

PACKAGE LEAFLET: INFORMATION FOR THE USER

SCHEDULING STATUS: S0

PROPRIETARY NAME (and dosage form): ALPHA Colds and Flu Effervescent Tablets 10's

ACTIVE INGREDIENTS:

Each effervescent tablet contains:	mg	%NRV	
Ascorbic Acid (Vitamin C)	1000 mg	1000%	
Sambucus nigra L. (Elderberry) [Fruit, as 20 mg of a 20:1 extract]	400 mg		**
N-Acetyl-Cysteine	300 mg		**
Caffeine Anhydrous	50 mg		**
Menthol Crystals	2.6 mg		**

*NRV (Nutrient Reference Values)

** NRV not available

Contains Sweeteners: Sucralose 25 mg per effervescent tablet

Contains Caffeine: 50 mg per effervescent tablet (one cup of instant coffee contains approximately 80 mg of caffeine)

Excipients: Lemon Flavour (150 mg), Quinolene Yellow Colouring (E104) (4 mg) and a proprietary effervescent blend (2783 mg).

The effervescent blend contains citric acid, sodium bicarbonate, isomalt, polyethylene glycol, silicon dioxide and Sucralose.

Complementary Medicine, Health Supplement

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.

Keep this leaflet. You may need to read it again.

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

Do not share ALPHA Colds and Flu with any other person.

Ask your healthcare provider or Pharmacist if you need more information or advice.

What is in this leaflet?

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

1. What ALPHA Colds and Flu is, and what it is used for

ALPHA Colds and Flu contains active ingredients designed to assist in alleviating symptoms and support recovery in the event of mild colds and flu.

Vitamin C

Vitamin C (ascorbic acid) is an anti-oxidant protecting organs, cells and blood vessels from free-radical damage. It helps to build and protect collagen in connective tissue, bones, teeth and skin. It also contributes to improved absorption of fats, proteins and iron from food while combatting fatigue and lack of energy.

Vitamin C also contributes to the normal function of the immune system. It may help to prevent colds and flu after contact. It may also help to reduce the severity of symptoms - in particular respiratory system related symptoms such as lung pathology - and the duration of the illness.

Elderberry

Elderberry contains substances which may prevent influenza viruses from entering the cell, thereby effectively inhibiting the replication of the viruses and preventing or reducing disease.

Elderberry contains several powerful antioxidants and may help to reduce stress and improve recovery after periods of intense stress.

Elderberry effectively supports the immune system without triggering a hyperactive immune response.

N-Acetyl Cysteine

Commonly referred to as NAC, N-acetyl Cysteine (or Acetyl Cysteine) is a highly effective mucolytic which means that it helps to loosen phlegm and make it easier for the body to expel. It is also a powerful antioxidant which is able to help the body to neutralise and excrete many harmful substances. In the case of upper respiratory tract infections, this may help in providing relief from symptoms and assist in shortening the duration of the condition.

Caffeine

Caffeine may assist in combatting the symptoms of colds and flu by temporarily promoting alertness and wakefulness, assisting to relieve fatigue and increasing mental activity.

Menthol

Menthol may provide a cooling and soothing effect in the mouth, throat and upper respiratory tract.

2. What you need to know before you take ALPHA Colds and Flu

Do not take ALPHA Colds and Flu:

- if you are hypersensitive (allergic) to any of the ingredients of ALPHA Colds and Flu (listed in section 6).
- If you have epilepsy, asthma, persistent or chronic cough, or other chronic lung conditions, do not use ALPHA Colds and Flu without prior consultation with your healthcare practitioner (due to the Menthol content of the product).
- if you suffer from hemochromatosis (due to the ability of Vitamin C to enhance absorption of Iron from food)

Warnings and precautions

Keep out of reach of children.

Unless otherwise prescribed, do not exceed the stated daily dose.

Vitamin supplements should not replace a balanced diet.

Consult a registered healthcare professional before taking ALPHA Colds and Flu if you have high blood pressure, glaucoma, and/or detrusor instability (overactive bladder syndrome) (Due to the Caffeine content of ALPHA Colds and Flu).

Use of caffeine may result in sleep deprivation.

Caffeine may increase blood pressure. Stop use of ALPHA Colds and Flu at least 2 days before any planned surgery.

Other medicines and ALPHA Colds and Flu

Always tell your healthcare provider if you are taking any other medicine.

The amount of Vitamin C available from ALPHA Colds and Flu is reduced by many other medicines including contraceptives, antibiotics, anti-histamines, anti-coagulants, anti-depressants and cortisone.

Vitamin C may affect the results of certain laboratory tests. Consult your healthcare provider and if necessary, stop taking ALPHA Colds and Flu a few days before the test.

Consumption with other medicines (e.g. bitter orange extract, synephrine, octopamine, ephedra, ephedrine) which increase blood pressure is not recommended (due to the Caffeine content of ALPHA Colds and Flu).

Do not use with other products containing camphor, menthol, eucalyptol and/or eucalyptus essential oil (due to the Menthol content of ALPHA Colds and Flu).

ALPHA Colds and Flu with food

Vitamin C may increase the absorption of Iron from food.

Consumption with other caffeine-containing products or foods (e.g. medications, coffee, tea, colas, cocoa, guarana, maté) is not recommended.

Pregnancy and breastfeeding

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 this medicine.

Safety in pregnancy has not been established.

NOTE: Total caffeine intake of more than 200 mg per day is not recommended during pregnancy or breastfeeding

3. How to take ALPHA Colds and Flu

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

Take ALPHA Colds and Flu exactly as described in this leaflet or as prescribed by your Doctor or Pharmacist.

Dosage and Directions for use

Adults and Children over 9 years of age: Take ONE effervescent tablet daily after a meal or as prescribed by your Doctor or Pharmacist. (Dissolve tablet in a glass of water and drink slowly).

Do not exceed the stated daily dosage.

If you take more ALPHA Colds and Flu than you should you may experience one or more loose stools, diarrhoea or vomiting

In the event of overdose, consult your Doctor or Pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ALPHA Colds and Flu, do not take a double dose to make up for forgotten doses.

4. Possible side effects

ALPHA Colds and Flu can have side effects.

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

If any of the following happens, stop taking ALPHA Colds and Flu and tell your doctor:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching.
- Diarrhoea or vomiting
- Depression, feeling tired or irritable.
- Dizziness and/or headache

5. How to store ALPHA Colds and Flu

Store all medicines out of reach of children.

- Store in a cool, dry place below 25°C .
- Keep lid firmly closed to exclude moisture
- Use within 30 days of opening.

6. Contents of the pack and other information

What ALPHA Colds and Flu contains

- The active substances are Vitamin C (1000 mg), Elderberry Extract (400 mg), N-Acetyl Cysteine (300 mg), Caffeine Anhydrous (50 mg) and Menthol Crystals (2.6 mg)
- The other ingredients are Lemon Flavour (150 mg), Quinolene Yellow (E104) colour (4 mg) and a proprietary effervescent blend (2783 mg)

The effervescent blend contains: Citric Acid, Sodium Bicarbonate, Isomalt, Polyethylene Glycol, Silicon Dioxide and Sucralose

What ALPHA Colds and Flu looks like and contents of the pack

Speckled pale yellow cylindrical effervescent tablet.

10 effervescent tablets in a polypropylene tube.

Applicant

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