



Mucosoft Complex Hot Drink 500 mg/200 mg powder for oral solution

Paracetamol + Acetylcysteine

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

- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3-5 days.

What is in this leaflet

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1. What Mucosoft Complex is and what it is used for

Mucosoft Complex is a combination medicinal product containing paracetamol and acetylcysteine. Paracetamol relieves pain and reduces fever. Acetylcysteine liquefies the secretion in the airways, promotes expectoration and facilitates breathing in the presence of a thick and viscous bronchial secretion.

Mucosoft Complex is used in adults and children aged 12 years and over for short term treatment, and for relief of symptoms such as muscle pains, sore throat, fever and unproductive cough accompanying acute viral infections, colds and flu.

You must talk to a doctor if you do not feel better or if you feel worse after 3-5 days.

2. What you need to know before you take Mucosoft Complex

Do not take Mucosoft Complex :

- if you are allergic to paracetamol, acetylcysteine or any of the other ingredients of this medicine (listed in section 6).
- if you have liver diseases, particularly liver failure.

This medicine is not suitable for children under the age of 12 years because the pharmaceutical form (powder for oral solution) does not allow correct dosing in this age group.

Warnings and precautions

Talk to your doctor or pharmacist before taking Mucosoft Complex.

Take special care with this medicine in the following cases:

- If the pain and cough persist for longer than 5 days, and the fever longer than 3 days, you should consult your doctor or pharmacist with a view to dose adjustment or change of treatment.
- During the treatment you should not take any other paracetamol-containing products. In case of need, consult your doctor or pharmacist.
- Long term use of high dose pain medications may cause a headache not influenced by the treatment with this product.
- Regular use of analgesics, particularly combination medicines, may lead to kidney impairment, or rarely to kidney failure.
- If used long term in high doses, especially in association with regular alcohol consumption, the risk of liver impairment is increased.
- If you suffer from bronchial asthma.
- If you have or have had a gastric or duodenal ulcer.
- If you have histamine intolerance manifesting with headache, abundant nasal secretion and itching.

Other medicines and Mucosoft Complex

Tell your doctor or pharmacist if you are taking, have recently taken or

might take any other medicines.

You should be aware that this medicine may change the effect of some concomitantly administered medicines. Therefore it is important to inform your doctor if you take:

- Metoclopramide (suppressing nausea and vomiting), domperidone (reducing the risk of blood clot formation) or cholestyramine (reducing the levels of cholesterol in the blood): these medicines may change intestinal absorption rate of paracetamol thus changing its potency.
- Drugs that reduce blood clotting, such as warfarin and other coumarin anticoagulants: paracetamol may enhance their effect and increase the risk of bleeding.
- Probenecid (increases uric acid production) and isoniazid (for treatment of tuberculosis) reduce significantly the elimination of paracetamol. Your doctor will assess if paracetamol dose reduction would be necessary.
- The antibiotic rifampicin and some medicines for treatment of epilepsy (carbamazepine, phenytoin, phenobarbital) may enhance the adverse effect of paracetamol on the liver.
- Lamotrigine (for treatment of depression): paracetamol may lead to its reduced effect.
- Antibiotics such as tetracycline, cephalosporin, penicillins: their effect may be weakened if coadministered with acetylcysteine, therefore there should be an interval of at least 2 hours between administration of the separate drugs.
- Cough suppressants : when coadministered with acetylcysteine, a dangerous build-up of bronchial secretion is possible because these drugs suppress the cough that makes it difficult to expectorate the secretion liquefied by acetylcysteine.
- Nitroglycerin: acetylcysteine may enhance the effects of nitroglycerin.

If you need to have an uric acid or blood sugar test performed in a laboratory, you should inform your doctor that you are taking this medicine. Paracetamol may alter the results of these tests.

Acetylcysteine may cause incorrect measurement of salicylate levels.

Mucosoft Complex with food, drink and alcohol

Alcohol consumption during administration of this drug should be avoided. You should know that concomitant use with alcohol may increase the risk of liver damage.

The effect of acetylcysteine is enhanced with the intake of large amount of liquids.

Pregnancy, breast-feeding and fertility

Pregnancy

The use of this medicine by pregnant or breast-feeding women is inadvisable. Its use during pregnancy and breastfeeding should be only in case of confirmed necessity.

Your doctor will assess whether you may be treated with this medicine if you are pregnant. He will evaluate the ratio between the benefit for you and the risks for your baby.

Breastfeeding

Your doctor will assess whether you may be treated with this medicine if you are breastfeeding. He will evaluate the ratio between the benefit for you and the risks for your baby.

Driving and using machines

Mucosoft Complex should be used with caution by drivers and persons whose everyday activities require increased alertness due to the acetylcysteine contained in it that may cause drowsiness, dizziness or

blood pressure lowering.

Important information about some components of Mucosoft Complex

This product contains as an excipient sugar (sucrose), therefore it is unsuitable for patients with inborn or acquired intolerance to some sugars. If your doctor has told you that you have such an intolerance, consult him before taking this product.

The product contains 1.78 g sugar (sucrose) in each dose which has to be considered in patients with diabetes mellitus.

3. How to take Mucosoft Complex

Treatment with this medicine should be conducted with the lowest possible dose required for achieving the desired effect, for the shortest possible duration.

The recommended dose is:

Adults and children aged 12 years and over:

One sachet 3-4 times daily at an interval of 4-6 hours.

The maximum daily dose of 4 g paracetamol for adults and 1.8 g for children, and 600 mg acetylcysteine, should not be exceeded, and the interval between the separate administrations should be at least 4 hours.

Children aged under 12 years

The use of the product is not recommended in this age group because of possible incorrect dosing.

Elderly patients

No dose adjustment is necessary.

Patients with renal impairment:

In patients with severe renal failure the intervals between administrations should be at least 8 hours (see section 4.4).

Method and duration of administration

Dissolve the contents of one sachet in a cup of sufficient amount of hot water (150 ml), stir and take the solution through the mouth.

It is recommended to drink plenty of liquids to promote the effect of acetylcysteine.

If the drug was not prescribed by a doctor, its use should not exceed 3-5 days. If your complaints persist or your condition worsens, you should seek medical advice.

If you take more Mucosoft Complex than you should

Paracetamol overdose, especially in children, may have serious consequences. It could manifest with nausea, vomiting, pallor, abdominal pain, sweating and drowsiness occurring mostly in the first 24 hours. An overdose (exceeding 10 g paracetamol) may precipitate a severe liver impairment and loss of consciousness.

Treatment of paracetamol overdose should be conducted in the hospital setting; therefore, at the appearance of overdose symptoms or in case of intake of the drug at a dose higher than the recommended one, you should immediately contact a doctor.

No cases of acetylcysteine overdose have been reported to date. In case of a higher dose intake, nausea, vomiting or diarrhea may occur.

If you forget to take Mucosoft Complex

If you forget to take a dose, do it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

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

The frequency of the reported adverse reactions is indicated below.

Uncommon (less than 1 in 100 patients)

Allergic reactions, headache, tinnitus, fast heart rate, inflammation of the mucous membrane of the mouth, abdominal pain, diarrhea, vomiting, burning feeling and nausea, hives (urticaria), itching, fever, blood

pressure lowering.

Rare (less than 1 in 1000 patients)

Difficulty breathing or wheezing (bronchospasm) particularly in patients with increased sensitivity to acetyl salicylic acid and other analgesics and antipyretics, indigestion.

Very rare (less than 1 in 10 000 patients)

Low platelet count, liver disorders, severe allergic reaction causing breathing difficulty or dizziness, swelling of the face or throat, haemorrhages.

Not known (cannot be estimated from the available data)

Facial oedema, bronchial obstruction

If you get any of the following side effects during your treatment with Mucosoft Complex, immediately discontinue the treatment and inform your doctor or visit the nearest hospital:

- Oedema of the face, tongue or throat which may cause difficulty breathing, fast heart rate, sudden and rapid blood pressure lowering;
- Shortness of breath and wheezing in the chest, blood pressure lowering (signs of a rapidly progressing allergic reaction);
- Itching, a feeling of heat in and under the tongue, palms and soles, skin rash, shortness of breath and wheezing in the chest;
- Occurrence of skin redness, blisters on the skin of hands, feet and soles, more rarely on the lips, face and genitals, peeling of the skin or impaired skin and mucous membrane integrity;

Reporting of side effects

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

4. How to store Mucosoft Complex

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

Store below 30°C.

Do not use this medicine after the expiry date which is stated on the sachet. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of change in its appearance.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Mucosoft Complex contains

- The active substances in 1 sachet are paracetamol 500 mg and acetylcysteine 200 mg.
- The other ingredients (excipients) are: sucrose, ascorbic acid, maltodextrin, citric acid anhydrous, sodium citrate, sodium cyclamate, saccharin sodium, silicon dioxide, colloidal anhydrous, strawberry flavour (mixture of aromatic substances and glucose).

What Mucosoft Complex looks like and contents of the pack

White or almost white powder with strawberry flavour.

Powder for oral solution 3.6 g in a sachet made of paper/aluminium/polyethylene.

Each pack contains 10 sachets.

Marketing Authorisation Holder and Manufacturer

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