

PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

COLDEEZ COUGH SYRUP

Ivy leaf, Thyme leaf, Marshmallow root

Contains sugar: Honey, 1 g per 2,5 mL dose and 2 g per 5 mL dose.

Contains preservatives: Potassium sorbate 0,1 % & Sodium benzoate 0,1 %

Complementary Medicine

D33.6 Discipline-Specific, Western Herbal

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 COUGH SYRUP is available without a doctor's prescription for you to support your health. Nevertheless, you still need to use COLDEEZ COUGH SYRUP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share COLDEEZ COUGH SYRUP with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- Consult your health care provider if symptoms persist for longer than one week or worsen during the use of the product.
- For children between 3- 4 years of age who suffer from a persistent or recurrent cough, please consult your health care provider for a medical diagnosis and advice before using this product.

What is in this leaflet

1. What COLDEEZ COUGH SYRUP is and what it is used for
2. What you need to know before you use COLDEEZ COUGH SYRUP
3. How to use COLDEEZ COUGH SYRUP
4. Possible side effects
5. How to store COLDEEZ COUGH SYRUP
6. Contents of the pack and other information

1. What COLDEEZ COUGH SYRUP is and what it is used for

COLDEEZ COUGH SYRUP can be used by adults and children aged 3 years and older.

It is a cough syrup with added honey and a combination of herbal ingredients that helps to relieve your cough. It loosens and thins phlegm in the airway, making it easier to clear from the lungs, and helps to alleviate the feeling of chest congestion.

2. What you need to know before you take COLDEEZ COUGH SYRUP

Do not use COLDEEZ COUGH SYRUP:

- If you are hypersensitive (allergic) to any of the ingredients in COLDEEZ COUGH SYRUP (listed in section 6) or other plants of the Ginseng, Mallow, or Mint families.
- For children under 3 years of age.
- If you have an intolerance to fructose or any other rare genetic disorder that affects how your body absorbs glucose and galactose.

Warnings and special precautions

Special care should be taken with COLDEEZ COUGH SYRUP.

- For children between 3- 4 years of age who suffer from a persistent or recurrent cough, please consult your health care provider for a medical diagnosis and advice before using this product.
- Consult a health care provider if you experience dyspnoea (shortness of breath), fever or purulent sputum (yellow or green with a thick, opaque consistency).
- Use with caution if you suffer from gastritis or have a gastric ulcer.
- Consult a health care provider if symptoms persist for longer than one week or worsen during the use of the product.
- Use during pregnancy and lactation is not recommended. Safety has not been established.
- Use with caution if you have diabetes mellitus. COLDEEZ COUGH SYRUP contains 1 g of honey per 2,5 mL dose and 2 g of honey per 5 mL dose, which may affect how well your body manages blood sugar (glucose) levels.
- Consult a health care provider before use if you have been informed or if you suspect that you have an intolerance to some sugars. COLDEEZ COUGH SYRUP should not be taken in some instances (see **Do not use**).
- Use with cough suppressants is not recommended. Consult a health care provider for medical advice.

Children and adolescents

Do not give COLDEEZ COUGH SYRUP to children under the age of 3 years.

Other medicine and COLDEEZ COUGH SYRUP

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

COLDEEZ COUGH SYRUP contains *Althea officinalis* L. (Marshmallow) root extract, which may delay the absorption of other medications taken at the same time. As a precautionary measure, the product should not be taken 30-60 minutes before or after taking other medication.

COLDEEZ COUGH SYRUP with food and drink and alcohol

No known interactions.

Pregnancy and breastfeeding and fertility

Use during pregnancy and lactation 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 health care provider for advice before taking COLDEEZ COUGH SYRUP.

Driving and use of machinery

It is not always possible to predict to what extent COLDEEZ COUGH SYRUP 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 COUGH SYRUP affects them.

COLDEEZ COUGH SYRUP contains citrus honey, glycerol, sodium benzoate, potassium benzoate, honey flavour, xanthan gum, citric acid monohydrate, and purified water.

COLDEEZ COUGH SYRUP contains 1 g of honey per 2,5 mL dose and 2 g of honey per 5 mL dose.

- It may affect how well the body manages blood sugar (glucose).
- Should not be used if you have a fructose intolerance or other rare genetic disorder that affects how your body absorbs glucose and galactose (see **Do not use COLDEEZ COUGH SYRUP**) as it may provoke digestive side effects.

3. How to take COLDEEZ COUGH SYRUP

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

Always use COLDEEZ COUGH SYRUP 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.

COLDEEZ COUGH SYRUP should be taken orally.

Shake the bottle well before use.

The usual dose is:

Children 3- 11 years: 2,5 mL three times a day.

Adults and children 12 years and older: 5 mL three times a day.

Do not give COLDEEZ COUGH SYRUP to children under the age of 3 years.

Do not take other medications 30-60 minutes before or after taking this product.

If you take more COLDEEZ COUGH SYRUP than you should

You may experience nausea, vomiting, diarrhoea, and agitation.

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 COUGH SYRUP

If you forget to take a dose of COLDEEZ COUGH SYRUP, 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 COUGH SYRUP can have side effects.

Not all side effects reported for COLDEEZ COUGH SYRUP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking COLDEEZ COUGH SYRUP, please consult your healthcare provider for advice.

If any of the following happens, stop taking COLDEEZ COUGH SYRUP 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.
- shortness of breath.
- rash or itching.
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to COLDEEZ COUGH SYRUP. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Side effects of which the frequency is not known

- nausea (feeling sick)
- vomiting
- diarrhoea (loose stools)

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 COUGH SYRUP.

5. How to store COLDEEZ COUGH SYRUP

- Store all medicines out of reach of children.
- Store in a cool, dry place at or below 25°C.
- Protect from light.
- Do not use after the expiry date stated on the label / carton / 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 COUGH SYRUP contains

Each 2,5 mL contains

The active substances:

<i>Hedera helix</i> (English ivy)	8,75 mg
[leaf, dry extract 5,5:1 providing 48,13 mg dried herb equivalent]	
<i>Thymus Vulgaris</i> (Thyme)	12,50 mg
[leaf, 1:10 liquid extract providing 1,25 mg dried herb equivalent]	
<i>Althea officinalis</i> L. (Marshmallow)	13,50 mg
[root, 10:1 extract providing 135 mg dried herb equivalent]	

The other ingredients are:

Citrus honey, glycerol, sodium benzoate, potassium benzoate, honey flavour, xanthan gum, citric acid monohydrate, purified water.

Each 5 mL contains

The active substances:

<i>Hedera helix</i> (English ivy)	17,50 mg
[leaf, dry extract 5,5:1 providing 96,25 mg dried herb equivalent]	
<i>Thymus Vulgaris</i> (Thyme)	25,00 mg
[leaf, 1:10 liquid extract providing 2,5 mg dried herb equivalent]	
<i>Althea officinalis</i> L. (Marshmallow)	27,00 mg
[root, 10:1 extract providing 270 mg dried herb equivalent]	

The other ingredients are:

Citrus honey, glycerol, sodium benzoate, potassium benzoate, honey flavour, xanthan gum, citric acid monohydrate, purified water.

What COLDEEZ COUGH SYRUP looks like and contents of the pack

A light brown, opaque, slightly viscous and sweet-tasting honey-flavoured syrup in an amber glass bottle, with white tamper-proof cap and measuring cup, which is placed in an outer carton.

Each bottle contains 150 mL COLDEEZ COUGH SYRUP.

Prospective Holder of Certificate of Registration

Talo Consumer Solutions (Pty) Ltd
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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

