SCHEDULING STATUS: S0

CEPACOL EFFERVESCENT

Multicomponent formulation, effervescent tablets

Vitamin C 500 mg, *Hedera helix* L. (Ivy Leaf) 35 mg, *Pelargonium sidoides* (African geranium) 12,5 mg, Zinc 12 mg, Vitamin A 379 µg RAE, Vitamin D_3 250 IU.

Contains sweetener: Sucralose 20 mg/tablet

Sugar free

Category D: Complementary Medicine

Discipline Specific: 33.7 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.

Cepacol Effervescent is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to take **Cepacol Effervescent** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **Cepacol Effervescent** with any another person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet?

1. What **Cepacol Effervescent** is and what it is used for.
2. What you need to know before you take **Cepacol Effervescent**
3. How to take **Cepacol Effervescent**
4. Possible side effects
5. How to store **Cepacol Effervescent**
6. Contents of the pack and other information.

1. What Cepacol Effervescent is and what it is used for

Cepacol Effervescent is a combination product which helps to relief symptoms of cold and flu such as sore throat, nasal congestion, sneezing and cough. It assists with chesty cough relief, opening of the airways, thinning of mucus and providing relief of coughs associated with inflammation of the airways. Supports the immune function within the upper respiratory tract and provides antioxidant support for the maintenance of good health.

2. What you need to know before you take Cepacol Effervescent

Do not take Cepacol Effervescent:

- If you are hypersensitive (allergic) to any of the active substances, or to plants of the Araliaceae family, or to any of the ingredients of **Cepacol Effervescent** (listed in section 6.1).

Warnings and precautions

Take special care with Cepacol Effervescent:

- If you experience the following symptoms of liver disease or damage: yellowing of the skin and whites of the eyes (jaundice), itching, passing dark urine, pain in the upper right portion of the stomach, tiredness, loss of appetite, stop taking **Cepacol Effervescent** and contact your doctor immediately.
- If you have had or are suffering from inflammation of the stomach lining (gastritis) or stomach ulcers.

Consult with your doctor or healthcare practitioner if:

- your symptoms persist for longer than 1 week, or
- your symptoms worsen, or
- you experience breathing difficulty, fever, or thick, yellowish phlegm.

Other medicines and Cepacol Effervescent

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

Tell your doctor or pharmacist if:

- You have an autoimmune disease (a disease caused by the body’s own defence system attacking normal tissue), e.g. multiple sclerosis, systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), and are taking immunosuppressive medicine (used to reduce the activity of the immune system). *Perlagonium sidoides* (as in **Cepacol Effervescent**) can stimulate your immune system and thereby weaken the effectiveness of your immunosuppressive medicine.

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 **Cepacol Effervescent**.

Cepacol Effervescent is not recommended during pregnancy and breastfeeding.

Driving and using machines

It is not always possible to predict to what extent **Cepacol Effervescent** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which **Cepacol Effervescent** affects you.

Cepacol Effervescent contains azo colouring agent (E129) which may cause allergic reactions.

3. How to take Cepacol Effervescent

Do not share medicines prescribed for you with any other person.
Always take **Cepacol Effervescent** exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:
Adults and children 14 years and older: Take 1 effervescent tablet twice daily.
Children 6-13 years: Take 1 effervescent tablet once daily.
Cepacol Effervescent is not recommended for children under 6 years of age.

For oral use.
Dissolve the effervescent tablet in a glass of water. The tablet dissolves quickly producing an effervescent drink. Drink the contents of the whole glass as soon as the effervescing has stopped.
You must see a doctor if your symptoms worsen or do not improve after 7 days.

If you take more Cepacol Effervescent 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 Cepacol Effervescent

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

4. Possible side effects

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

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

- The following symptoms of allergic reaction: swelling of lips and mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching and/or hives or fainting.
- Yellowing of the skin and whites of the eyes (jaundice), itching, passing dark urine, pain in the upper right portion of the stomach, tiredness, loss of appetite. These are the symptoms of liver damage or disease.

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

Tell your doctor if you notice any of the following:
<u>Less frequent side effects:</u>

- mild gastrointestinal complaints (diarrhoea, discomfort in upper and middle part of the belly, nausea or vomiting, difficulty swallowing), mild bleeding from the nostrils,
- mild bleeding of the gums,

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 or pharmacist. 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 **Cepacol Effervescent**.

5. How to store Cepacol Effervescent
Store all medicines out of reach of children.

- Store at or below 25 °C. Protect from light and moisture.
- Keep the container tightly closed.
- Keep in the original container until required for use.
- Do not use **Cepacol Effervescent** after the expiry date which is stated on the carton / label.
- 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 Cepacol Effervescent Contains

The active ingredients are:

Each tablet contains:	
Ascorbic acid (Vitamin C)	500 mg
Zinc citrate 3-hydrate providing Zinc (elemental)	39,2 mg 12,4 mg
Hedera helix L. (Ivy leaf) [leaf, standardised to provide min 10 % saponins]	35 mg
Pelargonium sidoides DC (African geranium) [root]	12,5 mg
Vitamin A acetate (Vitamin A)	379 µg RAE
Cholecalciferol (Vitamin D_3)	250 IU

The other ingredients are:
Allura red (E129), citric acid anhydrous (E330), carbowax sentry PEG 8000 macrogol, sodium bicarbonate (E500), sodium carbonate (E500), maltodextrin, malic acid (E296), sucralose (E955), raspberry flavour (656569).

What Cepacol Effervescent looks like and contents of the pack

Cepacol Effervescent tablets are white to off-white round tablets, which after effervescing in water produce a red solution.
10 or 20 tablets in a polyethylene tube with a desiccant lid, packed in a cardboard carton.
Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Customer Care: 0860 ADCOCK/232625

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SKEDULERINGSTATUS: S0

CEPACOL EFFERVESCENT

Multikomponent-formulasie, bruistablette

Vitamien C 500 mg, *Hedera helix* L. (Blaar van Engelse klimopplant) 35 mg, *Pelargonium sidoides* (Kalwerbossie) 12,5 mg, Sink 12 mg, Vitamien A 379 µg RAE, Vitamien D_3 250 IU.

Bevat versoeter: Sukralose 20 mg/tablet

Suikervry

Kategorie D: Komplementêre medisyne

Dissipline-spesifiek: 33.7 Kombinasieproduk

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

Lees hierdie hele voubiljet noukeurig deur omdat dit belangrike inligting vir u bevat.

Cepacol Effervescent is sonder 'n doktersvoorskrif beskikbaar, sodat u 'n minder ernstige siekte kan behandel. Nogtans moet u steeds **Cepacol Effervescent** versigtig gebruik om die beste resultate te kry.

- Hou hierdie voubiljet. U sal dit dalk weer moet lees.
- Moenie **Cepacol Effervescent** met enigiemand anders deel nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.
- U moet 'n dokter besoek indien u simptome vererger of ná 7 dae nie verbeter nie.

Wat in hierdie voubiljet is

1. Wat **Cepacol Effervescent** is en waarvoor dit gebruik word
2. Wat u moet weet voor u **Cepacol Effervescent** neem
3. Hoe om **Cepacol Effervescent** te neem
4. Moontlike newe-effekte
5. Hoe om **Cepacol Effervescent** te bêre
6. Inhoud van die verpakking en ander inligting.

1. Wat Cepacol Effervescent is en waarvoor dit gebruik word

Cepacol Effervescent is 'n kombinasieproduk wat help om die simptome van verkoues en griep te verlig, soos 'n seer keel, nasale kongestie, nies en hoes. Dit help om 'n aamborstige hoes te verlig, lugweë oop te maak, mukus te verdun en verligting te bied vir hoes wat met lugweginflammasie geassosieer word. Ondersteun die immuunfunksie binne die boonste

asemhalingskanaal en bied antioksidant-ondersteuning vir die instandhouding van goeie gesondheid.

2. Wat u moet weet voor u Cepacol Effervescent neem

Moenie Cepacol Effervescent neem:

- Indien u hipersensitief (allergies) vir enige van die aktiewe bestanddele, of plante in die Araliaceae-familie of enige van die ander bestanddele is nie (gelys in afdeling 6.1).

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met Cepacol Effervescent:

- Indien u die volgende simptome van lewersiekte of -skade ervaar: vergeling van die vel en wit dele van die oë (geelsug), gejeuk, uitskeiding van donker urien, pyn in die regterboonste gedeelte van die maag, moegheid, verminderde eetlus, staak die gebruik van **Cepacol Effervescent** en kontak dadelik u dokter.
- Indien u aan ontsteking van die maagwand (gastritis) of maagsere ly, of gely het.
- Raadpleeg u dokter of gesondheidsorgkundige indien:
    - u simptome langer as 1 week aanhou, of
    - u simptome vererger, of
    - u moeilike asemhaling, koors, of dik, gelerige slym ervaar.

Ander medisynes en Cepacol Effervescent

Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisynes in.)

Lig u dokter of apteker in indien:

- U 'n outo-immuunsiekte het ('n siekte waar die liggaam se eie verdedigingstelsel normale weefsel aanval), bv. veelvuldige sklerose, sistemiese lupus eritematose (SLE), rumatoïede artritis (RA), en immuunonderdrukkende medisyne neem (gebruik om die aktiwiteit van die immuunstelsel te verminder). *Pelargonium sidoides* (soos in **Cepacol Effervescent**) kan u immuunstelsel stimuleer en so die doeltreffendheid van u immuunonderdrukkende medisyne verswak.

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, vermoed dat u dalk swanger is of van plan is om 'n baba te kry, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgkundige vir raad voor u **Cepacol Effervescent** neem.

Cepacol Effervescent word nie aanbeveel tydens swangerskap en borsvoeding nie.

Bestuur en gebruik van masjinerie
Dit is nie altyd moontlik om te voorspel in watter mate **Cepacol Effervescent** met u alledaagse aktiwiteite sal inmeng nie. U moet seker maak dat u nie die bogenoemde aktiwiteite verrig tot u weet in watter mate **Cepacol Effervescent** u aantas nie.

Cepacol Effervescent bevat aso-kleurmiddel (E129) wat allergiese reaksies kan veroorsaak.

3. Hoe om Cepacol Effervescent te neem
Moenie medisynes wat aan u voorgeskryf is met enigiemand anders deel nie.
Neem altyd **Cepacol Effervescent** presies soos in hierdie voubiljet voorskryf of soos u dokter of apteker vir u gesê het. Raadpleeg u dokter of apteker indien u nie seker is nie.

Die gewone dosis is:
Volwassenes en kinders van 14 jaar en ouer: Neem 1 bruistablet twee keer per dag.
Kinders 6-13 jaar oud: Neem 1 bruistablet een keer per dag.
Cepacol Effervescent word nie vir kinders jonger as 6 jaar aanbeveel nie.

Vir mondelikse gebruik.
Los die bruistablet op in ’n glas water. Die tablet los vinnig op om ’n bruisdrankie te vorm.
Drink die inhoud van die hele glas sodra dit ophou bruis het.
U moet ’n dokter besoek indien u simptome vererger of ná 7 dae nie verbeter nie.

Indien u meer Cepacol Effervescent neem as wat u moes
In die geval van oordosis, raadpleeg u dokter of apteker. Indien nie een van die twee beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

Indien u vergeet om Cepacol Effervescent te neem
Moenie ’n dubbele dosis neem om vir vergete individuele dosisse te vergoed nie.

4. Moontlike newe-effekte
Cepacol Effervescent kan newe-effekte hê.
Nie alle newe-effekte wat vir **Cepacol Effervescent** aangemeld is, is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid sou verswak of indien u enige ongewenste effekte ervaar terwyl u **Cepacol Effervescent** neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van **Cepacol Effervescent** en lig dadelik u dokter in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- Die volgende simptome van ’n allergiese reaksie: swelling van die lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal, veluitslag of gejeuk en/of galbulte of floute.
- Vergeling van die vel en wit dele van die oë (geelsug), gejeuk, uitskeiding van donker urien, pyn in die regterboonste deel van die maag, moegheid, verminderde eetlus. Dit is simptome van lewerskade of -siekte.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk ’n ernstige reaksie op **Cepacol Effervescent** gehad. U sal dalk dringende mediese aandag of hospitalisasie moet ontvang.

Lig u dokter in indien u enige van die volgende opmerk:
<u>Minder algemene newe-effekte:</u>

- minder ernstige gastroïntestinale klagtes (diarree, ongemak in bo- en middelste deel van die buik, naarheid of braking, sluk moeilik), ligte bloeding uit die neusgate,
- ligte bloeding vanuit die tandvleis.

Indien u enige newe-effekte opmerk wat nie in hierdie voubiljet genoem is nie, lig asseblief vir u dokter of apteker in.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, raadpleeg u dokter of apteker. U kan newe-effekte ook regstreeks by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en elektronies aanmeldingsplatform (who-umc.org) wat op SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van **Cepacol Effervescent** te verskaf.

5. Hoe om Cepacol Effervescent te bêre
Bêre alle medisynes buite bereik van kinders.

- Bêre teen of benede 25 °C. Beskerm teen lig en vog.
- Hou die houer dig toe.
- Hou binne-in die oorspronklike houer tot benodig vir gebruik.
- Moenie **Cepacol Effervescent** gebruik ná die vervaldatum wat op die kartonhouer / etiket aangedui is nie.

- Neem alle ongebruikte medisyne na u apteker terug.
- Moenie ongebruikte medisyne in afvoepype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die verpakking en ander inligting

Wat Cepacol Effervescent bevat

Die aktiewe bestanddele is:

Elke tablet bevat:	
Askorbiensuur (Vitamien C)	500 mg
Sinksitraat 3-hidraat voorsien Sink (elementaal)	39,2 mg 12,4 mg
Hedera helix L. (blaar van Engelse klimopplant) [blaar, gestandaardiseer om min. 10 % saponiene te voorsien]	35 mg
Pelargonium sidoides DC (Kalwerbossie) [wortel]	12,5 mg
Vitamien A-asetaat (Vitamien A)	379 µg RAE
Cholekalsiferol (Vitamien D_3)	250 IU

Die ander bestanddele is:

"Allura" rooi (E129), watervrye sitroensuur (E330), "carbowax sentry" PEG 8000 makrogol, natriumbikarbonaat (E500), natriumkarbonaat (E500), maltodekstrien, appelsuur (E296), sukralose (E955), framboosgeursel (656569).

Hoe Cepacol Effervescent lyk en inhoud van die verpakking

Cepacol Effervescent tablette is wit tot naaswit ronde tablette wat, nadat dit in water gebruis het, 'n rooi oplossing vorm.

10 tot 20 tablette in 'n poliëtileenbuis met 'n droogmiddel-deksel, verpak in 'n kartonboksie.

Nie alle verpakkingsgroottes sal dalk bemark word nie.

Houer van Registrasiesertifikaat

Adcock Ingram Limited

New Road 1,

Erand Gardens,

Midrand, 1685

Kliëntesdiens: 0860 ADCOCK/232625

Hierdie voubiljet is mees onlangs hersien op

12 Augustus 2024

Registrasienommer

Moet toegeken word.

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