

Mucodex[®]

Powder for Solution 100mg, 600mg

Patient Information Leaflet

Description of Product

White to off white granular powder which forms a clear solution after reconstitution in warm water.

List of excipients: ascorbic acid, flavour orange DM6024, saccharin sodium, sucrose pharma grade.

Packaging for Mucodex Powder for Solution 100mg:

30 sachets of acetylcysteine 100mg

Packaging for Mucodex Powder for Solution 600mg:

30 sachets of acetylcysteine 600mg

What is the medicine?

Mucodex contains acetylcysteine, which make thick mucus in the airways thinner.

Name and strength of active ingredient

Each sachet of Mucodex Powder for Solution 100mg contains Acetylcysteine 100mg.

Each sachet of Mucodex Powder for Solution 600mg contains Acetylcysteine 600mg.

What is this medicine used for?

To loosen mucus and make it easier to cough up in respiratory tract conditions associated with sticky/thick mucus.

How much and how often should you use this medicine?

Adults and children above 6 years

2 sachets Mucodex 100mg, 2-3 times a day or

1 sachet of Mucodex Powder for Solution 600mg a day (preferably in the evening)

Children (2 – 6 years of age)

1 sachet Mucodex 100mg from 2 to 4 times a day, accordingly to the age.

Dissolve the contents of the sachets in a glass containing a small quantity of water, mixing it, if necessary, with a spoon. A palatable solution is thus obtained, which can be drunk directly from the glass.

It is preferable not to mix other drugs with Mucodex solution.

It is advisable to administer antibiotics 2 hours apart from Acetylcysteine.

The duration of treatment should be 5 to 10 days. if you do not feel better or if you feel worse, you must talk to a doctor.

When should you not take this medicine?

Do not take this medicine if you are allergic to acetylcysteine or to any excipients.

The medicine should not be used in children below 2 years of age. Mucolytic agents can induce respiratory obstruction in children under 2 years of age. Due to the physiological characteristics of the airways in this age group, the ability to expectorate may be limited.

Undesirable effects/side effects

Like all medicines, Mucodex can cause side effects, although not everybody gets them. In very rare cases, severe allergic reactions may occur such as anaphylactic shock and severe skin reaction. In rare cases the oral administration can be followed by shortness of breath, upset stomach and difficulty in breathing (bronchospasm).

There has been very rare reports of bleeding associated with the administration of acetylcysteine, and some of these bleeding episodes occurred as part of hypersensitivity reactions.

The most frequent side effects are headache, increased heart rate, inflammation of the mouth (stomatitis), itching (pruritus), hives (urticaria), nausea, vomiting, abdominal pain, fever, decrease in the blood pressure, diarrhoea and noises in the ears.

If you get any side effects, talk to your doctor or pharmacist.

What other medicine or food should be avoided whilst taking this medicine?

Antitussive drugs and mucolytic agents, like acetylcysteine, should not be concurrently administered, because the reduction in cough reflex could lead to accumulation of bronchial secretions.

Activated charcoal may reduce the effect of acetylcysteine.

Dissolution of acetylcysteine formulations concomitantly with other drugs is not recommended.

Reports of an inactivation of antibiotics resulting from acetylcysteine so far only relate to in-vitro tests in which the relevant substances were mixed directly. Nevertheless, when other oral drugs or antibiotics are required, it is advisable to administer them 2 hours apart from acetylcysteine.

This does not relate to loracarbef.

Concurrent administration of nitroglycerin and acetylcysteine has been shown to cause significant hypotension and enhance temporal artery dilation. If concurrent nitroglycerin and acetylcysteine therapy is necessary, patients should be monitored for hypotension, which can be severe, and warned of the possibility of headaches. Concurrent use of acetylcysteine and carbamazepine may result in subtherapeutic carbamazepine levels.

What should you do if you miss a dose?

If you forget to take a dose, take it as soon as possible. Take the next dose at the correct time, in accordance with instructions given by your doctor or pharmacist. However, if it is almost time to take the next dose, do not take the dose that you have missed. Take only the next dose, as per normal.

How should you keep this medicine?

Store at temperature not exceeding 30°C.

Signs & symptoms of overdose

If you take more Mucodex Powder for Solution than you should, you might experience nausea, vomit or diarrhoea.

What to do when you have taken more than the recommended dosage?

Contact your doctor.

Care that should be taken when taking this medicine?

Caution should be taken in patients suffering from or with a history of peptic ulcer especially in case of concomitant administration of other medicines with a known irritating effect on the gastric mucosa. Patients suffering from bronchial asthma must be strictly controlled during the therapy; if difficulty in breathing (bronchospasm) occurs, the treatment must immediately be suspended.

Acetylcysteine may moderately affect histamine metabolism, therefore caution should be used when administering the product for long-term therapy in patients with histamine intolerance, since symptoms of intolerance can occur (headache, vasomotor rhinitis, itching).

The use of Mucodex, particularly when administration is first started, can thin bronchial secretions, resulting in an increase in the volume of these secretions. If you are not able to adequately expectorate this increase volume of secretions, appropriate measures will be performed by your doctor.

The possible presence of a sulphureous odour does not indicate an alteration of the product but is a characteristic of the active ingredient contained in this preparation.

Mucodex Powder for Solution contains more than 2g of sucrose per sachet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Mucodex. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine. Diabetic patients should consult your healthcare professional if you are unclear about your sugar intake.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, cough suppressants as their ability to reduce cough reflex may lead to the accumulation of bronchial secretions.

Use during pregnancy and lactation

If you are pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

When should you consult your doctor?

Consult your doctor if you experience any of the undesirable effects listed in the table under the section of Undesirable effects.

Date of Revision: July 2021