PROFESSIONAL INFORMATION

Complementary Medicine

Discipline-Specific, Combination Product

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 for Kids

Chewable (gummy)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gummy contains:

Echinacea purpurea (Echinacea) [aerial part, dry extract 10:1 providing 150 mg dried herb equivalent]	15,00 mg
Sambucus nigra L. (Elderberry) [fruit, dry extract 20:1 providing 300 mg dried herb equivalent]	15,00 mg
Vitamin D3 (100 000 IU/ g) providing Cholecalciferol (Vitamin D3)	2,00 mg 5 mcg /200 IU
Vitamin C 97 % providing Ascorbic acid (Vitamin C)	103,10 mg 100,00 mg
Zinc gluconate providing Zinc (elemental)	14,286 mg 2,00 mg

Contains Sugar: Glucose 1131 mg per gummy.
Sucrose 986 mg per gummy.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Chewable (gummy)

Dark maroon bear-shaped gummy.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

ColdEez Colds & Flu Gummies for Kids is indicated for use in children from 3 years to 12 years of age.

It assists in the fight against colds and flu by maintaining and supporting the immune system.

4.2. Posology and method of administration

Posology

Children 3-12 years: Chew three gummies daily.

The recommended daily dose should not be exceeded.

ColdEez Colds & Flu Gummies for Kids:

- Should not be swallowed whole.
- Should not be used for longer than 8 weeks without consulting a relevant healthcare provider.
- Should be taken at least 2 hours before or 4 to 6 hours after other medications (see section 4.5).

Paediatric population

This product is indicated for children from 3 years to 12 years of age. It should not be given to children under 3 years of age.

Method of administration

For oral use.

4.3. Contraindications

- Hypersensitivity to the active ingredients or to other plants of the Asteraceae or Adoxaceae families or to any of the excipients listed in section 6.1.
- Progressive systemic disease such as tuberculosis, multiple sclerosis, AIDS and/or HIV infections or an autoimmune disorder.
- Hypercalcaemia and/or hypercalciuria
- Severe renal impairment.
- Hypervitaminosis D
- Hyperoxaluria
- Iron overload states
- Glucose-6-phosphate dehydrogenase deficiency

- Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.
- Children under 3 years of age.

4.4. Special warnings and precautions for use

Patients should not use this product for longer than 8 weeks without consulting a relevant healthcare provider.

Care should be taken in

- patients with dyspnoea, fever, or purulent sputum.
- patients with symptoms that persist or worsen.
- patients taking immunosuppressants.
- individuals with atopic conditions. This product contains Echinacea, which may stimulate the immune system function and may theoretically exacerbate autoimmune diseases. Patients with atopy, or a genetic tendency toward allergic conditions, may be more likely to experience an allergic reaction when taking this product.
- concurrent use with other medication metabolised by cytochrome P450 3A4 (see section 4.5).
- pregnancy and lactation (see section 4.6)
- mild to moderate renal impairment
- elderly patients
- patients with cardiac failure undergoing deferoxamine treatment (see section 4.5).
- patients with diabetes mellitus. This product contains 1131 mg glucose & 986 mg sucrose per gummy.

Care should be taken:

- This product contains glucose and sucrose, which may be harmful to teeth.

4.5. Interaction with other medicines and other forms of interaction

ColdEez Colds & Flu Gummies for Kids may interact with certain medicines.

Caution is advised when used concurrently with:

- immunosuppressants (e.g. basiliximab, azathioprine, corticosteroids, ciclosporin, mycophenolic acid, tacrolimus). Echinacea may reduce the effectiveness of these products.
- medication metabolised by cytochrome P450 3A4 (CYP 3A4 substrates) (e.g., carbamazepine, diazepam, zolpidem, esomeprazole, lansoprazole, hydrocortisone, venlafaxine, diltiazem, verapamil, and atorvastatin). Echinacea interacts with the cytochrome P450 enzyme system and may therefore potentially interact with medications metabolised by

the same enzymes. This interaction could potentially alter the effectiveness and side effects of those medications.

- medication metabolised by cytochrome P450 3A4, as vitamin D may affect the levels of these medications.
- deferoxamine. Use with caution/monitor. Ascorbic acid increases the availability of iron for chelation with deferoxamine. Ascorbic acid should be avoided in patients with cardiac failure undergoing deferoxamine treatment. Clinical cardiac monitoring is recommended for patients using products containing ascorbic acid.
- medicines affected by urine pH. Ascorbic acid may acidify urine, altering excretion.
- certain antibiotics (e.g., fluoroquinolones). Oral zinc supplements may reduce the absorption and effect of these antibiotics. This product should be taken at least 2 hours before or 4 to 6 hours after an antibiotic.

Concurrent use is not recommended with:

- beclomethasone, inhaled. The product contains Echinacea, which decreases the effects of inhaled beclomethasone by pharmacodynamic antagonism.
- digoxin. Vitamin D can increase or potentiate the effect of digoxin when given with calcium or in patients with hypercalcaemia.
- warfarin. Ascorbic acid decreases anticoagulant effects.
- aluminium hydroxide. Vitamin D increases levels. Avoid coadministration. Chronic use of aluminium-containing antacids in conjunction with vitamin D can lead to aluminium retention and possible toxicity.

4.6. Fertility, pregnancy and lactation

Pregnancy

Not established. In the absence of sufficient data, use during pregnancy is not recommended.

Breast-feeding

Not established. In the absence of sufficient data, use during pregnancy is not recommended.

Fertility

No fertility data available.

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.

This product may affect the ability to drive and use machines due to possible side effects (see section 4.8).

4.8. Undesirable effects

a) Summary of the safety profile

Use should be discontinued if a hypersensitivity reaction occurs.

b) Tabulated summary of adverse reactions

Echinacea purpurea

Classification	Frequency	Side effects
Immune system disorders	Unknown	Hypersensitivity reactions, such as anaphylaxis (can include rash, itching, angioedema, difficulty in swallowing or breathing, bronchospasm, fainting).
Nervous system disorders	Unknown	Dizziness, headache
Respiratory, thoracic and mediastinal disorders	Unknown	Sore throat
Gastrointestinal disorders	Unknown	Abdominal pain, diarrhoea, nausea, vomiting, unpleasant taste
General disorders and administration site conditions	Unknown	Fever Fatigue

***Sambucus nigra* L.**

Classification	Frequency	Side effects
Immune system disorders	Unknown	Hypersensitivity reactions, such as anaphylaxis (can include rash, itching, angioedema, difficulty in swallowing or breathing, bronchospasm, fainting).
Renal and urinary disorders	Unknown	Diuresis

Cholecalciferol (Vitamin D3)

Classification	Frequency	Side effects
Metabolism and Nutrition Disorders	Unknown	Hypercalcaemia (which can include fatigue or weakness, nausea, vomiting, constipation, loss of appetite, frequent urination, increased thirst, muscle aches and cramps, confusion). Hypercalciuria (which can include haematuria, burning or pain during urination, lower back or side pain).
Skin and Subcutaneous Tissue Disorders	Unknown	Pruritus, rash, urticaria

Ascorbic acid (Vitamin C)

Classification	Frequency	Side effects
Nervous system disorders	Unknown	Faintness, headache
Vascular disorders	Unknown	Flushing
Gastrointestinal disorders	Unknown	Diarrhoea, dyspepsia, nausea, vomiting.
Renal and urinary disorders	Unknown	Flank pain Hyperoxaluria (which can include back pain, haematuria, frequent urination, painful urination, nausea, vomiting)
Investigations	Unknown	Interference with laboratory tests involving oxidation-reduction reactions. e.g., blood and urine glucose testing, nitrite and bilirubin levels, and leucocyte count testing.

Zinc gluconate

Classification	Frequency	Side effects
Nervous system disorders	Unknown	Drowsiness, confusion, severe or worsening headaches.
Gastrointestinal disorders	Unknown	Nausea, vomiting, gastric irritation
Investigations	Unknown	Elevations of serum alkaline phosphatase, amylase, and lipase.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9. Overdose

In overdose, side effects can be precipitated and/or be increased by severity (see section 4.8). Treatment of overdosage is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

D33.7 Complementary Medicines

Discipline- Specific, Combination Product.

5.2. Pharmacokinetic properties

The pharmacokinetic properties have not been established.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Blackcurrant Liquid Essence No. 1

Citric Acid

Gelatine

Glucose

Purified water

Sodium Citrate

Sucrose

6.2. Incompatibilities

None known.

6.3. Shelf life

24 months

6.4. Special precautions for storage

Store in a cool, dry place at or below 25 °C.

Store in the original container.

Keep the container tightly closed.

Protect from light/moisture.

6.5. Nature and contents of container

Dark maroon bear-shaped gummies in a square plastic container with a square, white, child-resistant plastic cap.

Pack size: 60

Not all pack sizes may be marketed.

6.6. Special precautions for disposal

No special requirements.

7. PROSPECTIVE HOLDER OF CERTIFICATE OF REGISTRATION

Talo Consumer Solutions (Pty) Ltd
30 Bell Crescent
Hennopspark ext 7
Centurion
0172

8. REGISTRATION NUMBER

To be allocated.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

10. DATE OF THE REVISION OF TEXT

February 2026