

PROFESSIONAL INFORMATION

**BRONCHILIFT**  
Cough & Cold (syrup)

agera™

**SCHEDULING STATUS:** **S2**

**PROPRIETARY NAME AND DOSAGE FORM:**  
**BRONCHILIFT Cough & Cold (syrup)**

**COMPOSITION:**

Active substances per 5 ml syrup:  
Pelargonium 370 *Pelargonium sidoides* (DC.) root extract 28.57 mg  
*Hedera helix* L. Dry Leaf extract 35 mg  
Inactive ingredients:  
Citric acid, flavonating, g<sub>2</sub> cinnin, multodextrin, microcrystalline cellulose, carmellose sodium and water  
Contains preservatives: Potassium sorbate (0.035 % w/v), sodium benzoate (0.045 % w/v)  
Contains sorbitol (2.5 g/5 ml)  
Contains sweetener: CSA 80 16.41 mg/5 ml (acesulfame potassium, sodium saccharin and sodium cyclamate)

Alcohol, sugar, lactose and tartrazine free

**CATEGORY AND CLASS:**

D33.6 Western Herbal Medicine. Complementary Medicine.

**PHARMACOLOGICAL ACTION:**

*Pelargonium sidoides* DC. and *Hedera helix* L. are well known traditional remedies for the treatment of productive coughs associated with symptoms of cold and flu. *Hedera helix* extract has been shown to help loosen, and calm painful coughing through relaxation of bronchial muscles, resulting in bronchodilation.

**INDICATIONS:**

**BRONCHILIFT COUGH & COLD** is a traditional herbal medicinal product for the symptomatic treatment of the common cold and the **BRONCHILIFT COUGH & COLD** has spasmolytic, expectorant and mucolytic properties, assisting with the relief of a productive cough.

**CONTRAINDICATIONS:**

Hypersensitivity to the active substance, or to plants belonging to the *Ericaceae* family (ivy, ginseng, etc).

Previous history of hepatotoxicity.

**WARNINGS AND SPECIAL PRECAUTIONS:**

Do not use in children under the age of 6 years.  
• Concentrate use with spirituous substances such as cocaine or dextromethorphan is not recommended without medical advice.  
• Cases of hepatotoxicity and hepatitis have been reported with *Pelargonium sidoides*. Should signs of hepatotoxicity occur (stomach pain, nausea, vomiting, fever, yellowing of the skin and eyes, dark urine, light stools) **BRONCHILIFT COUGH & COLD** must be stopped immediately and a doctor should be consulted.  
• Caution is recommended in patients with gastritis or gastric ulcers.  
• If dyspepsia (distention of breath or laboured breathing), fever or persistent spasm (yellow or green sputum) occurs, please consult your doctor or pharmacist.  
• Contains sorbitol and may have a laxative effect. Patients with the rare hereditary condition of sorbitol intolerance should not take **BRONCHILIFT COUGH & COLD**.

**Effects on the ability to drive and use machinery:**

No studies on the effect of **BRONCHILIFT COUGH & COLD** on the ability to drive or operate machinery were performed. It is unlikely that **BRONCHILIFT COUGH & COLD** would affect the ability to drive or operate machinery.

**INTERACTIONS:**

None known.

**PREGNANCY AND LACTATION:**

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use of **BRONCHILIFT COUGH & COLD** during pregnancy and lactation is not recommended.

**DOSAGE AND DIRECTIONS FOR USE:**

Children aged 6 to 12 years old: Take 5 ml two times daily

Children above 12 years of age: Take 5 ml three times daily

Adults: Take 5 ml three times daily

Take one dose in the morning, at lunch and in the evening.

Do not exceed the recommended dose.

**SIDE EFFECTS:**

***Pelargonium sidoides* DC:**

**Blood and the lymphatic system disorders:** Nasal and gingival bleeding (*frequency unknown*).

**Gastrointestinal disorders:** Diarrhoea, epigastric discomfort, nausea or vomiting, and dysphagia (*frequency unknown*).

**Hepato-biliary disorders:** Hepatotoxicity (*frequency unknown*).

**General disorders and administrative site conditions:** Allergic reactions (*frequency unknown*).

***Hedera Helix* L.:**

**Gastrointestinal disorders:** Nausea, vomiting and diarrhoea (*frequency unknown*).

**Skin and subcutaneous tissue disorders:** Urticaria, skin rash, dyspnoea (*frequency unknown*).

If other adverse reactions not mentioned above occur, please see your doctor, pharmacist or healthcare professional.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

***Hedera helix* L.:**  
Overdose can provoke nausea, vomiting, dizziness and agitation.  
Treatment is symptomatic and supportive.

**IDENTIFICATION:**

Reddish brown syrup with a sweet taste.

**PRESENTATION:**

Amber 200 ml plastic bottle with a white plastic tamper evident cap.

**STORAGE INSTRUCTIONS:**

Store at or below 25 °C.

Protect from humidity and light.

**KEEP OUT OF SIGHT AND REACH OF CHILDREN.**

**REGISTRATION NUMBER:**

To be allocated upon registration.  
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or its intended use.

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

agera Health (Pty) Ltd

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**DATE OF PUBLICATION OF THE PACKAGE INSERT:**

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**PATENT INFORMATION LEAFLET**

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority (SAHPRA) for its quality, safety or its intended use. This medicine is not intended to diagnose, treat, cure or prevent any disease.

Complementary Medicine. Western Herbal Medicine.

**SCHEDULING STATUS:** **S2**

**PROPRIETARY NAME AND DOSAGE FORM:**  
**BRONCHILIFT Cough & Cold (syrup)**

Read all of this leaflet carefully because it contains important information for you.  
• This medicine is available without prescription. However, you still need to use **BRONCHILIFT COUGH & COLD** as directed to get the best results from it.  
• Keep this leaflet. You may need to read it again.  
• Do not share this medicine with any other person.  
• Ask your Doctor or Pharmacist if you need more information or advice.  
• You must consult a doctor or qualified healthcare professional if your symptoms worsen or do not improve after 7 days.

**1. WHAT BRONCHILIFT COUGH & COLD CONTAINS:**

Active substances per 5 ml syrup:  
Pelargonium 370 *Pelargonium sidoides* (DC.) 28.57 mg  
*Hedera helix* L. Dry Leaf extract 35 mg  
Inactive ingredients:  
Citric acid, flavonating, glycerine, multodextrin, microcrystalline cellulose, carmellose sodium and water  
Preservatives: Potassium sorbate (0.035 % w/v), sodium benzoate (0.045 % w/v)  
Contains sweetener: sorbitol (2.5 g/5 ml)  
Contains sweetener: CSA 80 16.41 mg/5 ml (acesulfame potassium, sodium saccharin and sodium cyclamate)  
Alcohol, sugar, lactose and tartrazine free.

**2. WHAT IS BRONCHILIFT COUGH & COLD USED FOR:**

**BRONCHILIFT COUGH & COLD** is a traditional herbal medicinal product for the symptomatic treatment of the common cold and the **BRONCHILIFT COUGH & COLD** has spasmolytic, expectorant and mucolytic properties, assisting with the relief of a productive cough.

**3. BEFORE YOU TAKE GIVE BRONCHILIFT COUGH & COLD:**

**Do not take GIVE BRONCHILIFT COUGH & COLD**

• If you are hypersensitive (allergic) to any of the listed ingredients or to plants belonging to the *Ericaceae* family (ivy, ginseng, etc).  
• If your child is under the age of 6 years.  
• If you have a previous history of liver damage.

**Take special care with BRONCHILIFT COUGH & COLD**

• If you start experiencing stomach pain, nausea, vomiting, fever, yellowing of the skin and eyes, dark urine or light stools. **BRONCHILIFT COUGH & COLD** must be stopped immediately and a doctor should be consulted.  
**Consult your doctor or qualified healthcare professional before taking GIVE this medicine if:**

• You are already taking a medicine to help stop your coughing, such as cocaine or dextromethorphan.  
• If you have a pre-existing gastrointestinal condition like diarrhoea, gastric ulcer (stomach ulcer) or gastric inflammation (lining of stomach). Taking **BRONCHILIFT COUGH & COLD** might exacerbate the condition.  
• You have difficulty breathing, have a fever or bloody yellow or green sputum, consult your doctor or qualified healthcare professional.

**Pregnancy and Breastfeeding:**

• If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **BRONCHILIFT COUGH & COLD**.  
• The safety of this product during pregnancy and breastfeeding has not been established, therefore the use of this product during pregnancy and breastfeeding is not recommended.

**Effects on the ability to drive and use machinery:**  
No studies on the effect of **BRONCHILIFT COUGH & COLD** on the ability to drive or operate machinery were performed. It is unlikely that **BRONCHILIFT COUGH & COLD** would affect the ability to drive or operate machinery.

**Important information about some of the ingredients of BRONCHILIFT COUGH & COLD:**  
This medicine contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Sorbitol may have a laxative effect or cause diarrhoea. Do not exceed the recommended dosage.

**Using other medicines with BRONCHILIFT COUGH & COLD:**  
Always tell your healthcare professional if you are taking any other medicine, including complementary or traditional medicines.

**4. HOW TO TAKE BRONCHILIFT COUGH & COLD:**  
For oral use only.  
Always take **BRONCHILIFT COUGH & COLD** exactly as per dosage instructions or as directed by your Doctor or Pharmacist.  
Do not exceed the recommended dose.

**Shake the bottle well each time before use.**

The usual dose is:  
Children aged 6 to 12 years old: Take 5 ml two times daily.  
Children above 12 years of age: Take 5 ml three times daily.  
Adults: Take 5 ml three times daily.  
Take one dose in the morning, at midday and in the evening.

If the symptoms worsen or persist, please consult your healthcare practitioner. Do not take BRONCHILIFT COUGH & COLD for more than 7 consecutive days.

**If you take more BRONCHILIFT COUGH & COLD than you should:**  
If you take more than the recommended dose (more than three times the daily dose), you may experience nausea, dizziness, vomiting or feel excitable (agitated). In this case speak to your doctor, pharmacist or qualified healthcare practitioner and take the bottle with you. *(Symptoms of overdose arise. Discontinue use of the medicine. Treatment is symptomatic and supportive.)*

**If you forget to take BRONCHILIFT COUGH & COLD:**  
If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule (see "HOW TO TAKE BRONCHILIFT COUGH & COLD"). Do not take a double dose to make up for forgotten individual doses.

**If you have any questions, or are unsure about anything, please ask your doctor, pharmacist or qualified healthcare practitioner.**

5. **POSSIBLE SIDE-EFFECTS:**  
Like all medicines, this product may have side-effects, although not everybody gets them. They are listed below:
- Allergic reactions, such as skin rash, red itchy skin and shortness of breath have been reported. *(Hypersensitivity reactions)*
  - Gastrointestinal disorders such as nausea, vomiting, discomfort, difficulty swallowing and diarrhoea have been reported. *(Hypersensitivity reactions)*
  - Hepatotoxicity or liver damage has been reported – stomach pain, nausea, vomiting, fever, yellowing of the skin and eyes, dark urine or light stools. *(Hypersensitivity reactions)*
  - Mild nose and gum bleeding have been reported. *(Low Progestin)*
  - There may be a laxative effect due to the ingredient acetaminophen.
- Not all side-effects reported for BRONCHILIFT COUGH & COLD are included in this leaflet. Should your general health worsen or if you experience any unreported effects while taking the medicine, please consult your doctor, pharmacist or other healthcare professional for advice.
- If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. **STORAGE AND DISPOSING OF BRONCHILIFT COUGH & COLD:**
- Store at or below 25 °C
  - Store away from light
  - Store in a dry place
  - Store in the original container
  - Keep the container tightly closed
  - Do not use after the expiry date stated on the label
  - Return all unused medicine or medicine in doses or average systems (e.g. sachets)
  - Do not dispose of unused medicine or medicines in drains or sewerage systems (e.g. toilets)

**KEEP OUT OF REACH OF CHILDREN**

7. **PRESENTATION OF BRONCHILIFT COUGH & COLD:**  
Amber 200 ml plastic bottle with a white plastic tamper evident cap.

8. **IDENTIFICATION OF BRONCHILIFT COUGH & COLD:**  
Fuchsia berry strip with a white cap.

9. **REGISTRATION NUMBER/REFERENCE NUMBER:**  
To be allocated.

10. **NAME AND ADDRESS OF REGISTRATION HOLDER:**  
Agera Health (Pty) Ltd  
6A Bovenstrand Park  
Trompsburg Drive  
Bulweria 7530  
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**PASIENTINLIGTINGSBLAD**  
Hierdie oorgeskreëde medisyne is een deur die SAKPKA-gereguleer vir die gehalte, veiligheid en die korrekte gebruik daarvan.

Komplementêre Medisyne Westerse Kruis.

**SKEDULERINGSSTATUS: S2**

**BEWYSMAKING (van oorspronklike):**  
**BRONCHILIFT Cough & Cold (stroop).**

Lees hierdie bele voorskrif noukeurig deur aangestien dit belangrike inligting vir u bevat.

- Hierdie medisyne is beskikbaar sonder voorskrif, alhoewel u steeds BRONCHILIFT COUGH & COLD moet gebruik, soos aangevyn op die bote toelating te sien.
- Hoe hierdie voorskrif, dit mag enige wese dat dit weer moet lees.
- Moenie hierdie medisyne met enige reumatoid nie.
- Van u dokter of apoteker indien u meer inligting of advies benodig.
- U moet u dokter raadpleeg indien u enige ander wese van u voerbetre funksie 7 dae nie.

1. **WAT BRONCHILIFT COUGH & COLD BEVAAT:**  
Alkomele bestanddele per 5 ml stroop:  
Plegiprasin 570 (Plegiprasin natrium DC) ysterd-sterk 28,57 mg  
Hydrokortison 1, (Hydrokortison) 33 mg  
Ondansetron bestaande:  
Gruisid, glicoliet, indolokstien, mikroskopiese selulose, karbomellak natrium, silieseum en water.  
Bevat bekwamekde: kaliumsuorbat (0,035 % w/v), natriumbensoaat (0,045 % w/v)  
Bevat versueter: SLS 80 16,41 mg/5 ml (bevat sennafium kalium, natriumbenzoaat en natriumglikoliet).  
Alkohol, suiker, laktose en tetrasteen vry.

2. **WAARVOOR WORD BRONCHILIFT COUGH & COLD GEBRUIK:**  
BRONCHILIFT COUGH & COLD is 'n indolokstien, kortsuorbat medisyne vir die simptomatiese behandeling van verkoue en griep. BRONCHILIFT COUGH & COLD het spasmolytiese, slegelindende en mukolitiese eienskappe, wat help met die verligting van 'n produktiewe hoest.

3. **VOOR BRONCHILIFT COUGH & COLD NIEGEGEE:**  
**Moenie BRONCHILIFT COUGH & COLD niegegee:**
- Indien u hipertensie het vir enige van die bestanddele of plante wat aan die *Jeunonia-sintetiese* behoort (blom, ginseng, ens.)
  - Indien u kind jonger as 6 maande oud is.
  - Indien u 'n geskiedenis van lewensdele het.

**Niem spesiale sorg met BRONCHILIFT COUGH & COLD:**

- Indien u swanger, swaai, bevind, koos, goet verligting van die vet en of, dokter sams, of ligte stoele, begin vry, moet BRONCHILIFT COUGH & COLD onmiddellik gestop en u dokter geraadpleeg word.

**Raadpleeg u dokter of geskwalifiseerde gesondheidspraktisyne voor u hierdie medisyne gebruik:**

- U moet u dokter raadpleeg indien u enige ander medisyne gebruik.
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**Swangerskap en borstvoeding:**

- Indien u swanger is of bevoort is, moet u BRONCHILIFT COUGH & COLD niegegee.
- Die veiligheid van hierdie produk tydens swangerskap en borstvoeding is nie bepaal nie, daarom word die gebruik van BRONCHILIFT COUGH & COLD tydens swangerskap en borstvoeding nie aanbeveel nie.

**Bestuur en die gebruik van medisyne:**  
Geen navorsing is gedoen om te sien of die effek op die versueter om te bestaande te bestaande te bestaande is. Dit is onseker of die gebruik van BRONCHILIFT COUGH & COLD die versueter om te bestaande te bestaande te bestaande is.

**Belangrike inligting met betrekking tot die gebruik van BRONCHILIFT COUGH & COLD:**  
Hierdie medisyne bevat sekere bestanddele wat u dokter moet weet dat u 'n allergiese reaksie het op sekere bestanddele, raadpleeg u dokter voor u hierdie medisyne neem. Sê byvoorbeeld "Ek het 'n allergiese reaksie op die volgende bestanddele: ...".

**Gebruik van BRONCHILIFT COUGH & COLD met ander medisyne:**  
U moet u dokter raadpleeg indien u enige ander medisyne gebruik, insluitend komplementêre of tradisionele medisyne.

4. **HOE OM BRONCHILIFT COUGH & COLD TE NEEM:**  
Vir oral gebruik slegs.  
BRONCHILIFT COUGH & COLD moet altyd presies gebruik word soos per doseringaanwysings aangevyn, en soos deur u dokter of apoteker aanbeveel.  
Moenie die aanwysings, dit anders nie.  
**Skud die bottel deeglik elke keer voor gebruik.**  
Die gewone dosis is:  
Kinders 6 tot 12 jaar oud: Neem 5 ml twee maal per dag.  
Kinders ouer as 12 jaar: Neem 5 ml drie maal per dag.  
Volwassenes: Neem 5 ml drie maal per dag.

Neem een dosering in die oggend, een in middag en een sams.  
Indien die simptome versueter of voortaan, raadpleeg asseblief u mediese praktisyne.  
Moenie BRONCHILIFT COUGH & COLD vir meer as 7 agtereenvolgende dae neem nie.

**Indien u meer BRONCHILIFT COUGH & COLD neem as wat u moet:**  
Indien u meer as die aanwysings neem (meer as die twee of drie doseringe) gebruik, kan u oewerhoof, maagpyn, braken, diarree of agitate ontwikkel. In so 'n geval, praat met u dokter, apoteker of geskwalifiseerde gesondheidspraktisyne om te sien hoe u voel. Neem 5 ml drie maal per dag.

**Indien u vergeet om BRONCHILIFT COUGH & COLD te neem:**  
Indien u 'n dosis vergeet het, neem dit nie op as u dit vergeet het. Indien u sams die volgende dosis, oewerhoof, maagpyn, braken, diarree of agitate ontwikkel, dan is die volgende dosis nie, dan die volgende dosis en en lew terge na u gewone doseringe. Moenie BRONCHILIFT COUGH & COLD TE NEEM. Moenie 'n dubbele dosis neem om te vergoed vir die vergete individuele dosis nie.

**Indien u enige vroeë het of onseker is oor enige teel, raadpleeg asseblief u dokter, apoteker of geskwalifiseerde gesondheidspraktisyne.**

5. **MOGELIKE NIE-EFFEKTE:**  
Soos alle medisyne mag hierdie produk moontlik neuse-effekte het, alhoewel nie almal dit kry nie. Hier is 'n lys van moontlike neuse-effekte:
- Allergiese reaksies soos verligting, roos en jekeringe wat op kortstydlike is aangevyn. *(Hypersensitiwiteit)*
  - Gastrointestinale reaksies soos maagpyn, braken, abdominale ongemak, diarree en pretensie om te dra. *(Hypersensitiwiteit)*
  - Hepatotoksies of lewensdele in aangevyn - maagpyn, braken, koors, goet verligting van die vet en of dokter sams, of ligte kleur stoele. *(Hypersensitiwiteit)*
  - Ligte maag- en ginseng-bleeding is aangevyn. *(Hypersensitiwiteit)*
  - Daar mag 'n laksatoriese effek wese as gevolg van die bestanddele sams.

Nie alle neuse-effekte aangevyn vir BRONCHILIFT COUGH & COLD is aangevyn in hierdie voorskrif nie. Indien u algemeen gesondheid versueter of ander nadelige reaksies voortsien wat nie hier gelyk is nie, moet u u dokter, apoteker of gesondheidspraktisyne asseblief geraadpleeg word.

6. **STOOR, BEWARGING EN BESKIKKING VAN BRONCHILIFT COUGH & COLD:**
- Stoor in of onder 25 °C
  - Stoor weg van lig
  - Stoor in 'n droë plek
  - Stoor in die oorspronklike bottel
  - Hou die bottel deeglik gesluit
  - Moenie gebruik na die vervaldatum getoon op die etiket nie
  - Varsorg alle oewerhoof medisyne terug in u afval
  - Moenie oewerhoof medisyne of middels weggoe in dreine of rioolstelsels (bv. toilette) nie.

**HOU BUITE REIK VAN KINDERS**

7. **AANBEHING VAN BRONCHILIFT COUGH & COLD:**  
200 ml bruin plastiek bottel met 'n wit plastiek postvrye dop.

8. **IDENTIFIKASIE VAN BRONCHILIFT COUGH & COLD:**  
Roofvrye stroop met 'n soet smaak.

9. **REGISTRASIE-NUMMER/VERWYSINGSNUMMER:**  
Sê toegesien word.

10. **NAAM EN BESIGHEIDSADERES VAN DIE HOUER VAN DIE REGISTRASIE-NUMMER:**  
Agera Health (Pty) Ltd  
Bovenstrandpark 6A  
Trompsburg Drive  
Bulweria 7530  
Cape Town  
South Africa  
info@agerapharm.co.za  
www.agerahealth.co.za



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