

DissoNac Effervescent Tablet 200mg

DissoNac Effervescent Tablet 600mg

Acetylcysteine (200mg and 600mg)

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What is DissoNac used for

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

How DissoNac works

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

Before you use DissoNac

- When you must not use it

Do not use DissoNac effervescent tablets:

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

- Before you start to use it

If any of the conditions mentioned below apply to you, you

should tell your doctor before taking this medicine:

- If you are experiencing bronchial asthma.
- If you have a peptic ulcer.
- If you have kidney or liver problems.
- If you are pregnant or breastfeeding.

Caution is advised if you need to be on 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 together with tablet DissoNac effervescent.
 - If you need to use medicines to control or prevent infection (antibiotics), you are advised to take two hours before or after the tablet DissoNac effervescent.
 - Cough suppressants should not be used at the same as tablet DissoNac tablet, because you must be able to cough up the loosened phlegm.
 - DissoNac 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* (medicine against diarrhea), it can reduce the effect of the tablet DissoNac effervescent.
- Tell doctor or pharmacist you your if you are taking or newly taking any other medicines besides from tablet DissoNac, including medicine that obtained without prescription.

How to use DissoNac

-How much to use

200 mg:

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

Adult: 200 mg 3 times a day.

600mg:

Adults: 600mg, once a day

Dissolve the effervescent tablet in half a glass of water, avoid addition medicine other in solution. Drink with 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 exactly as prescribed. Check with your doctor or pharmacist if you are unsure.

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

-If 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 DissoNac effervescent tablets ". Do not take a double dose to make up for a forgotten dose.

-If you take 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.

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While using DissoNac

-Things you must do

Take your medicine as told by your doctor.

-Things you must not do

- Do not take too many tablets.
- Do not stop treatment earlier than planned. Contact your doctor or pharmacist before stopping.
- Do not take any new medicines without consulting with your doctor.
- Do not give DissoNac effervescent tablet to other people even if they have the same symptoms or condition as yours.

-Things to be careful of

- If you are experiencing bronchial asthma then you should not take this medicine.
- If you have peptic ulcer, DissoNac can irritate your wall stomach. In particular, if you use other drugs it is known to irritate gastric wall.
- Very rare reports of reactions serious hypersensitivity with fever (high), skin redness, joint pain and / or eye infection (Stevens-Johnson syndrome), and acute hypersensitivity reaction accompanied by fever and blisters on skin or peeling skin (*Lyell syndrome*) associated with tablet use DissoNac effervescent. However, in most cases, at least at least one other drug has used, which the possibility big cause reaction this.
- If new changes to skin or mucous membranes occur, you must see a doctor with immediately and stop using acetylcysteine. As the thick phlegm becomes more liquid, the amount will increase, especially at beginning of treatment. If you can't efficiently cough up this liquid, you must consult a doctor so that the adequate measures can be taken to remove phlegm.
- Medicines, such as DissoNac that dissolves phlegm (mucolytics) can

block the children's airways below age 2 years, due to the characteristics of the respiratory tract in this age group. This might limit their ability to cough up phlegm. Therefore, DissoNac should not be used by children under 2 years old year.

- DissoNac effervescent tablets not suitable for use of child and teenagers more younger than 18 years old.
- When opening the packaging, you may smell a slight sulfur (rotten eggs) smell.

Consult your doctor if any of the above-mentioned warnings are apply to you, or have applied to you in the past.

Side effects

Like all medicine, this medicine can cause side effects, although not everyone gets it.

Very rare side effects

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

- Severe allergic reactions and threatening life. The signs may include: rash, problem swallowing or breathing, swelling in lips, face, throat or tongue.
- Severe Bleeding
- Blistering, peeling, bleeding, or fluid-filled patches anywhere which part of your skin. This includes lips, eyes, mouth, nose, genitals, hands or feet. You may have serious skin problems.
- Shock (drop in blood pressure that severe, fatigue, anxiety, weak pulse, clammy skin, decreased awareness) because sudden blood dilation due to severe hypersensitivity to certain materials (*anaphylactic shock*).
- Sudden fluid accumulation in the skin and membranes mucus (eg throat or tongue), difficulty breathing and / or itchy and skin rash, often as a result of an allergic reaction (*angioedema*).

Rare side effects

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

- Shortness of breath due to muscle spasms of the respiratory tract (bronchospasm).
- Difficulty breathing or shortness of breath (dyspnea).
- Indigestion with symptoms of fullness in the upper abdomen, abdominal pain, belching, nausea and heartburn (dyspepsia).

Uncommon side effects

- Hypersensitivity
- Headache
- Ringing in the ears (tinnitus)
- Inflammation of the oral mucous membrane (stomatitis)
- Diarrhea
- Fever (pyrexia)
- Low blood pressure
- Stomach ache
- Nausea
- Vomiting

If you have or have had a gastric or duodenal ulcer, acetylcysteine may have an adverse effect on your gastrointestinal mucous membranes.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please contact your doctor or pharmacist.

Consult your doctor or pharmacist if you find that the effects of the tablet DissoNac are too strong or not strong enough.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

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Storage and Disposal of DissoNac

-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

This medicine should not be disposed of through waste water or household waste. Ask your pharmacist how dispose of medicines that are no longer needed. This measure will help to protect the environment.

Product Description

-What it looks like

DissoNac 200mg Effervescent Tablet

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

DissoNac 600mg Effervescent Tablet

Light yellow, round shaped tablet, flat on both sides. When dissolved in water,

the tablet produces a light yellow solution.

-Ingredients

Active ingredients:

DissoNac 200mg Effervescent Tablet

Each tablet contains acetylcysteine 200 mg

DissoNac 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, Orang flavour 10888-71, Orange flavour 12026-31, β -Carotene 1% cws/m, Ascorbic acid

- MAL Number

MAL26036017XZ

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

Aetos Pharma Sdn Bhd

No. 66B, Tingkat 2, Jalan Cerdas, Taman Connaught, 56000 Kuala Lumpur, Malaysia.

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30 January 2026

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