



Mucosoft 600 mg powder for oral solution Acetylcysteine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

This is an over-the-counter medicine. Nevertheless, in order to get best results from treatment, you have to follow carefully the instructions for use of the medicinal product.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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1. What Mucosoft is and what it is used for

Mucosoft is a medicinal product that is used for liquefying and facilitating expectoration of tough bronchial secretion in acute and chronic diseases bronchus and lungs, such as tracheobronchitis, bronchitis, pneumonias, cystic fibrosis.

2. What you need to know before you take Mucosoft

Do not take Mucosoft:

- If you have hypersensitivity to the active ingredient acetylcysteine or to any of the excipients;
- If you have an active gastric and duodenal ulcer;
- If you have Asthma.

IF NOT SURE, ALWAYS ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Warnings and Precautions

Patients suffering from bronchial asthma should be carefully monitored during therapy: if bronchospasm occurs, treatment should be immediately discontinued.

The medicine should be used cautiously by elderly with respiratory failure.

Aspiration is possible if great quantity of the secretions are liquified, especially in small children and immobilized patients.

Acetylcysteine should not be used by patients with decreased ability of expectoration, unless aspiration is

applied during their treatment.

It should not be used in children under 14 years of age due to the high content of the active substance.

Other medicines and Mucosoft

In order to avoid potential drug interactions, please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those that you have bought over-the-counter.

- During use of the medicinal product in combination with antitussive agents, bronchial secretion retention may occur as a result of suppression of the cough reflex.
- Mucosoft should not be administered with oral antibiotics at one and the same time. An interval of at least 2 hours between administrations is recommended.
- The concomitant administration of MUCOSOFT with glycerol trinitrate (nitroglycerine) may result in enhancement of nitroglycerine effects – blood vessel dilation and inhibition of platelet aggregation.

Mucosoft and food, drink and alcohol

There is no evidence of foods and drinks that should be avoided.

Pregnancy, breast-feeding and fertility

Ask your doctor or pharmacist for advice before using any medicine.

Particular caution is required, if Mucosoft is used during pregnancy or breast-feeding, since there is no sufficient experience with the use of the product during these periods. You may use Mucosoft during pregnancy and breast-feeding only if your doctor considers it clearly necessary.

Driving and using machines

There are no data for impairment of the ability for concentration and the reaction time during driving or machine use upon acetylcysteine administration.

3. How to take Mucosoft

The usual dose of Mucosoft is:

Adults and children over 14 years of age:

1 sachet once daily (equivalent to 600 mg acetylcysteine).

Due to the high content of the active substance, Mucosoft should not be used in children less than 14 years of age. For this purpose, there are appropriate medicinal products with lower active substance content.

Method of administration

Oral administration.

The one sachet content is dissolved in a cup of hot water and drunk still warm, after meals.

Fluid intake enhances the secretolytic effect of the medicine.

Treatment duration depends on the severity of the disorder and is determined individually (in acute conditions – from 5 to 10 days, in chronic conditions – 1-2 months).

The medicine should not be used for more than 5 days without consulting a doctor.

If you are not sure, check with your doctor or pharmacist.

If you take more Mucosoft than you should

No cases with severe signs or symptoms of intoxication due to overdose were reported upon oral administration of acetylcysteine, even in treatment with high doses.

Symptoms of overdose

Symptoms of overdose may include nausea, vomiting, diarrhea, pains or heartburn. Overdose in small children may cause hypersecretion.

Treatment of overdose

If necessary, symptomatic treatment (bronchial aspiration) is initiated.

If you inadvertently or willfully have taken a higher than the recommended in this leaflet dose, inform your doctor or pharmacist.

4. Possible side effects

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

The assessment of the adverse drug reactions is based on their frequency data:

very common: affect more than 1 in 10 treated patients
common: affect less than 1 in 10 and more than 1 in 100 treated patients

uncommon: affect less than 1 in 1,000 and more than 1 in 1,000 treated patients

rare: affect less than 1 in 10 and more than 1 in 10,000 treated patients

very rare: affect less than 1 in 10 000, including isolated cases

General disorders:

Uncommon: allergic reactions (itching, urticaria, skin rashes, breathlessness, increased heart rate and blood pressure reduction), headache, fever.

Very rare: anaphylactic reactions to shock.

Respiratory ways:

Rare: breathing difficulty, bronchospasm – mainly in patients with hyper-reactive respiratory system, suffering from bronchial asthma.

Alimentary tract:

Uncommon: inflammation of the oral mucosa, abdominal pain, nausea, vomiting and diarrhea.

In rare cases acetylcysteine administration was associated with bleeding partially due to hypersensitivity reactions.

Isolated cases of seizures, loss of consciousness, acute psychotic reactions with schizophrenia features,

overdose with combination of medicines resulting in hypotension, liver impairment, apathy and drowsiness, Stevens-Johnson syndrome, toxic epidermal necrolysis, impetigo, anaemia with leukopenia and thrombocytopenia, loss of hearing, conjunctivitis, enterocolitis, exudative bronchitis, intrauterine death were reported.

If any adverse drug reaction gets serious or you notice other, unlisted in this leaflet adverse reactions, please inform your doctor or pharmacist.

4. How to store Mucosoft

Do not use Mucosoft after the expiry date which is stated on the package.

Store at temperature below 30°C.

Keep this medicine out of the sight and reach of children.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.

By reporting side effects you can help provide more information on the safety of this medicine.

5. Contents of the pack and other information

What Mucosoft contains

- The active substances are: for one sachet

Acetylcysteine 600 mg

- The other ingredients are: mannitol, sodium cyclamate, lemon flavor, silica, colloidal anhydrous.

What Mucosoft looks like and contents of the pack

Mucosoft is an off-white mixture of powder and dry agglomerates intended for oral solution preparation.

Each box contains 10 sachets and a patient information leaflet.

Marketing Authorisation Holder and Manufacturer

Adipharm EAD.

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