with food. Separate the intake of the product from other medicines by 4 hours unless otherwise specified.

If your child takes more EFFERFLU C IMMUNE BOOSTER JUNIOR than he/she should:

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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, stomach cramps, diarrhoea, lack of coordination, dizziness, kidney stones, blood disorders, hair loss, nail changes, dry itchy skin or rash, metallic taste, garlic odour of breath, irritability, lack of energy and numbness and pain in the hands and feet.

If you forget to give your child a dose of EFFERFLU C IMMUNE BOOSTER JUNIOR:

The missed dose can be taken as soon as you remember. If it is almost time for the next dose, skip the missed dose and the next intended dose can be taken. A double dose may not be taken to make up for the missed dose.

4. Possible side effects

EFFERFLU C IMMUNE BOOSTER JUNIOR can have side effects.

Not all side effects reported for EFFERFLU C IMMUNE BOOSTER JUNIOR are included in this leaflet. Should your child's general health worsen, or if he/she experiences any untoward effects while taking EFFERFLU C IMMUNE BOOSTER JUNIOR, please consult your healthcare provider for advice.

If any of the following happens, stop using EFFERFLU C IMMUNE BOOSTER JUNIOR 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

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- rash or itching.

These are all very serious side effects. If your child has them, he/she may have had a serious allergic reaction to EFFERFLU C IMMUNE BOOSTER JUNIOR. Your child 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)
- haemolysis in patients with glucose-6-phosphate dehydrogenase deficiency (begins with rapid heart rate, shortness of breath, dark or yellow/orange urine, fever and yellowing of the skin)
- cardio-respiratory distress (characterised by chest pain or discomfort, rapid and irregular heartbeat, shortness of breath and unexplained wheezing)
- impaired kidney function (symptoms may include fever, abdominal or lower back pain, nausea, vomiting, fatigue or muscle weakness).

These are all serious side effects. Your child 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 (copper deficiency with associated

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sideroblastic anaemia and neutropenia, iron deficiency, reduction in serum HDL levels, haemolytic anaemia)

- sideroblastic anaemia (fatigue, weakness, the sensation of a pounding or racing heart (palpitations), shortness of breath, headaches, irritability, and chest pain)
- reduction in blood pressure (dizziness, fainting, blurred vision, nausea, lack of concentration)
- increased infection as a result of your immune system not working properly
- irritability, lethargy
- dizziness, drowsiness, headache
- 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)
- abdominal pain, indigestion, nausea, vomiting, stomach cramps, diarrhoea, gastric irritation and other gastrointestinal disturbances, metallic taste in the mouth
- skin-related reactions, redness of the skin, rash, itching
- 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 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 JUNIOR.

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

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5. How to store EFFERFLU C IMMUNE BOOSTER JUNIOR

Store all medicines out of reach of children.

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

Protect from light and moisture.

After reconstitution:

Consume immediately after dissolving the effervescent tablet in water.

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 JUNIOR contains

The active substances are:

Ascorbic acid (vitamin C), zinc, echinacea and selenium.

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

The other ingredients are:

Berry flavour, citric acid anhydrous, mannitol, polyethylene glycol 6000, polysorbate 60, polyvinylpyrrolidone K30, red raspberry, sodium bicarbonate, sucralose.

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

EFFERFLU C IMMUNE BOOSTER JUNIOR (berry flavour) effervescent tablets are speckled pink, smooth, cylindrical, bevelled edge tablets.

EFFERFLU C IMMUNE BOOSTER JUNIOR 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.

Reconstitution:

Dissolve effervescent tablet in half to one glass of cold water (see section 3).

Holder of Certificate of Registration

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