

PATIENT INFORMATION LEAFLET

Complementary Medicine

Combination product

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

SCHEDULING STATUS **S0**

COLDEEZ, effervescent tablet

Elderberry *Sambucus Nigra* fruit (20:1 extract)
Pelargonium (*Pelargonium sidoides* root, 10:1 extract providing 200,00 mg dried herb)
Echinacea (*Echinacea Purpurea* Extract 10:1)
Vitamin D3
Ascorbic acid
Zinc Gluconate
Contains sugar:
Sorbitol powder: 500,0 mg
Contains sweetener:
Sodium Saccharin: 23,0 mg
Sodium Cyclamate: 20,0 mg

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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

Coldeez is available without a doctor's prescription, for you to treat a mild illness and to maintain your health. Nevertheless, you still need to use Coldeez carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Coldeez 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 is and what it is used for
2. What you need to know before you take Coldeez
3. How to take Coldeez
4. Possible side effects
5. How to store Coldeez
6. Contents of the pack and other information

1. What Coldeez is and what it is used for

Coldeez contains herbal ingredients and vitamins and is used to support and maintain the immune system.

2. What you need to know before you take Coldeez

Do not take Coldeez:

- if you are hypersensitive (allergic) to vitamin C (ascorbic acid), vitamin D, zinc, *Pelargonium*, *Echinacea*, *Sambucus Nigra* or to any of the other ingredients of Coldeez (listed in section 6);
- if you suffer from immune related diseases;
- if you suffer from iron overload;
- if you suffer from hyperoxaluria (a rare condition characterised by recurrent kidney and bladder stones).

Warnings and precautions

Take special care with Coldeez:

- If you have a history of kidney stones as high doses of vitamin C can increase the risk of stone formation.
- If you have a history of autoimmune disease, a disease that happens when the body's natural defence system can't tell the difference between your own cells and foreign cells, causing the body to mistakenly attack normal cells.
- If you have a history or genetic tendency for allergic reactions, you may be more likely to experience an allergic reaction when taking *Echinacea*.
- If you have high levels of calcium or Vitamin D, or suffer from malabsorption of nutrients, or an electrolyte imbalance.
- If you have heart disease.
- If you have kidney disease.

Other medicines and Coldeez

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 the immune system.
- Desferrioxamine, a medicine given to treat iron toxicity.
- Coldeez may decrease the efficacy of medicines such as basliximab, azathioprine, corticosteroids, ciclosporin, amiodarone, methotrexate, ketoconazole, daclizumab, muromab, mycophenolic acid, mycophenolate mofetil, sirolimus, tacrolimus, indinavir, cyanocobalamin, disulfiram, copper, ciprofloxacin and other fluoroquinolones, iron, penicillamine, tetracyclines, diltiazem, verapamil, atorvastatin, and thiazide diuretics.
- The use of Coldeez and antacids may lead to aluminium toxicity.
- Warfarin.
- Coldeez may enhance the effects of calcipotriene, digoxin, and certain medicines that are metabolised by a specific enzyme in the liver (cytochrome P450 3A4 (CYP 3A4) substrates.)

Pregnancy, breastfeeding and fertility

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.

Driving and using machines

It is not always possible to predict to what extent Coldeez 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 measure to which Coldeez affects them.

It is not expected that Coldeez will affect mental and / or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and / or sound coordination and vision e.g. driving, riding, flying, sailing, operating machines / equipment.

Coldeez contains sugar (sorbitol) and sodium

- Coldeez contains Sorbitol which may have an effect on the control of your bloodsugar levels if you suffer from Diabetes Mellitus.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Coldeez.
- This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Coldeez

Do not share medicines prescribed for you with any other person. Always take Coldeez exactly as described in this leaflet or as your healthcare professional has told you. Check with your healthcare professional if you are not sure.

The usual dose is:

Adults:

One effervescent tablet dissolved in water, three times daily.

Children 6 to 12 years:

One effervescent tablet dissolved in water, once daily.

Dissolve the effervescent tablet in one glass of water. Then drink the contents of the whole glass.

If you take more Coldeez than you should

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

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

4. Possible side effects

Coldeez can have side effects.

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

If any of the following happens, stop taking Coldeez and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Breathing difficulties.

- Asthma.

- Kidney and bladder stones.

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

Tell your doctor if you notice any of the following:

Frequent

- Diarrhoea.
- Discomfort of the stomach area.
- Nausea.
- Vomiting.
- Difficulty in swallowing.

Less frequent

- Inflammation of the oesophagus.
- Stomach obstruction.

Frequency unknown:

- Bleeding gums.
- Nose bleeds.
- Inflammation of the liver, or toxic effects on the liver.
- Lowering in blood pressure.
- Dizziness.
- Headache.
- Stomach cramps.
- Haemolysis, a medical term used to describe the destruction of red blood cells. This occurs in patients suffering from the rare disease called glucose-6-phosphate dehydrogenase deficiency.
- Impairment in kidney function.
- Increase in frequency of urination.
- Interference with certain laboratory tests.
- Weakness.
- Dry mouth.
- Copper deficiency.
- Iron deficiency.
- Reduction in serum cholesterol (HDL) levels.
- Immune system depression.
- Headaches.
- Drowsiness.
- Indigestion.
- Irritation of the stomach lining.
- Gastric ulcers.
- Metallic taste in the mouth.

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 "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of Coldeez.

5. How to store Coldeez

Store all medicines out of reach of children.

- Store at or below 25 °C.

- Store in the original package/ container.

- Keep the container tightly closed.

- Protect from light / moisture.

- Do not store in a bathroom.

- 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 the pack and other information

What Coldeez contains

The active substances are:

Elderberry	20,0 mg
<i>Sambucus Nigra</i> Fruit (20:1 extract)	
<i>Pelargonium</i>	20,0 mg
(<i>Pelargonium Sidoides</i> root, 10:1 extract providing 200,00 mg dried herb)	
<i>Echinacea</i>	30,0 mg
(<i>Echinacea Purpurea</i> Extract 10:1)	
Vitamin D3 (333 IU).....	3,33 mg
Ascorbic acid (Vitamin C)	343,64 mg
Zinc Gluconate, equivalent to elemental zinc	8,33 mg

The other ingredients are:

- Aerosil 200
- Carmoisine red colourant
- Citric acid anhydrous
- Effervescent soda
- Orange flavour F211S
- Polyethylene glycol 6000
- Quinoline yellow colourant
- Sodium cyclamate
- Sodium saccharin
- Sorbitol
- Talc

What Coldeez looks like and contents of the pack

A round, flat speckled effervescent tablet. Twelve effervescent tablets are packed in a round white polyethylene canister, with a white polyethylene closure with a built-in silicone desiccant.

Holder of Certificate of Registration

Talo Consumer Solutions (Pty) Ltd
30 Bell Crescent
Hennospark ext 7
Pretoria
Tel: 0120100815

This leaflet was last revised in

July 2023

Registration number

To be allocated.

Access to the corresponding Professional Information

Can be obtained from the SAHPRA website: www.sahpra.org.za

PASIËNTINLIGTINGSBLAD

Komplimentêre Medisyne

Kombinasieprodukt

Hierdie ongeregistreerde medisyne is nie deur SAHPRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

SKEDULERINGSSTATUS S0

COLDEEZ, bruistablet

Elderberry *Sambucus Nigra* vrug (20:1 ekstrakt)

Pelargonium (*Pelargonium sidoides* wortel, 10:1 ekstrakt verskaf

200,00 mg gedroogde kruie)

Echinacea (*Echinacea Purpurea* ekstrakt 10:1)

Vitamiën D3

Askorbiensuur

Sinkglukonaat

Bevat suiker:

Sorbitol poeier: 500,0 mg

Bevat versoeter:

Natriumsakkarie: 23,0 mg

Natriumsiklamaat: 20,0 mg

Hierdie medisyne bevat minder as 1 mmol natrium (23 mg) per tablet, dit wil sê in wese 'natriumvry'.

Lees die hele inligtingsblad noukeurig deur aangesien dit belangrike inligting vir jou bevat.

Coldeez is beskikbaar sonder 'n dokter se voorskryf, vir jou om 'n ligte siekte te behandel en om jou gesondheid te handhaaf. Nietemin moet jy Coldeez steeds versigtig gebruik om die beste resultate daaruit te verkry.

- Bewaar hierdie pamflet. Jy sal dit dalk weer moet lees.
- Moenie Coldeez met enige ander persoon deel nie.
- Vra jou gesondheidsorgverskaffer of apteker as jy meer inligting of advies benodig.

Wat is in hierdie inligtingsblad

1. Wat is Coldeez en waarvoor word dit gebruik
2. Wat moet jy weet voordat jy Coldeez neem
3. Hoe om Coldeez te neem
4. Moontlike nuwe-effekte
5. Hoe om Coldeez te bewaar
6. Inhoud van die pakkie en ander inligting

1. Wat is Coldeez en waarvoor word dit gebruik

Coldeez bevat kruiebestanddele en vitamien e en word gebruik om die immuunstelsel te ondersteun en in stand te hou.

2. Wat jy moet weet voordat jy Coldeez neem

Moet nie Coldeez neem:

- as jy hipersensitief (allergies) is vir vitamien C (askorbiensuur), vitamien D, sink, *Pelargonium*, *Echinacea*, *Sambucus Nigra* of vir enige van die ander bestanddele van Coldeez (gelys in afdeling 6);
- as jy aan immuunverwante siektes ly;
- as jy aan ysterooriading ly;
- as jy aan hiperoksaliurie ly ('n seldsame toestand wat gekenmerk word deur herhalende nier- en blaasstene).

Waarskuwings en voorsorgmaatreëls

Wees versigtig met Coldeez:

- As jy 'n geskiedenis van nierstene het aangesien hoë dosisse vitamien C die risiko van steenvorming kan verhoog.
- As jy 'n geskiedenis van outo-immuun siekte het, 'n siekte wat ontstaan wanneer die liggaam se natuurlike verdedigingstelsel nie die verskil tussen jou eie selle en vreemde selle kan onderskei nie, wat veroorsaak dat die liggaam verkeerdlik normale selle aanval.
- As jy 'n geskiedenis van genetiese neiging vir allergiese reaksies het, kan jy meer geneig wees om 'n allergiese reaksie te ervaar wanneer jy *Echinacea* neem.
- As jy hoë vlakke van kalsium of Vitamiën D het, of ly aan wanabsorpsie van voedingsstowwe, of 'n elektrolietwanbalans.
- As jy hartsiektes het.
- As jy niersiektes het.

Ander medisyne en Coldeez

Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in).

Lig jou dokter spesifiek in as jy die volgende neem:

- Medisyne wat die immuunstelsel onderdruk.
- Desferriksamien, 'n medisyne wat gegee word om ystertoksitasiteit te behandel.
- Coldeez kan die doeltreffendheid verminder van medisyne soos bastilksimab, asatiopreen, kortikosteroïede, siklosporien, amiodaron, metotreksaat, ketokonasool, daklismab, muromb, mikofenolsuur, mikofenolaatmofetil, sirolimus, takrolimus, indinavir, cyanocobalamin, disulfiraam, koper, siprofloksasien en ander fluorokinolone, yster, pensiliamien, tetrasiklene, dilitasem, verapamiel, atorvastatien en tiasieddiuretika.
- Die gebruik van Coldeez en teensuurmiddels kan lei tot aluminiumtoksitasiteit.
- Warfariën.
- Coldeez kan die uitwerking van kalsipotriëen, digoksien en sekere medisyne wat deur 'n spesifieke ensiem in die lewer gemetaboliseer word (sitochroom P450 3A4 (CYP3A4) substrate) versterk.

Swangerskap, borsvoeding en vrugbaarheid

As jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy Coldeez neem.

Bestuur en gebruik van masjiene

Dit is nie altyd moontlik om te voorspel tot watter mate Coldeez met die daglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet verseker dat hulle nie by bogenoemde aktiwiteite betrokke raak nie totdat hulle bewus is van die mate waartoe Coldeez hulle beïnvloed. Daar word nie verwag dat Coldeez geestelike en / of fisiese vermoëns sal beïnvloed om take of aktiwiteite uit te voer wat geestelike waaksaamheid, oordeel en / of klank koördinasie en visie vereis nie, bv. bestuur, ry, vlieg, seil, bestuur van masjiene / toerusting.

Coldeez bevat suiker (sorbitol) en natrium

Coldeez bevat sorbitol wat 'n uitwerking op die beheer van jou bloedsuiker kan hê as jy ly aan diabetes mellitus.

- As jy deur jou dokter gesê is dat jy 'n intoleransie teenoor sommige suikers het, kontak jou dokter voordat jy Coldeez neem.
- Hierdie medisyne bevat minder as 1 mmol natrium (23 mg) per tablet, dit wil sê in wese 'natriumvry'.

3. Hoe om Coldeez te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem Coldeez altyd presies soos beskryf in hierdie pamflet of soos jou gesondheidsorgverskaffer jou vertel het. Bevestig met jou gesondheidsorgverskaffer as jy onseker is.

Die gewone dosis is:

Volwassenes:

Een bruistablet, drie keer per dag.

Kinders 6 tot 12 jaar:

Een bruistablet een keer per dag.

Los die bruistablet op in een glas water. Drink dan die inhoud van die hele glas.

Indien jy meer Coldeez neem as wat jy moes

In die geval van oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of vergiftigingsentrum.

Indien jy vergeet om Coldeez te neem

Moenie 'n dubbeldosis neem om op te maak vir vergeete individuele dosisse nie.

4. Moontlike nuwe-effekte

Coldeez kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir Coldeez aangemeld is, is in hierdie pamflet ingesluit nie. Indien u algemene gesondheid verswak of as u enige nadelige effekte ervaar tervyl u Coldeez gebruik, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

As enige van die volgende gebeur, hou op om Coldeez te neem en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal;
- uitslag of jeuk;
- flou word.

Dit is alles baie ernstige nuwe-effekte. As jy dit het, het jy dalk 'n ernstige reaksie op Coldeez gehad. Miskien benodig jy dalk dringende mediese hulp of hospitalisasie.

Vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- Asemhalingsprobleme.
- Asma.
- Nier- en blaasstene.

Dit is alles ernstige nuwe-effekte. Jy benodig dalk dringende mediese hulp.

Vertel jou dokter as jy enige van die volgende opmerk:

Gereeld

- Diarree.
- Ongemak van die maagarea.
- Naarheid.
- Braking.
- Moeilikheid om te sluk.

Minder gereeld:

- Inflammasie van die slukderm.
- Maagobstruksies.

Frekwensie onbekend:

- Bloeiende tandvleis.
- Neusbloeding.
- Inflammasie van die lewer, of toksiese effekte op die lewer.
- Verlagings in bloeddruk.
- Duiseligheid.
- Hoofpyn.
- Maagkrampe.
- Hemolise, 'n mediese term wat gebruik word om die vernietiging van rooibloedselle te beskryf. Dit kom voor by pasiënte wat ly aan die seldsame siekte genaamd glukose-6-fosfaatdehidrogenase-tekort.
- Inkorting van nierfunksie.
- Toename in frekwensie van urinering.
- Inmenging met sekere laboratoriumtoetse.
- Swakheid.
- Droë mond.
- Kopertekort.
- Ystertekort.
- Verlagings in serum cholesterol (HDL) vlakke.
- Immuunstelsel onderdrukking.
- Hoofpyn.
- Lomerigheid.
- Spysverteringsprobleme.
- Irritasie van die maagwand.
- Maagsere.
- Metaalsmaak in die mond.

Indien u enige nuwe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van nuwe-effekte

Indien jy nuwe-effekte ervaar, praat met jou dokter, apteker of verpleegster. Jy kan ook nuwe-effekte aan SAHPRA rapporteer via die **"6.04 Adverse Drug Reactions Reporting Form"**, wat aanlyn beskikbaar is onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van Coldeez te verskaf.

5. Hoe om Coldeez te bewaar

Bewaar alle medisyne buite bereik van kinders.

- Bewaar by of benede 25 °C.
- Bewaar in die oorspronklike verpakking/houer.
- Hou die houder dig toe.
- Beskerm teen lig / vog.
- Moenie in 'n badkamer stoor nie.
- Moet nie na die vervaldatum soos aangedui op die etiket / karton / bottel gebruik nie.
- Gee alle ongebruikte medisyne terug aan u apteker.
- Moenie ongebruikte medisyne in dreine of rioelstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pakkie en ander inligting

Wat Coldeez bevat

Die aktiewe bestanddele is:

Elderberry	20,0 mg
<i>Sambucus Nigra</i> Vrug (20:1 ekstrakt)	
<i>Pelargonium</i>	200,0 mg
(<i>Pelargonium sidoides</i> wortel 10:1 ekstrakt verskaf 200,00 mg gedroogde kruie)	
<i>Echinacea</i>	30,0 mg
(<i>Echinacea Purpurea</i> Ekstrakt 10:1)	
Vitamiën D3 (333 IU).....	3,33 mg
Askorbiensuur (Vitamiën C)	343,64 mg
Sinkglukonaat, gelykstaande aan elementêre sink	8,33 mg

Die ander bestanddele is:

- Aerosil 200
- Karmoisine rooi kleurstof
- Watervrye sitroensuur
- Bruissoda
- Lemoen geursel F211S
- Poliëtileenglikol 6000
- Kinolien geel kleurstof
- Natriumsiklamaat
- Natriumsakkarie
- Sorbitol
- Talk

Hoe Coldeez lyk en die inhoud van die pakkie

'n Ronde, plat gespikkelde bruistablet. Twaalf bruistablette word verpak in 'n ronde wit poliëteleen houër, met 'n wit poliëteleen sluiting met 'n ingeboude silikoon droogmiddel.

Houer van die registrasiesertifikaat

Talo Consumer Solutions (Pty) Ltd
Bell Crescent 30
Hennospark ext 7
Pretoria
Tel: 0120100815

Hierdie inligting is voorgeen hiersien in

Julie 2023

Registrasienumer(s)

TBA

Toegang tot die ooreenstemmende professionele inligting

Aanlyn beskikbaar op SAHPRA se webstuipe: www.sahpra.org.za



PRO-PRINT (PTY) LTD
THE PROFESSIONALS IN PRINT

REPRO

Date: 1 December 2023
Operator: Jacky Pistorius
Customer: Wrapsa
Product Name: Coldeez Eff Tablet PIL
Product Code: --
Dimensions: 140 x 340 mm
Fold Size: 140 x 30
Font Size: 6 point Helvetica
Colours: (1) Black
--
Barcode: --
Pharmacode: --
Stock: 50 gsm
Proof Status: 1st (First)

Proof read by: _____

Reset: **Alterations:** **Disk/Possie:**

No alterations - Proceed as soon as possible

Note alterations - Further proof is required

PLEASE CHECK CAREFULLY.

Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.

Signature: **Date:**

PROOF NOT READ – NO COPY SUPPLIED