

## **Acetylcysteine effervescent tablets 200mg , 600mg**

### **What is Acetylcysteine Bruis and where is it used for**

Acetylcysteine Bruis Teva is a medicine that breaks down tough, sticky mucus, making it more liquid and easier to cough up. It can be used for respiratory conditions such as asthma, bronchitis (inflammation of the lining of the airways), emphysema, cystic fibrosis (a condition that affects the production of mucus), and bronchiectasis (long-term dilation of a branch of the airway).

### **When should you not use this medication or be extra cautious with it?**

#### **When should you not use this medication?**

You are allergic to any of the ingredients in this medicine.

Children under 2 years of age should not use this medication.

Children and pregnant women with phenylketonuria (phenylketonuria is a certain inherited metabolic disorder) should not use this medication.

#### **When should you be extra cautious with this medication?**

If you suffer from periodic attacks of breathing difficulties due to muscle spasms and swelling of the mucous membranes of the airways, often accompanied by coughing and the production of mucus (asthma bronchiale), you may experience breathing difficulties due to muscle spasms of the airways (bronchospasm). If such an attack occurs, you should immediately stop using this medication and consult a doctor.

- If you have or have had a stomach ulcer, as this medication may irritate your stomach lining. Especially when you are using other medications that are known to irritate the stomach lining.
- There have been very rare reports of severe hypersensitivity reactions with (high) fever, red spots on the skin, joint pain, and/or eye inflammation (Stevens-Johnson syndrome) or acute hypersensitivity reactions accompanied by fever and blisters on the skin or peeling of the skin (Lyell's syndrome) that could be related to the use of this medication. In most cases, however, at least one other medication that was likely the cause of these reactions was used.
- If new changes occur in the skin or mucous membranes, you should immediately consult a doctor and stop using acetylcysteine immediately.
- Especially at the beginning of treatment, the liquefaction of the mucus due to the medication may increase its volume. If you are unable to effectively cough up this liquid mucus, you should consult a doctor so that adequate measures can be taken to remove the mucus.
- Medications such as Acetylcysteine bruise Teva that dissolve mucus (mucolytics) can block the airways of children under 2 years of age due to the properties of the airways in this age group. This can limit the ability to cough up mucus. Therefore, this medication should not be used by children under 2 years of age.
- Acetylcysteine bruise Teva 600 mg is not suitable for children between 2 and 18 years of age.
- It may happen that you detect a slight sulfur odor (the smell of rotten eggs) when opening the package. This is a property of the active substance and is normal. It does not indicate a change in the medicine.

#### **Do you use any other medications besides Acetylcysteine Bruis Teva?**

Have you used any other medications recently or is there a possibility that you will use other medications soon? Please tell your doctor or pharmacist about it.

Do not dissolve other medications together with this one. If you need to use antibiotics to fight or prevent infections, it is recommended to take them two hours before or after taking this medication. During the use of this medication, cough suppressants should not be used because it is necessary to be able to cough up the loosened mucus.

This medication can enhance the blood pressure-lowering effect of nitroglycerin (a medication used to treat chest pain (angina pectoris)). Caution is advised. When using activated charcoal (a medication against traveler's diarrhea), the effect of Acetylcysteine Bruis Teva may decrease.

#### **Pregnancy and breastfeeding**

Are you pregnant, do you think you may be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medication.

##### **Pregnancy**

Due to the aspartame content, pregnant women with phenylketonuria should not use this medication. The data from studies on the use of acetylcysteine in pregnant women is limited. No direct or indirect harmful effects on pregnancy or the development of the child before, during, and after birth were found in animal studies. Use this medication only after careful consideration of the pros and cons during pregnancy.

##### **Breastfeeding**

It is not known whether acetylcysteine passes into breast milk. Use this medication only after careful consideration of the pros and cons during breastfeeding.

##### **Driving and using machines**

There is no information available on the effect of acetylcysteine on driving ability and the ability to use machines. However, an effect is unlikely.

#### **Acetylcysteine Bruis Teva contains aspartame**

- Acetylcysteine Bruis Teva 200 mg contains 10 mg of aspartame in each effervescent tablet.
- Acetylcysteine Bruis Teva 600 mg contains 20 mg of aspartame in each effervescent tablet.

Aspartame is a source of phenylalanine. It can be harmful if you have phenylketonuria (PKU), a rare inherited disorder in which phenylalanine accumulates because the body cannot convert it properly.

#### **Acetylcysteine Bruis Teva contains sodium**

Acetylcysteine Bruis Teva 200 mg contains 147 mg of sodium (an important component of table salt) per effervescent tablet. This corresponds to 7.4% of the recommended maximum daily amount of sodium in the diet for an adult.

Contact your doctor or pharmacist if you need to take the maximum dose of 3 effervescent tablets per day for a prolonged period, especially if you have been advised to follow a low-sodium diet.

Translation:

Acetylcysteine bruise Teva 600 mg contains 145 mg of sodium (an important component of table salt) per effervescent tablet. This corresponds to 7.3% of the recommended maximum daily intake of sodium in the diet for an adult. If you need to take the maximum dose of 1 effervescent tablet per day for a long time, especially if you have been advised to follow a low-sodium diet, contact your doctor or pharmacist.

Acetylcysteine bruise Teva contains glucose and sucrose. Acetylcysteine bruise Teva 200 mg contains 19.9 mg of glucose and 2.2 mg of sucrose per effervescent tablet. Acetylcysteine bruise Teva 600 mg contains 19.9 mg of glucose and 2.2 mg of sucrose per effervescent tablet. If your doctor has told you that you are intolerant to certain sugars, contact your doctor before taking this medicine.

#### **How to use this medicine?**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. If you are unsure about the correct use, please contact your doctor or pharmacist.

#### **Dosage**

The recommended dosage is as follows: This medicine should not be used in children under 2 years of age.

- Effervescent tablets 200 mg
- Adults and children over 7 years old
- 3 times a day (=24 hours) 1 effervescent tablet of 200 mg.
- Children aged 2 to 7 years
- 2 times a day 1 effervescent tablet of 200 mg.
- Effervescent tablets 600 mg

**Adults:** 1 time per day (=24 hours) 1 effervescent tablet of 600 mg.

In patients who have difficulty coughing up (elderly and weakened patients), it is recommended to take the effervescent tablet in the morning.

#### **Method of use**

Dissolve the effervescent tablet in half a glass of water just before use, stir and drink immediately. Acetylcysteine may only be dissolved in water. The effervescent tablets should not be dissolved in milk or other beverages. Drinks are dissolved.

Acetylcysteine effervescent tablets can be taken before or after meals. Do not use the effervescent tablets for more than 14 days without consulting a doctor.

#### **Have you used too much of this medicine?**

Symptoms that may occur include nausea, vomiting, and diarrhea. If you have taken too much of this medicine, contact your doctor or pharmacist immediately.

#### **Did you forget to use this medicine?**

If you miss a dose and it is almost time for your next dose, do not take the "missed" dose, but continue with the schedule as indicated under "How to use this medicine".

Do not take a double dose to make up for a missed dose.

If you have any other questions about the use of this medicine, please contact your doctor or pharmacist.

#### **Possible Side Effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you experience any of the following side effects, stop using this medicine immediately and contact your doctor or go to the emergency department of a nearby hospital: Shock (severe drop in blood pressure, pallor, restlessness, weak pulse, clammy skin, decreased consciousness) due to sudden vasodilation resulting from severe hypersensitivity to certain substances (anaphylactic shock).

Sudden accumulation of fluid in the skin and mucous membranes (e.g. throat or tongue), breathing difficulties, and/or itching and rash, often as an allergic reaction (angioedema).

The above reactions are very serious side effects. If these reactions occur in you, it is possible that you have a serious allergic reaction to this medicine. You need urgent medical care or need to be hospitalized.

These very serious side effects are very rare (occurring in less than 1 in 10,000 users). Bleeding is also very rare.

Inform your doctor if you experience any of the following side effects: These side effects are rare (occurring in less than 1 in 10,000 users): Shortness of breath due to muscle cramps in the airways (bronchospasms), Difficulty breathing, shortness of breath, or tightness in the chest (dyspnea), Disordered digestion with symptoms of fullness in the upper abdomen, pain in the stomach area, belching, nausea, and heartburn (dyspepsia).

These side effects sometimes occur (in less than 1 in 100 users): Hypersensitivity

This can manifest as bronchospasm and dyspnea (see above), accelerated heartbeat (tachycardia), itching (pruritus), skin rash with intense itching and formation of bumps (urticaria) and angioedema, Headache, Ringing in the ears (tinnitus), Inflammation of the oral mucosa, (stomatitis), Diarrhea, Fever (pyrexia), Low blood pressure, Abdominal pain, Nausea, Vomiting

If you have or have had stomach or intestinal ulcers, acetylcysteine may have an unfavorable effect on your gastric mucosa.

If you experience a lot of side effects, or if you have a side effect that is not listed in this leaflet, please contact your doctor or pharmacist.

**How to store this medicine?**

Store below 30°C. Keep the tablet container tightly closed to protect against moisture. Do not use this medicine after the expiry date which is stated on the packaging after 'EXP'. That is a month and a year. The last day of that month is the expiration date. After opening the tablet container, it is still usable for 18 months.