

PATIENT INFORMATION LEAFLET

EXTAL FORT 1200 mg effervescent tablet

Taken by mouth.

- **Active substance:** Each effervescent tablet contains 1200 mg acetylcysteine.
- **Inactive substance:** Ascorbic acid, citric acid anhydrous, sodium hydrogen carbonat anhydrous, sodium citrate dihydrate, lactose anhydrous DC (cow's milk), mannitol SD, sucralose lemon aroma, PEG 8000 micronization, magnesium stearate, pure water.

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

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

EXTAL FORT is a white round effervescent tablet. In cardboard box with cap polypropylene tube containing molecular sieve and silica gel contains 20 effervescent rablet.

EXTAL FORT use as a medicine that after it dissolved in the water.

EXTAL FORT contains acetylcysteine as active substance. Acetylcysteine is an amino acid cysteine derivative. It is an expectorant medicine.

EXTAL FORT is a mucolytic drug used in the treatment of bronchial secretion disorders, bronchopulmonary diseases, in cases where expectoration should be facilitated, excretion, reduction and regulation of dense viscous sputum should be facilitated.

It is also used to prevent liver failure due to high dose paracetamol intake. EXTAL FORT reduces the formation of sputum in case of colds and inflammation of the respiratory tract. Dilutes the sputum formed, makes it easier to cough.

2. Things to consider before you start to take EXTAL FORT

DO NOT TAKE EXTAL FORT in the following situations:

If you are allergic to acetylcysteine or any of the other ingredients of this medicine, you don't use this medicine.

USE CAREFULLY EXTAL FORT in the following situations

- If you have asthma and bronchospasm, consult your doctor before using EXTAL FORT,
- If you have liver or kidney disease,
- If you have discomfort such as wound or esophageal dilatation of your stomach or intestine,
- If you have cirrhosis,
- If you have epilepsy

Consult your doctor before using EXTAL FORT.

If you notice any changes in your skin and around the eyes while using EXTAL FORT, consult 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.

Usage of EXTAL FORT with food and drink

There are no known drawbacks in the use of EXTAL FORT with food and drink. Abundant fluid intake promotes the expectorant effect of EXTAL FORT.

Pregnancy

Consult your doctor or pharmacist before using this medication.

It is not known whether EXTAL FORT has any harmful effects on the mother or the baby. If you are pregnant or planning to become pregnant, consult your doctor before using EXTAL FORT.

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 exactly whether acetylcysteine passes into breast milk. EXTAL FORT should not be used unless mandatory during breastfeeding. Ask your doctor if you should continue breastfeeding.

Driving and using machines

No adverse effects of acetylcysteine on vehicle and machine use have been reported.

Important information about some of the inactive ingredients of EXTAL FORT

This medicinal product contains 194.3 mg sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

Each effervescent tablet contains 380.00 mg lactose. 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.

Each effervescent tablet contains 139.65 mg mannitol. May have a mild laxative effect.

Taking other medicines

In addition to EXTAL FORT, consult your doctor before taking any medication.

The effect of EXTAL FORT or other drugs may change when used in combination with certain drugs.

If you are using any of the following drugs, be sure to consult your doctor before taking EXTAL FORT.

- Antitussives medicines (If EXTAL FORT is used in combination with these drugs, there may be a significant increase in the secretion of the respiratory tract due to reduced cough reflex.)

- Antibiotics (should not be used simultaneously with tetracyclines, cephalosporins, aminoglycosides, penicillins, macrolides and amphotericin B (should be used for at least 2 hours between use if necessary)).
- Nitroglycerin (used as vasodilator in the treatment of heart diseases)
- Carbamazepine (used in the treatment of epilepsy)
- EXTAL FORT and activated charcoal should not be used together.

Please inform your doctor or pharmacist if you are using or have recently used any medicine with or without a prescription.

3. How to take EXTAL FORT?

Instructions for proper use and dose / application frequency:

The dose prescribed for EXTAL FORT unless otherwise prescribed by the doctor is as follows:

Adolescents and adults over 14 years of age;

In order to reduce increased secretion and facilitate excretion in respiratory diseases, 1 effervescent tablet is administered once a day.

Paracetamol intoxication; loading dose 140 mg/kg, maintenance dose 70 mg/kg every 4 hours (total 17 dose) are recommended.

- Always follow your doctor's instructions when using EXTAL FORT. If you are unsure, ask your doctor or pharmacist.
- EXTAL FORT should not be used for more than 4-5 days unless advised otherwise by the doctor.
- 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 to your doctor.
- Patients receiving antibiotic treatment should take EXTAL FORT 2 hours before or after taking the antibiotic.

Administration way and method:

EXTAL FORT used only by mouth.

EXTAL FORT after meals are dissolved in a glass of water to drink. The drug prepared by dissolving in water should be drunk without waiting. Effervescent tablets should not be chewed or swallowed.

Different age groups

Usage for children:

For children under 14 years of age, it is recommended to use the appropriate form of acetylcysteine-containing products for this age group.

Usage for elderly:

There is no specific use for this age group, it should be used in doses recommended for adults. 1 effervescent tablet is used once a day.

Special use cases

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

Kidney/Liver Failure:

- EXTAL FORT should not be used in patients with hepatic and renal failure to avoid the provision of more nitrogenous substances.
- If you have kidney or liver problems, consult your doctor before using EXTAL FORT.
- In order to be sure that the drug is effective, it is important for the doctor to follow the development at regular doctor checks.
- Unless your doctor recommends otherwise follow these instructions.

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

If you use more EXTAL FORT than you need:

If you have an impression that you took EXTAL FORT more than you need, talk to your doctor or pharmacist.

If you forget to use EXTAL FORT:

If you forget to take the time you need to take it, if you remember it, then take the dose, then continue to your usual treatment.

Do not take double doses to compensate for forgotten doses.

Possible effects of termination of treatment with EXTAL FORT

Your doctor will advise you how long your treatment with EXTAL FORT will last. Do not stop treatment early because stopping EXTAL FORT treatment may make your disease worse.

Do not discontinue your medication without consulting your doctor.

4. What are possible side effects?

Like all medicines, people who are sensitive to substances contained in EXTAL FORT may have side effects. however, these effects may not be seen in everyone.

Stop using EXTAL FORT and IMMEDIATELY contact your doctor or go to emergency service of the nearest hospital if any of the following happens:

- Allergic reactions (itching, hives, skin rashes, difficulty breathing, acceleration of heart rate and drop in blood pressure).
- Hypersensitivity responses to shock (rash, itching, sweating, dizziness, swelling of tongue, lips and trachea, obstruction of airway, nausea, vomiting). In addition, bleeding has been reported rarely due to the use of acetylcysteine in hypersensitivity reactions.

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

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

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The following category indicates the frequency of undesirable effects.

Rare: Fewer than 1 in 1000 patients are affected

Rare:

- Narrowing of the bronchi (shortness of breath, difficulty breathing.)
- Inflammation in the mouth
- Nausea
- Vomiting
- Heart burn
- Diarrhea
- Fever

If you get any side effects not listed in this leaflet, please give information to your doctor or pharmacist.

Reporting side effects

Talk to your doctor, pharmacist or nurse if you have any side effects that are included or not in the leaflet. Also report any side effect you may encounter to the "Drug Side Effects Report" at www.titck.gov.tr or call 0 800 314 00 08 "Turkey Pharmacovigilance Center (TUFAM)" side effect notification line. By reporting side effects, you will contribute to learning more about the safety of the medicine you are using.

5. How to store EXTAL FORT?

Keep EXTAL FORT out of the reach and sight of children, in the its original package.

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

Use as agreeable with expiration dates.

Do not use EXTAL FORT after the expiration date on the packaging.

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

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

Registration Holder: Terra İlaç ve Kimya San. Tic. A.Ş.

Ümraniye/ İstanbul

Manufacturer: Abdi İbrahim İlaç San. ve Tic. A.Ş.

Esenyurt / İstanbul

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