

**EXTAL® 600 mg effervescent tablet**  
Drink after dissolve the effervescent tablet in water  
Taken by mouth.

**Active Ingredient:** Each effervescent tablet contains 600 mg Acetylcysteine.  
**Inactive Ingredients:** Anhydrous citric acid, povidone K30, sucralose, polyethylene glycol, sodium bicarbonate, anhydrous lactose (from cow milk), lemon flavor, ethanol.

**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.*  
• *If you have any further questions, please ask to your doctor or pharmacist.*  
• *This medicine is prescribed only for you. Do not pass it on to others.*  
• *If you visit a doctor or hospital during usage of this medicine, please give information to your doctor that you are taking this medicine.*  
• *Please strictly follow instructions in this prescribing leaflet. Do not take **lower or higher dose** than recommended dose.*

**What is in this leaflet:**

1. What EXTAL is and what it is used for?
2. What you need to know before you take EXTAL.
3. How to take EXTAL?
4. What are possible side effects?
5. How to store EXTAL?

**1. What EXTAL is and what it is used for?**

EXTAL round, yellow-white, both sides flat tablets. 10 and 20 effervescent tablets are packed in a polypropylene tube package and carton box with instructions for use.  
EXTAL is a drug that is used after drinking completely dissolved in water.  
EXTAL contains acetylcysteine as active ingredient. Acetylcysteine is a cysteine derivative that is an amino acid. It has expectorant effect.  
EXTAL is a mucolytic drug that is used to treat bronchialrelease disorders in cases of bronchopulmonary (bronchial and pulmonary) diseases where intensive sputum is to be expelled, reduced, density regulated, expectoration (sputum elimination) must be facilitated.  
It is also used to prevent hepatic insufficiency due to high doses of paracetamol ingestion.  
EXTAL reduces sputum formation in cases of colds and inflammation of the respiratory tract (bronchitis). It dilutes the resulting sputum and makes it easier to cough.

**2. What you need to know before you take EXTAL.**

**DO NOT USE EXTAL**

- If you are allergic to acetylcysteine or any of the other ingredients of this medicine.
- Children under 2 years of age may not use this medicine.

**Warnings and precautions:**

- If you have a history of asthma and bronchospasm (bronchospasm), you should consult your doctor before using EXTAL,
  - If you have liver or kidney disease,
  - If your stomach or intestine has a discomfort such as a wound (ulcer) or vein expansion in the food pipe,
  - Patients with cirrhosis (liver disease)
  - Sara (epilepsy) patient is absent,
  - If you have histamine intolerance (specify: headache, rhinitis accompanied by nasal discharge, pruritus, etc.), use this medicine carefully.
- Before using EXTAL consult your doctor.  
• If you notice any changes in your skin or eye area when using EXTAL® (eg redness, itching, fluid-filled bubbles, blood sedimentation), contact your doctor immediately.  
Please consult your doctor if any of the abovementioned warnings are apply to you, or have applied to you in the past.

**Taking EXTAL with food and drink**

EXTAL® can be taken with food and drink.  
Abundant fluid intake enhances the expectoratory (mucolytic) effect of EXTAL.

**Pregnancy**

*Consult your doctor or pharmacist before using this medication.*  
It is not known exactly whether EXTAL® has any harmful effects on the mother or baby. If you are pregnant or plan to become pregnant, contact your doctor before using EXTAL.  
*If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.*

**Breast-feeding**

*Consult your doctor or pharmacist before using this medication.*  
It is not known whether acetylcysteine is excreted in breast milk. Only use EXTAL after careful consideration of the benefits and risks during breast-feeding. If you are pregnant or breast-feeding, contact your doctor or pharmacist before any medicine.

**Driving and using machines**

EXTAL should not affect your ability to drive or operate machinery.

**Important information about some of the inactive ingredients of EXTAL**

This medicinal product contains 109.46 mg sodium per dose. To be taken into consideration by patients on a controlled sodium diet.  
Each effervescent tablet contains 323.34 mg lactose and 13.33 mg sucralose. If you have previously been told by your doctor that you have intolerance to certain sugars, you should consult your doctor before taking this medicinal product.  
This medicinal product contains less than 100 mg of ethanol (alcohol).

**Taking other medicines**

In addition to EXTAL, consult your doctor before taking any medication.  
• The combination of EXTAL with antitussive drugs is not suitable.  
• The antibiotic group of EXTAL should not be used with drugs (eg tetracycline, cephalosporin, aminoglycoside, penicillin, macrolide and amphotericin B). If two drugs need to be used together, there should be a 2 hour period between them.  
• Consult your physician before using EXTAL nitroglycerin (used in heart disease) and carbamazepine (used in epilepsy).  
• EXTAL and activated charcoal should not be used together.  
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**3. How to take EXTAL®?**





**Instructions for proper use and dose / application frequency:**

If not otherwise prescribed by the doctor, the dose prescribed for EXTAL is as follows:

- Adults and adolescents over 14 years of age:  
One or two times a day an effervescent tablet (600 mg - 1200 mg per day) is dissolved in a glass of water and drunk.
- Under 14 years of age:  
It is recommended to use EXTAL 200 mg effervescent tablet to adjust the dose in children under 14 years of age.  
In children between 6 and 14 years: 400 mg of acetylcysteine is used daily.  
In children between 2 and 5 years: 200 mg - 300 mg acetylcysteine is used daily.
- In paracetamol poisoning:  
The loading dose is administered as 140 mg / kg and the maintenance dose is given as 70 mg / kg (17 doses) in 4 hours.
- Unless your doctor recommends otherwise follow these instructions.

**Administration way and method:**

EXTAL is drunk after a meal in a glass of water.  
Unless your doctor recommends otherwise follow these instructions.  
• Remember to take your medicine on time.  
• The expectorant effect of EXTAL is increased by fluid intake.  
• EXTAL should be used at the frequency and duration recommended by the physician.  
• Your doctor will tell you how long your treatment will last with EXTAL. Do not interrupt treatment early because you can not get the desired result.

ÜRÜN ADI	EXTAL 600 MG KT		ORJİNAL 	NUMUNE 	ÇALIŞMA NO.	1
DEĞİŞİKLİK TARİHİ	14.08.2018		EBAT	160X300	BIÇAK NO.	
HAZIRLAYAN	RENKLER		MALZEME CİNSİ	1. Hamur 60 g	AÇIKLAMA  8 punto çalışıldı.	
 Anadolü Savaşı ve Ticari A.Ş.	Black 		FARMA KOD			
			KONTROL NO			

**Different age groups:****Use in children:**

Children under 2 years of age should be given only with the suggestion and control of a doctor.

**Use in the elderly:**

There is no specific dose recommendation for patients older than 65 years.

**Special use cases:**

EXTAL should not be used more than 4-5 days without the doctor's recommendation.

Patients receiving antibiotics should take EXTAL 2 hours before or after taking antibiotics.

Paracetamol can be used in physician control at high doses in poisoning.

**Kidney / Liver failure:**

- EXTAL should not be administered to patients with liver or renal insufficiency in order to avoid providing more nitrogenous material.
- If you have kidney or liver problems, consult your doctor before using EXTAL.

*If you notice that the effect of EXTAL is too strong or not strong enough, talk to your doctor or pharmacist.*

**If you take more EXTAL than you should:**

- Gastrointestinal system problems such as nausea, vomiting and diarrhea may occur.
- Severe side effects and poisoning statements have not been observed even at very high doses.
- There is a risk of excessive excretion of body secretions in breastfed babies.

*If you use EXTAL more than necessary, talk to a doctor or pharmacist. Your doctor may treat you with signs of poisoning if necessary.*

**If you forget to take EXTAL**

If you have forgotten to take a dose, immediately take an effervescent tablet. If it is almost time of the next dose, do not take the forgotten dose and then continue the schedule given by your doctor.

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

**Possible effects after completion of EXTAL treatment**

Give up the treatment of EXTAL can cause your illness to get worse.

Do not give up the treatment unless indicated by your doctor.

**4. What are the possible side effects?**

Like all medicines, EXTAL can cause side effects on people, who have sensitivity to any of other ingredients of this medicine.

**If you get any of the following side effects, stop taking EXTAL and tell your doctor IMMEDIATELY, or contact the emergency service at your nearest hospital:**

- Allergic reactions (itching, hives, redness of skin, difficulty in breathing, acceleration in heart rate and blood pressure drop).
- Symptoms such as anaphylactic reactions (such as rash, itching, sweating, dizziness, swelling in the tongue, lips and pus, obstruction of the airway, nausea and vomiting) may be seen. Very rarely, bleeding episodes due to the use of acetylcysteine have been reported in the context of hypersensitivity reactions.

These are all very serious side effects. If any of these are present in you, you have a serious allergy to EXTAL.

You may need to have an emergency medical intervention or hospital admission. These very serious side effects are very rare.

Side effects are classified according to the following frequency ratings:

Very common (may affect up to 1 in 10 patients)

Common (may affect up to 1 in 100 patients)

Uncommon (may affect up to 1 in 1000 patients)

Rare (may affect up to 1 in 10,000 patients)

Very rare (less than 1 in 10,000 patients)

Unknown (frequency cannot be estimated from the available data)

**Uncommon:**

- Headache
- Itching
- Hives (urticaria)
- Rash
- Exanthema (fumes or stains on the skin of infectious diseases)
- Bronchial narrowing (shortness of breath, difficulty breathing)
- Tachycardia (normal speed work of the heart)
- Blood pressure drop
- Stomatitis (inflammation in the mouth)
- Abdominal pain
- Nausea
- Vomiting
- Diarrhea

**Rare:**

- Shortness of breath (dyspnoea)
- Bronchospasm (contraction of bronchial smooth muscles), difficult breathing

**Very Rare:**

- Fever
  - Anaphylactic reactions that go as far as the stomach
- These are the minor side effects of EXTAL. Your next physician visit will be improved by changing the concentration, amount, or frequency of administration of the drug used.

If you encounter any side effects not mentioned in these instructions for use, please inform your doctor or pharmacist.

**Reporting of Side Effects**

If you get any side effects listed or not listed in this leaflet, please give information to your doctor, pharmacist or nurse. You can also report side effects directly to Turkish Pharmacovigilance Center (TUFAM) by calling 0 800 314 00 08 or by clicking "Medicine Side Effect Notice" icon at [www.titck.gov.tr](http://www.titck.gov.tr) By reporting the occurred side effects, you can help provide more information on the safety of this medicine.

**5. How to store EXTAL?**

*Keep EXTAL out of sight and reach of children, and store in its package.*

Keep this medicine at room temperature lower than 25°C.

Remember to close the cover after each use.

**Use in accordance with the expiration date.**

*Do not use EXTAL after the expiry date, which is stated on the package.*

If you notice any defects in the product and/or package, do not use EXTAL.

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

**Registration Holder:** Terra İlaç ve Kimya San. Tic. A.Ş.  
Ümraniye/İstanbul

**Manufacturer:** Pharmactive İlaç San. ve Tic. A.Ş.  
ÇOSB- Kapaklı / Tekirdağ

*This leaflet is approved on 05/04/2018.*