PROPRIETARY NAME AND DOSAGE FORM

WELLVITA® IMMUNO 2-PLUS (tablets)

COMPOSITION

Wellvita® Immuno Zinc + C: Each tablet contains Zinc amino acid chelate 125 mg (equivalent to 25 mg elemental zinc) and Vitamin C 1000 mg.
Wellvita® Immuno Vit D3: Each tablet contains Vitamin D3 1000 IU.

Other ingredients: Talc, micro-crystalline cellulose, magnesium stearate and silicon dioxide. Sugar free.

PHARMACOLOGICAL CLASSIFICATION

D 34.12 Multiple substance formulation Complementary medicine - Health Supplement

Wellvita® Immuno-2 Plus supports a healthy immune system.

CONTRA-INDICATIONS

Do not use this medicine if you are hypersensitive (allergic) to any of the ingredients in the formulation. Not suitable for children younger than 14 years, unless under medical supervision.

WARNINGS AND SPECIAL PRECAUTIONS

If you suffer from any serious ailments (including blood-iron disorders or sickle cell disease) or conditions (such as HIV, diabetes or kidney disease); or if you are taking any prescribed medication (including antibiotics, cisplatin or warfarin), please check with your healthcare provider before taking this medicine.

- Consult your healthcare provider before taking vitamin D3 if you are on digoxin, thiazide diuretics (such as indapamide, hydrochlorothiazide, chlorthalidone and chlorothiazide) or using magnesium-containing antacids.
- · Vitamin D3 might cause dizziness and may have an influence on your ability to drive or use machinery. Do not drive or operate machinery until you know how it affects you.
- Zinc might lower blood sugar levels. Use cautiously if you are suffering from diabetes; people with haemochromatosis may absorb larger amounts of zinc. Zinc might also interfere with the absorption of iron, copper, magnesium and calcium. Consult your healthcare provider for
- further advice.

Porphyria: Safety has not been established.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

PREGNANCY AND LACTATION

If you are pregnant or breastfeeding, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

INTERACTIONS

If you are taking other medicines regularly, including complementary or traditional medicines, or start taking any additional medicines while taking this medicine, consult your healthcare provider for advice.

Zinc can affect the absorption of certain antibiotics (such as tetracycline, penicillamine and quinolone). Take zinc either two hours before or four hours after any other medication to prevent absorption problems and do not take zinc if you are taking a medicine called cisplatin. Vitamin C might affect the metabolism of certain medicines. These can include, but are not limited to protease inhibitors, estrogen, fluphenazine, warfarin and statins. Consult your healthcare provider for more information. Vitamin D3 should be used with caution in patients taking digoxin, because hypercalcemia (high blood calcium levels) may precipitate abnormal heart rhythms. Concurrent administration of thiazide diuretis (such as chlorothiazide, chlorthalidone, hydrochlorothiazide and indapamide) and vitamin D3 to hypoparathyroid patients may cause hypercalcemia, which may be transient or may require discontinuation of vitamin D. Hypermagnesemia (high blood levels of magnesium) may develop if you use vitamin D3 with magnesium-containing antacids, particulary in patients with chronic renal failure.

DOSAGE AND DIRECTIONS FOR USE

Adults:

Wellvita® Immuno Zinc + C: Take one tablet daily.

Wellvita® Immuno Vit D3: Take one tablet daily after a meal.

SIDE EFFECTS

Side effects for zinc can include stomach upset, nausea, vomiting, metallic taste, headache, irritability, lethargy and diarrhoea. Vitamin D3 side effects may include hypercalcemia and anaemia. Some symptoms of hypercalcemia include fatigue, headache, loss of appetite, dry mouth, metallic taste, nausea, vomiting, abdominal cramps, constipation, diarrhoea, dizziness, muscle pain and irritability. Side effect for vitamin C may include heartburn, nausea, diarrhoea, headache or stomach cramps. Not all side effects reported for this medicine has been reported. Should your general health worsen or if you experience any untoward effects while taking this medicine, discontinue use immediately and consult your doctor, pharmacist or other healthcare provider for advice.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

In case of an overdose, or suspected overdose, contact your healthcare provider immediately. Treatment is symptomatic and supportive.

IDENTIFICATION

Wellvita® Immuno Zinc + C: Yellow tablet. Wellvita® Immuno Vit D3: White round tablets.

PRESENTATION

2 x 30 tablets are packed in separate plastic containers. The 2 containers are packed into a unit carton.

STORAGE INSTRUCTIONS

Store all medicines out of reach of children. Store in a cool dry place below 25 °C and keep away from direct sunlight

NAME AND BUSINESS ADDRESS OF THE APPLICANT

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