

## PROFESSIONAL INFORMATION

### Complementary Medicine: Discipline-Specific Traditional

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

### SCHEDULING STATUS

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#### 1. NAME OF THE MEDICINE

ColdEez Colds & Flu Gummies, gummy.

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

<i>Echinacea Purpurea</i> (aerial part) [Extract 10:1]	15,00 mg
<i>Sambucus Nigra L.</i> (fruit) [Extract 20:1]	15,00 mg
Vitamin D3 (Cholecalciferol)	5,00 mcg (200 IU)
Vitamin C (as Ascorbic acid BP)	100,00 mg
Zinc (as Zinc gluconate)	2,00 mg

Contains sugar:	Sucrose	850 mg per chew tablet
	Liquid glucose	975 mg per chew tablet

For full list of excipients, see section 6.1.

#### 3. PHARMACEUTICAL FORM

Bear shaped gummy.

#### 4. CLINICAL PARTICULARS

##### 4.1. Therapeutic indications

ColdEez Colds & Flu Gummies assists with the symptoms associated with colds and flu. It may be beneficial during the flu season and may assist the immune system in fighting colds and flu.

##### 4.2. Posology and method of administration

###### Posology

The usual dose for acute use is:

Children 2 to 3 years of age: 2 gummies daily

Children 4 to 12 years of age: 3 gummies daily

Consult with your doctor or healthcare practitioner if symptoms persist for longer than 14 days.

Do not exceed the recommended dose.

Do not swallow whole.

Not for use in children under the age of 2 years old.

Maintenance dose:

Children 2 to 3 years of age: 1 gummy daily

Children 4 to 12 years of age: 1-2 gummies daily

Do not use for periods longer than 3 months.

### **Method of administration**

For oral use.

### **4.3. Contraindications**

- Hypersensitivity to the active ingredients and to other plants of the Asteraceae (Compositae) or to any of the excipients listed in section 6.1.
- Echinacea is not recommended in cases of progressive systemic disorders and autoimmune disease such as tuberculosis, leucosis, collagenoses, multiple sclerosis, AIDS, or HIV-infections.
- Avoid use during pregnancy and lactation, as safety has not been established. See section 4.6

### **4.4 Special warnings and precautions**

ColdEez Colds & Flu Gummies should be used with care in:

- Patients under treatment for any medical condition should consult their healthcare practitioner before using this product.
- ColdEez Colds & Flu Gummies does not intend to prevent or cure any form of illness or disease and should not replace any medication. If you suffer from a chronic medical condition, consult your healthcare practitioner before using ColdEez Cold & Flu gummies.
- Do not exceed the recommended daily dosage without consulting a medical doctor.
- If symptoms persist or worsen, consult a health care practitioner.

*Echinacea purpurea (L.):*

The use is not recommended in cases of progressive systemic disorders, autoimmune diseases, immunodeficiencies, immunosuppression and diseases of the white blood cell system.

If the symptoms worsen or high fever occurs during the use of the medicinal product, a doctor or qualified health care practitioner should be consulted.

There is a possible risk of allergic reactions in sensitive individuals. Those patients should consult their doctor before using *Echinacea*.

There is a possible risk of anaphylactic reactions in atopic patients. Atopic patients should consult their doctor before using *Echinacea*.

*Sambucus Nigra [Extract 20:1] (Elderberry):*

If the symptoms worsen or high fever occurs during the use of the medicinal product, a doctor or qualified health care practitioner should be consulted.

If dyspnoea, fever or purulent sputum occurs, a doctor or a health care practitioner should be consulted.

**ColdEez Colds & Flu Gummies contains sucrose:**

Patients with rare hereditary problems such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take this medicine.

**ColdEez Colds & Flu Gummies contains liquid glucose:**

Patients with rare glucose-galactose malabsorption should not take this medicine.

**5. Interaction with other medicines and other forms of interaction**

No adverse effects have been reported with the concomitant use of ColdEez Colds & Flu Gummies.

If you have a medical condition or are taking any medication, please consult your doctor before taking new medicines or supplements.

**6. Fertility, pregnancy and lactation**

Safety in pregnancy and lactation has not been established.

**4.7 Effects on ability to drive and use machines**

No studies on the effect on the ability to drive and use machines have been performed.

**8. Undesirable effects**

Side effects may include:

- Nausea

- Vomiting
- Diarrhoea
- Colic

If you experience any side effects, discontinue use immediately and consult your medical practitioner or pharmacist for advice.

### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorization of ColdEez Colds & Flu Gummies is important. It allows continued monitoring of the benefit/risk balance of ColdEez Colds & Flu Gummies. Health care providers are asked to report any suspected adverse reactions to the South African Health Products Regulatory Authority (SAHPRA) via the 6.04 Adverse Drug Reaction Reporting Form, found online under SAHPRA's publications: <https://sahpra.org.za/Publications/Index/8>.

### **9. Overdose**

Excessive doses may increase the risk of experiencing side effects (see section 4.8). Treatment of overdosage is symptomatic and supportive.

## **2. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Category D Medicine: Discipline-Specific Traditional D 33.7 Combination Product

## **3. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Blackcurrant Liquid Essence No. 1

Citric Acid

Gelatine

Liquid glucose

Sodium Citrate

Sucrose

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

2 years

### **6.4 Special precautions for storage**

Store at or below 25 °C.  
Protect from direct sunlight.

**6.5 Nature and contents of container**

60 Bear shaped gummies in a container

**6.6 Special precautions for disposal**

No special requirements.

**7. HOLDER OF CERTIFICATE OF REGISTRATION**

Talo Consumer Solutions (Pty) Ltd

30 Bell Crescent

Hennospark

0172

**8. REGISTRATION NUMBER**

Will be allocated by SAHPRA upon registration.

**9. DATE OF FIRST AUTHORISATION**

Will be allocated by SAHPRA upon registration.

**10. DATE OF REVISION OF TEXT**

This leaflet was last revised in March 2024.