

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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COLDEEZ® COLDS & FLU GUMMIES FOR KIDS

Echinacea, Elderberry, Vitamin D3, Vitamin C, Zinc

Contains sugar: 1131 mg glucose and 986 mg sucrose per gummy.

Complementary Medicine

D33.7 Discipline- Specific, Combination Product.

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

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

COLDEEZ COLDS & FLU GUMMIES FOR KIDS is available without a doctor's prescription for you to support your health. Nevertheless, you still need to use COLDEEZ COLDS & FLU GUMMIES FOR KIDS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share COLDEEZ COLDS & FLU GUMMIES FOR KIDS with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What COLDEEZ COLDS & FLU GUMMIES FOR KIDS is and what it is used for
2. What you need to know before you take COLDEEZ COLDS & FLU GUMMIES FOR KIDS
3. How to take COLDEEZ COLDS & FLU GUMMIES FOR KIDS
4. Possible side effects
5. How to store COLDEEZ COLDS & FLU GUMMIES FOR KIDS
6. Contents of the pack and other information

1. What COLDEEZ COLDS & FLU GUMMIES FOR KIDS is and what it is used for

COLDEEZ COLDS & FLU GUMMIES FOR KIDS is a complementary medicine that contains the following active ingredients: Echinacea, Elderberry, Vitamin D3, Vitamin C and Zinc.

COLDEEZ COLDS & FLU GUMMIES FOR KIDS assists in the maintenance and support of the immune system.

2. What you need to know before you take COLDEEZ COLDS & FLU GUMMIES FOR KIDS

Do not take COLDEEZ COLDS & FLU GUMMIES FOR KIDS:

- if you are hypersensitive (allergic) to any of the ingredients in COLDEEZ COLDS & FLU GUMMIES FOR KIDS (listed in section 6) or to any plants in the Daisy or Moschatel family.
- if you have any progressive systemic disease (where the body's systems gradually break down or attack themselves), such as tuberculosis, multiple sclerosis, AIDS, and/or HIV infections, or an autoimmune disorder.
- if you have too much calcium in your blood (hypercalcaemia) and/or too much calcium in your urine (hypercalciuria).
- if your kidney function is severely impaired (kidneys have significantly lost their ability to filter waste and excess fluid from your blood).
- if you have too much Vitamin D in the body (hypervitaminosis D).
- if you have too much oxalate in your urine (hyperoxaluria).
- if you have any condition where the body stores too much iron (iron overload states).
- if you have a glucose-6-phosphate dehydrogenase deficiency (a genetic condition where the body doesn't have enough of an enzyme called G6PD, which helps red blood cells function properly).
- if you have a rare hereditary problem of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency (inherited metabolic disorders where the body is missing specific enzymes needed to break down certain sugars).

Do not give COLDEEZ COLDS & FLU GUMMIES FOR KIDS:

- to children younger than 3 years of age.

Warnings and special precautions

Special care should be taken with COLDEEZ COLDS & FLU GUMMIES FOR KIDS.

- This product should not be used for longer than 8 weeks without consulting a relevant healthcare provider.
- If you are having trouble breathing (dyspnoea), or if you have a fever, or phlegm that is thick and yellow/ green (purulent sputum), please consult a healthcare provider.
- If you have symptoms that persist for longer than one week or worsen while taking COLDEEZ COLDS & FLU GUMMIES FOR KIDS, please consult a healthcare provider.

Consult a healthcare provider before use:

- if you are taking medications that suppress (weaken) your immune system.
- if you have allergies or a history of allergic conditions such as asthma, eczema, hay fever, or any autoimmune condition. COLDEEZ COLDS & FLU GUMMIES FOR KIDS contains Echinacea, which may stimulate your immune system, and which could possibly make certain immune-related conditions worse. If you have a genetic tendency toward allergies, you may also have a higher risk for an allergic reaction to Echinacea.
- if you are taking any other medication that is broken down (metabolized) by a liver enzyme called CYP3A4, such as carbamazepine, diazepam, zolpidem, esomeprazole, lansoprazole, hydrocortisone, venlafaxine, diltiazem, verapamil, and atorvastatin (see **Other medicine and COLDEEZ COLDS & FLU GUMMIES FOR KIDS**).
- if you are pregnant or breastfeeding. Use is not recommended when pregnant or breastfeeding (see **Pregnancy and breastfeeding and fertility**).
- if you have mild to moderate kidney impairment (if your kidneys are not functioning as well as they should).
- when the person is considered elderly.
- if you have heart failure and are receiving treatment with deferoxamine (a medication that helps remove excess iron from the body).
- if you have diabetes mellitus. This product contains 1131 mg glucose & 986 mg sucrose per gummy, which may affect glycaemic control (how well blood sugar levels are managed).

COLDEEZ COLDS & FLU GUMMIES FOR KIDS contains glucose and sucrose, which may be harmful to teeth.

Children and adolescents

Do not give COLDEEZ COLDS & FLU GUMMIES FOR KIDS to children under 3 years of age.

Other medicine and COLDEEZ COLDS & FLU GUMMIES FOR KIDS

Always tell your healthcare provider if you are taking any other medicine (this includes all complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Medicines that suppress (weaken) your immune system, such as basiliximab, azathioprine, corticosteroids, ciclosporin, mycophenolic acid, and tacrolimus.
- Medication that is broken down (metabolized) by a liver enzyme called CYP3A4, such as carbamazepine, diazepam, zolpidem, esomeprazole, lansoprazole, hydrocortisone, venlafaxine, diltiazem, verapamil, and atorvastatin.
- Deferoxamine (a medication that helps remove excess iron from the body).
- Medicines affected by the pH of urine.

- Antibiotics (medications that fight bacterial infection). This product should be taken at least 2 hours before or 4 to 6 hours after an antibiotic.
- Beclomethasone inhalation (medication used to prevent asthma attacks).
- Digoxin (medication used to treat congestive heart failure).
- Warfarin (medication used to treat and prevent blood clots).
- Aluminium hydroxide (antacid used for the symptomatic relief of heartburn, indigestion, etc.)

COLDEEZ COLDS & FLU GUMMIES FOR KIDS with food and drink and alcohol

None known.

Pregnancy and breastfeeding and fertility

Use during pregnancy or while breastfeeding is not recommended.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking COLDEEZ COLDS & FLU GUMMIES FOR KIDS.

Driving and use of machinery

COLDEEZ COLDS & FLU GUMMIES FOR KIDS may cause drowsiness or dizziness (see **Possible side effects**) and may thus affect the ability to drive and use machines.

It is not always possible to predict to what extent COLDEEZ COLDS & FLU GUMMIES FOR KIDS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the extent to which COLDEEZ COLDS & FLU GUMMIES FOR KIDS affects them.

COLDEEZ COLDS & FLU GUMMIES FOR KIDS contains Blackcurrant Liquid Essence No. 1, citric acid, gelatine, glucose, purified water, sodium citrate, sucrose.

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this product. This product contains glucose and sucrose and should not be taken if you have a rare hereditary problem of fructose intolerance, glucose-galactose malabsorption, or sucrase-isomaltase insufficiency (inherited metabolic disorders in which the body is missing specific enzymes needed to break down certain sugars).

3. How to take COLDEEZ COLDS & FLU GUMMIES FOR KIDS

Do not share medicines prescribed for you with any other person.

Always use COLDEEZ COLDS & FLU GUMMIES FOR KIDS exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The recommended daily dosage for children 3-12 years:

Chew three gummies daily.

Do not exceed the recommended daily dose.

Do not swallow whole.

Do not use for longer than 8 weeks without consulting a relevant healthcare provider.

COLDEEZ COLDS & FLU GUMMIES FOR KIDS should be taken at least 2 hours before or 4 to 6 hours after other medications (see **Other medicine and COLDS & FLU GUMMIES FOR KIDS**).

Route of administration: oral

If you take more COLDEEZ COLDS & FLU GUMMIES FOR KIDS than you should

You may experience sudden onset or increased severity of the side effects.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take COLDEEZ COLDS & FLU GUMMIES FOR KIDS

If you forget to take a dose of COLDEEZ COLDS & FLU GUMMIES FOR KIDS, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you have missed.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

COLDEEZ COLDS & FLU GUMMIES FOR KIDS can have side effects.

Not all side effects reported for COLDEEZ COLDS & FLU GUMMIES FOR KIDS are included in this leaflet.

Should your general health worsen or if you experience any untoward effect while taking COLDEEZ COLDS & FLU GUMMIES FOR KIDS, please consult your healthcare provider for advice.

If any of the following happen, stop taking COLDEEZ COLDS & FLU GUMMIES FOR KIDS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, and mouth or throat, which may cause difficulty in swallowing or breathing
- wheezing, coughing, shortness of breath and chest tightness due to bronchospasm (when the muscles in your airways constrict)
- rash or itching
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to COLDEEZ COLDS & FLU GUMMIES FOR KIDS. You may need urgent medical attention or hospitalisation

If any of the following happen, stop taking COLDEEZ COLDS & FLU GUMMIES FOR KIDS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- severe or worsening headaches
- fever
- dizziness
- confusion

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequency unknown:

- headache
- fatigue
- weakness
- drowsiness
- flushing
- sore throat
- pain in the side of your body (specifically between your lower ribs and hip)
- back pain
- muscle aches and cramps
- abdominal cramps or pain
- indigestion
- constipation
- diarrhoea (loose stool)
- nausea (feeling sick)
- vomiting
- unpleasant taste
- loss of appetite
- increased thirst
- if your body is producing more urine than usual
- frequent urination
- burning or pain during urination
- blood in urine

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of COLDEEZ COLDS & FLU GUMMIES FOR KIDS.

5. How to store COLDEEZ COLDS & FLU GUMMIES FOR KIDS

- Store all medicines out of reach of children.
- 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.
- Do not use after the expiry date stated on the bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of this pack and other information

What COLDEEZ COLDS & FLU GUMMIES FOR KIDS contains

The active substances per gummy are:

<i>Echinacea purpurea</i> (Echinacea) [aerial part, dry extract 10:1 providing 150 mg dried herb equivalent]	15,00 mg
<i>Sambucus nigra</i> 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

The other ingredients are:

Blackcurrant Liquid Essence No. 1, citric acid, gelatine, glucose, purified water, sodium citrate, sucrose

What COLDEEZ COLDS & FLU GUMMIES FOR KIDS looks like and contents of the pack

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

Pack size: 60

Prospective Holder of Certificate of Registration

Talo Consumer Solutions (Pty) Ltd

30 Bell Crescent

Hennospark ext 7

Pretoria

Tel: 012 010 0815

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Registration number

To be allocated

Access to the corresponding Professional Information

Can be obtained by scanning the QR code below.

Email: info@tcsbrands.co.za

Telephone: 012 010 0815