

# Stacytine Effervescent Tablet

Consumer Medication Information Leaflet (RiMUP)

Acetylcysteine (200 mg and 600 mg)

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## What is Stacytine used for

All respiratory tract diseases leading to the formation of thick secretions difficult to be expectorated, such as acute and chronic bronchitis, laryngitis, sinusitis, tracheitis, influenza, bronchial asthma and (as complementary treatment) mucoviscidosis.

## How Stacytine works

Acetylcysteine belongs to a group of medicines called mucolytics which work by thinning the phlegm so that it can be coughed up more easily.

## Before you use Stacytine

### When you must not use it

Do not use Stacytine effervescent tablets:

- If you are allergic to acetylcysteine or any of the other ingredients of this medicine.
- If you have inherited disorder that causes an amino acid called phenylalanine to build up in your body or you are allergic to aspartame (artificial sweetener).
- In children under 2 years.

### Before you start use it

If any of the situations mentioned below apply to you, you should tell your doctor before taking this drug:

- If you suffer of bronchial asthma.
- If you have or have had a peptic ulcer.
- If you have kidney or liver problems.
- If you are pregnant or breast-feeding.

Caution is advised if you need to be on a controlled sodium (low sodium/low salt) diet.

The mild sulfur odour (smell of rotten eggs) on opening the packages does not indicate deterioration of the product but is due to the active ingredient.

## Taking other medicines

- If you are using other medicines, do not dissolve them together with Stacytine effervescent tablets.
  - If you need to use medicines to control or prevent infections (antibiotics), you are advised to take these two hours before or after Stacytine effervescent tablets.
  - Cough suppressants should not be used at the same time as Stacytine effervescent tablets, as you must be able to cough up the loosened phlegm.
  - Stacytine effervescent tablets may increase the blood pressure-lowering effect of nitroglycerin (a medicine used against tight painful feeling in the chest (angina pectoris). Caution is advised.
  - If you use activated charcoal (a medicine against traveller's diarrhoea), it may decrease the effect of Stacytine effervescent tablets.
- Tell your doctor or pharmacist if you are taking or have recently taken any other medicines apart from Stacytine effervescent tablets, including medicines obtained without a prescription.

## How to use Stacytine

### How much to use

#### **200 mg:**

Children over 2 years: 100 – 200 mg 2 times a day.

Adult: 200 mg 3 times a day.

#### **600 mg:**

Adults: 600 mg once daily.

Dissolve the effervescent tablet in half a glass of water, avoid the addition of other medicines to the solution. Drink the solution immediately.

### When to use it

- Patients who have difficulty coughing up phlegm (elderly and weakened patients), are advised to take the effervescent tablet in the mornings.
- Use as directed by your doctor or pharmacist.

### How long to use it

Always use this medicine exactly as prescribed. Check with your doctor or pharmacist if you are not sure.

Do not use this medicine for longer than 14 days without consulting a doctor.

### If you forget to use it

If you have forgotten to take a dose and it is almost time for the next dose, do not take the 'forgotten' dose, but continue the schedule as given under "How to use Stacytine effervescent

tablets". Do not take a double dose to make up for a forgotten dose.

### If you use too much (overdose)

- Symptoms that may occur are nausea, vomiting and diarrhoea.
- Contact your doctor immediately or go to nearest emergency department if you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Bring the pack with any remaining tablets with you.

## While you are using it

### Things you must do

Take your medicine exactly as your doctor has told you.

### Things you must not do

- Do not take too many tablets.
- Do not stop the treatment earlier than planned. Contact your doctor or pharmacist before stopping.
- Do not take any new medicines without consulting your doctor.
- Do not give Stacytine effervescent tablets to anyone else, even if they have the same symptoms or condition as you.

### Things to be careful of

- There have been very rare reports of serious hypersensitivity reactions with (high) fever, skin redness, joint pains and/or eye infection (Stevens-Johnson syndrome), and acute hypersensitivity reactions accompanied by fever and blisters on the skin or peeling of the skin (Lyell syndrome) which were associated with the use of Stacytine effervescent tablets. However, in most cases, at least one other medicine was used, which was most likely the cause for this reaction.
- If new changes to the skin or mucous membranes occur, you must immediately consult a doctor and stop using acetylcysteine.
- As the thick phlegm becomes more fluid, its volume will increase, especially at the beginning of the treatment. If you are unable to efficiently cough up this fluid phlegm, you must consult a doctor so that adequate measures can be taken to remove the phlegm.
- Medicines, such as Stacytine that dissolve phlegm (mucolytics) may block the airways of children under the age of 2, due to the characteristics of the airways in this age group. This may limit their ability to cough up phlegm.

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## Acetylcysteine (200 mg and 600 mg)

Therefore, Stacytine must not be used by children under the age of 2. Consult your doctor if any of the above-mentioned warnings apply to you, or have applied to you in the past.

### Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### Very rare side effects

If any of the following side effects occur, immediately stop using Stacytine effervescent tablets and contact your doctor or go to the emergency room of a nearby hospital.

- Severe, life-threatening allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling on your lips, face, throat or tongue.
- Severe bleeding.
- Blistering, peeling, bleeding, scaling, or fluid filled patches on any part of your skin. This includes your lips, eyes, mouth, nose, genitals, hands or feet. You may have a serious skin problem.
- Shock (severe drop in blood pressure, paleness, restlessness, weak pulse, clammy skin, decreased consciousness) due to a sudden widening of the blood vessels as a result of severe hypersensitivity to certain ingredients (anaphylactic shock).
- Sudden fluid accumulation in the skin and mucous membranes (e.g. throat or tongue), breathing difficulties and/or itching and skin rash, often as a result of an allergic reaction (angioedema).

The above-mentioned reactions are very serious side effects. If you experience any of these reactions it is possible that you have a hypersensitivity reaction to Stacytine effervescent tablets. You will require emergency medical care or need to be admitted to the hospital.

### Rare side effects

Inform your doctor if you experience any of the following side effects:

- Shortness of breath due to muscle cramping of the airways (bronchospasms).
- Difficulty breathing, shortness of breath or breathlessness (dyspnoea).
- Impaired digestion with symptoms of fullness in the upper abdomen,

gastric pain, belching, nausea and heartburn (dyspepsia).

### Uncommon side effects

- Hypersensitivity
- Headache
- Ringing in the ears (tinnitus)
- Inflammation of the oral mucous lining (stomatitis)
- Diarrhoea
- Fever (pyrexia)
- Low blood pressure
- Abdominal pain
- Nausea
- Vomiting

If you suffer from gastric or duodenal ulcers or have had these in the past, acetylcysteine may have an unfavourable effect on your gastrointestinal mucous membrane.

If any of the side effects become serious, or you notice any side effects not mentioned in this leaflet, contact your doctor or pharmacist.

Consult with your doctor or pharmacist if you notice that the effect of Stacytine effervescent tablets is too strong or not strong enough.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) [Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

### Storage and Disposal of Stacytine

#### Storage

- The expiry date of this pack is printed on the box. Do not use this pack after this date.
- Store in a well-closed container, in a dry place. Protect from light and moisture. Do not store above 30°C.
- Keep out of reach of children.

#### Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### Product description

#### What it looks like

Stacytine 200mg Effervescent Tablet:  
Off-white to light yellow, round-shaped tablet, flat on both sides. When dissolved in water, the tablet

effervesces to produce a light yellow solution.

#### Stacytine 600mg Effervescent Tablet:

Light yellow, round-shaped tablet, flat on both sides. When dissolved in water, the tablet effervesces to produce a light yellow solution.

#### Ingredients

##### Active ingredient:

Stacytine 200mg Effervescent Tablet:  
Each tablet contains acetylcysteine 200 mg

Stacytine 600mg Effervescent Tablet:  
Each tablet contains acetylcysteine 600 mg

##### Inactive ingredients:

- Sodium bicarbonate
- Citric acid anhydrous
- Sorbitol
- Sodium carbonate anhydrous
- Sodium benzoate
- Polyethylene glycol 6000
- Copovidone
- Aspartame
- Saccharin sodium
- Orange flavor 10888-71
- Orange flavor 12026-31
- β-Carotene 1% cws/m
- Ascorbic acid

##### MAL number

Stacytine 200mg Effervescent Tablet:

Stacytine 600mg Effervescent Tablet:

### Manufacturer and Product Registration Holder

#### Manufacturer:

**STELLAPHARM J.V. CO., LTD. - BRANCH 1**

(A Joint Venture Company of Auxilto GmbH, Germany)

No. 40 Tu Do Avenue, Vietnam-Singapore Industrial Park, An Phu Ward, Thuan An Town, Binh Duong Province, Vietnam.

#### Product Registration Holder:

**STADPHARM SDN. BHD.**

E-9-01, Oasis Square, Ara Damansara, No. 2, Jalan PJU 1A/7A, 47301 Petaling Jaya, Selangor Darul Ehsan, Malaysia.

#### Date of revision:

09/02/2021

#### Serial Number:

NPRA (R2) 20/99