



PATIENT INFORMATION LEAFLET

NACOSEL 300 mg / 3 mL ampoule containing solution

It is administered intravenously, intramuscularly, respiratory (inhalation) or trachea (intrathecal).

Sterile

Drug substance: Each 3 mL ampoule contains 300 mg acetylcysteine.

Excipients: Disodium EDTA, sodium hydroxide, water for injection.

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

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.*
- *Tell your doctor that you are taking this medicine when you go to the doctor or hospital during the use of this medicine.*
- *Follow exactly what is written in this instruction. Do not use **high or low** doses other than the recommended dosage.*

What is in this leaflet:

- 1. What NACOSEL is and what it is used for?***
- 2. What you need to know before you use NACOSEL***
- 3. How to use NACOSEL?***
- 4. What are the possible side effects?***
- 5. How to store NACOSEL***

Headings are included.

1. What NACOSEL is and what it is used for?

NACOSEL is available in packages of 5 and 10 ampoules containing 300 mg of acetylcysteine. NACOSEL contains acetylcysteine as drug substance. Acetylcysteine is a cysteine derived agent which is an amino acid. It has expectorant effect.

NACOSEL is used in the treatment of bronchial secretion (respiratory secretion) disorders in bronchopulmonary (bronchial and lung) diseases, where the expulsion of dense viscous sputum, reduction, regulation of its density should be facilitated expectoration.

It is also used to prevent liver failure due to high dose paracetamol intake.

NACOSEL reduces the formation of sputum in case of colds and inflammation of the airways (bronchitis). Dilutes the sputum formed, makes it easier to cough.

2. What you need to know before you use NACOSEL

DO NOT USE NACOSEL

If;

- Do not use the drug product if you are hypersensitive to any of the excipients in the



composition of NACOSEL or acetylcysteine .

USE NACOSEL CAREFULLY in the following cases

If;

- If you have a history of asthma and bronchospasm, consult your doctor before using NACOSEL,
- If you have liver or kidney disease,
- If you have diseases such as ulcers in your stomach or intestines and vein enlargement in the esophagus,
- If you have cirrhosis,
- If you have epilepsy,

Consult your physician before using NACOSEL.

- If you notice any changes in your skin and around the eyes (e.g. redness, itching, fluid-filled papula, blood blister) when using NACOSEL, consult your doctor immediately.

Please consult your doctor if these warnings apply to you, even at any time in the past.

Use of NACOSEL with food and drink

There is no known harm in using NACOSEL with food and drink.

Plenty of fluid intakes support the mucolytic effect of NACOSEL.

Pregnancy

Consult your doctor or your pharmacist before using the drug.

It is unknown whether NACOSEL has any harmful effects on the mother or the baby. If you are pregnant or planning to become pregnant, consult your doctor before using NACOSEL.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or your pharmacist before using the drug.

It is unknown whether NACOSEL has passed into breast milk. NACOSEL should not be used unless it is mandatory during breastfeeding.

Consult to your doctor if you should continue breastfeeding.

Driving and using machines

No adverse effects of NACOSEL on driving and using machines have been reported.

Important information about some of the excipients contained in NACOSEL

NACOSEL contains approximately 42.34 mg sodium per ampoule. This should be considered for patients on a controlled sodium diet.

Use with other medicines

The effect of NACOSEL or other drugs may change when used in combination with certain



drugs.

If you are using any of the following drug products, please consult your doctor before using NACOSEL.

- Antitussives (NACOSEL may be used in combination with these drugs, which may lead to a significant increase in the secretion of the respiratory tract due to reduced cough reflex.)
- Antibiotics (NACOSEL should not be used concurrently with various antibiotics (tetracyclines, cephalosporins, aminoglycosides, penicillins, macrolides and amphotericin B), but should be used at least 2 hours apart if necessary).
- Nitroglycerin (used as a vasodilator in the treatment of heart diseases)
- Carbamazepine (used in the treatment of epilepsy)

Since acetylcysteine administered as nebulization (vapor distribution of a liquid for treatment) and lavage (washing of an organ or a site) may interfere with various metals such as iron, copper, aerosol device must be made of non-interacting material such as glass, plastic or stainless steel.

If you are currently using or taking any prescription or over-the-counter medication, please inform your doctor or pharmacist.

3. How to use NACOSEL

Instructions for appropriate use and dose / administration frequency:

Your physician will determine the dose of your drug product and administer it to you depending on your illness.

- Always follow your doctor's instructions when using NACOSEL. If you are unsure, ask your doctor or pharmacist.
- NACOSEL should not be used for more than 4-5 days unless advised otherwise by the doctor. Do not exceed the recommended dose.
- Depending on your response to treatment, your doctor may recommend a higher or lower dose. Do not exceed the recommended dose.
- Do not change the dose or discontinue treatment without talking with your doctor.

Route and method of administration:

NACOSEL is only for parenteral administration (intravenous or muscular), inhalation administration (by inhalation) and intrathecal administration (into the trachea). Your doctor will determine the dose of your drug product depending on your illness and administer it to you (regardless of whether you are hungry or full).

Various age groups:

Use in children:

There is no special use, the appropriate dose for the children should be administered by the doctor.

Use in the elderly:

No specific use, should be used in doses recommended for adults.

Special conditions of use:



High doses can be used under control of doctor for paracetamol poisoning.

Renal/Hepatic failure:

NACOSEL should not be administered in patients with hepatic or renal failure to avoid the release of more nitrogenous substances (see section Do not use NACOSEL in the following cases).

- If you have hepatic or renal failure, consult your doctor before using NACOSEL.
- In order to ensure that the drug is effective, it is important that the doctor follows the development at regular doctor checks.
- Unless your doctor recommends otherwise, follow this patient information leaflet.
- Your doctor will advise you how long your treatment with NACOSEL will last. Do not conclude the treatment early, because concluding NACOSEL may make your disorder worse.

Please talk to your doctor or pharmacist if you feel that the effect of NACOSEL is too strong or too weak.

If you have used more NACOSEL than you should

- Gastrointestinal disorders such as nausea, vomiting and diarrhea.
- Even at very high doses, no severe side effects and signs of poisoning were observed.
- There is a danger of excessive body secretions in breastfeeding babies.

If you have used more NACOSEL than you should, talk a doctor or pharmacist. If necessary your physician can treat you with signs of poisoning.

If you forget to use NACOSEL

Do not worry. If you forget to take NACOSEL, take it immediately when you remember. Remember that if the next dose is close, skip this dose and take the dose on time and resume with normal use.

Do not take a double dose to make up for forgotten doses.

Effects which may occur when treatment with NACOSEL is discontinued

Discontinuing NACOSEL treatment may cause your disease to be worsened.

Do not discontinue your medication without consulting your doctor.

4. What are the possible side effects?

As with all medicines, there may be side effects in people who are sensitive to the ingredients of NACOSEL.

If you notice any of the following, stop using NACOSEL and inform your doctor IMMEDIATELY, or apply to the emergency service of the nearest hospital:

- Allergic reactions (itching, hives, skin redness, difficulty breathing, acceleration of heart rate



and drop in blood pressure).

- Hypersensitivity responses leading to shock (anaphylactic reactions - rash, itching, sweating, dizziness, swelling of the tongue, lips and trachea, obstruction of the airway, nausea, vomiting may occur). In addition, bleeding has been reported rarely due to the use of acetylcysteine in hypersensitivity reactions.

These are all very serious side effects.

If you have one of these, you have a serious allergy to NACOSEL. You may need urgent medical attention or hospitalization.

All of these very serious side effects are very rare.

The frequency of adverse events is reported using the following categories.

Very common	: can be seen at least 1 out of 10 patients.
Common	: can be seen less than one in 10 patients, but more than one in 100 patients.
Uncommon	: can be seen less than one in 100 patients, but more than one in 1,000 patients.
Rare	: can be seen less than one in 1.000 patients, but can be seen more than 10,000 patients in one.
Very rare	: can be seen less than one in 10,000 patients.
Unknown	: cannot be estimated from available data.

Uncommon:

- Allergic reactions

Rare:

- Narrowing of the bronchi (Shortness of breath, difficulty breathing.)
- Inflammation in the mouth
- Nausea
- Vomiting
- Pyrosis
- Diarrhea

Very rare:

- Hypersensitivity responses, which can go up to shock
- Fever
- Bleeding

If you experience any side effect not mentioned in this patient information leaflet, inform your doctor or your pharmacist.

Reporting of the side effects:

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects



directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store NACOSEL

Keep NACOSEL out of the sight and reach of children, and in its packaging.

Store at room temperature below 30°C.

Ampoule should be opened just before parenteral administration. An opened ampoule can be stored in the refrigerator for 24 hours, but should not be administered as parenteral. Any unused product or waste material must be disposed in accordance with the local requirements.

Use in compliance with the expiry date.

Do not use NACOSEL after the expiration date stated on the packaging.

Do not use NACOSEL if you notice any damage in the product and/or its package.

Do not throw away drugs that have expired or are not used! Give them to the collection system determined by the Ministry of Environment and Urbanization.

Marketing Authorization Holder:

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