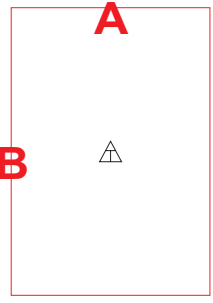



Ürün Adı TIOFIX 18 mcg Discair Inhalation Powder
Tasarım Kodu LB-TX1860KT01
Ürün Cinsi Kullanma Talimatı
Punto Ölçüsü : 9 pt

	A : 190 mm B : 450 mm Kağıt : 1. hamur Markası : Edixion Gramajı : 45 gr/m ²
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Hazırlayan Özgür AY

PACKAGE LEAFLET: INFORMATION FOR THE USER

TIOFIX 18 mcg Discair Inhalation Powder To be used by oral respiratory route.

- **Active substance(s):** Each inhalation dose contains 21.7 mcg tiotropium bromide anhydrous equivalent to 18 microgram tiotropium.
- **Excipient:** Lactose

Read all of this PACKAGE 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, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *Tell your doctor that you are using this medicine, when you go to doctor or hospital while using this medicine.*
- *Comport all informations in this leaflet. Do not use **high or low dose** besides the dose recommended for you.*

What is in this leaflet:

1. What TIOFIX is and what it is used for
2. What you need to know before you take TIOFIX
3. How to take TIOFIX
4. Possible side effects
5. How to store TIOFIX

Handles are included.

1. What TIOFIX is and what it is used for

- TIOFIX contains tiotropium bromide anhydrous in powder form for oral inhalation use.
- TIOFIX is available in cardboard boxes that include an inhalation device within a safe packaging, that contains 30 and 60 doses of inhalation powder in Alu/Alu blisters, along with the patient information leaflet.
- Tiotropium, is a long-term, specific bronchodilator agent that is generally called an anti-cholinergic agent in clinical medicine. It helps to open your airways and makes it easier to get air in and out of the lungs.
- TIOFIX, helps patients with chronic obstructive pulmonary disease (COPD) to breathe more easily. COPD is a chronic lung disease leading to symptoms such as coughing and shortness of breath. The term COPD is associated with the conditions chronic bronchitis and emphysema. As COPD is a chronic disease, you should take TIOFIX not only when you have breathing problems or other symptoms of COPD but also regularly, every day. Regular use of TIOFIX is also beneficial during the long periods of shortness of breath that occur in relation with your disease. It helps keep you active during longer periods of time. Moreover, daily use of TIOFIX, may help prevent the occurrence of short-term worsening of your symptoms (COPD exacerbations/ flare-ups) that may last several days. When administered by the respiratory route, it acts selectively on the local bronchi. Bronchodilation that occurs following the inhalation of tiotropium, is primarily a local effect (on the airways), not a systemic one.

In patients with moderate to severe COPD (chronic obstructive pulmonary disease), regular use of TIOFIX may reduce the likelihood of flare-ups and may resolve the symptoms of the disease and improve the quality of life.

The effect of this medicine lasts for 24 hours, therefore you only need to take it once a day. For correct use of TIOFIX please see section 3. How to take TIOFIX? And the instructions for the use of the inhalation device.

2. What you need to know before you take TIOFIX

DO NOT take TIOFIX.

If:

- You are allergic (hypersensitive) to tiotropium or lactose intolerant; this medicine contains lactose; (See. "Excipient" above)
- You are allergic to atropine or similar drugs such as ipratropium or oxitropium
- You are younger than 18 years of age.

TAKE SPECIAL CARE with TIOFIX in the conditions listed below:

- TIOFIX is indicated for the long-term maintenance treatment of your chronic obstructive pulmonary disease. It is not a rescue medicine and should not be used for the treatment of sudden shortness of breath or wheezing (acute episodes of bronchospasm).
- Sudden allergic manifestations may occur following the inhalation of TIOFIX including rashes, swelling, wheezing, or difficulty breathing. If you have these symptoms, you should seek immediate medical attention.
- If you have glaucoma (increased pressure in the eye), have problems passing urine due to prostate or bladder problems, TIOFIX may make these problems worse.
- If you have any problems with your kidneys, talk to your doctor before using this medicine.
- Inhaled medicines such as TIOFIX may cause tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation. If this occurs, please consult your doctor immediately.
- Take care not to let the inhalation powder enter your eye. This may result in precipitation or worsening of narrow angle glaucoma, which is a disease of the eyes. Eye pain or discomfort, blurred vision, seeing halos around lights or colored images in association with red eyes may be signs of an acute attack of narrow-angle glaucoma. Eye symptoms may be accompanied by headache, nausea or vomiting. You should stop using tiotropium and immediately consult your doctor, preferably an eye specialist, when signs and symptoms of narrow-angle glaucoma appear.
- Dry mouth, which has been observed with anti-cholinergic treatment, may in the long term be associated with dental caries. Therefore, you should pay attention to oral hygiene.
- Please talk to your doctor if you have had a heart attack within the last 6 months or if you have had a life-threatening/unstable (unstable) heart rhythm disorder or severe heart failure within the last year. In such a case, it is important to decide whether you can use TIOFIX.
- Do not take TIOFIX more frequently than once daily.

- You should learn the proper use of TIOFIX.

Please consult your doctor if any of these warnings applies to you or it did in the past.

Taking TIOFIX with food and drink

No interactions are expected between it and food and beverages, as TIOFIX is administered by the respiratory route. However, concurrent food or beverage intake should be avoided during the administration of the medicine.

Pregnancy

Please consult with your doctor or pharmacist before taking this medicine.

You should not use this medicine during pregnancy, unless specifically recommended by your doctor. If you do become pregnant while you are taking TIOFIX, you should consult with your doctor immediately.

Breast-feeding

Please consult with your doctor or pharmacist before taking this medicine.

You should not use this medicine while you are breastfeeding a baby, unless specifically recommended by your doctor.

Driving and using machines

Dizziness, blurred vision, or headache may occur and influence the ability to drive and use machinery. If this occurs, you should avoid activities requiring a clear mind such as driving and using machinery.

Important information about some of the excipients of TIOFIX

There are no excipients that require special warning in the content of TIOFIX.

Using together with other drugs

Please tell your doctor or pharmacist if you are taking/have taken similar medicines for your lung disease, such as ipratropium or oxitropium.

No specific side effects have been reported when TIOFIX has been taken together with other products used to treat COPD. These medicines include reliever inhalers (e.g. salbutamol), methylxanthines (theophylline) and/or oral and inhaled steroids (e.g. prednisolone).

Please inform your doctor or pharmacist if you are taking, or have recently taken, any other prescription or non-prescription medicines.

3. How to take TIOFIX

Instruction for proper use and dose/administration frequency:

Adults/ elderly

Follow your doctor's instructions about when and how to take your medicine. If you are unsure ask your doctor or pharmacist. You should try to take TIOFIX at the same time every day. This is important because TIOFIX is effective over 24 hours.

Route and method of administration

The recommended dose is 1 inhalation dose (18 micrograms of tiotropium) by mouth, inhaled once a day. Do not take more than the recommended dose.

The medicine reaches your lungs when you breathe in through the inhaler. Therefore, it is important that you breathe deeply and forcefully through the mouthpiece of the device.

The use of the inhaler will be shown to you by the doctor or another healthcare professional. If you have any problems using the device, ask your doctor, nurse or pharmacist to show you how the device works.

While using TIOFIX, you should be careful not to get the powder in your eyes. If you get dust in your eyes, your vision may be blurred, your eyes may hurt and/or become red. In such a case, wash your eyes immediately with lukewarm water. Then talk to your doctor right away about what else you should do. If you feel that your breathing is getting worse, you should tell your doctor as soon as possible. Detailed information on use is available in the instructions for use. See attached instructions for inhaler instructions.

Different age groups:

Use in children: TIOFIX should not be used in children and adolescents under the age of 18, as there is no experience.

Use in elderly: TIOFIX can be used at recommended doses in the elderly with normal functioning kidneys.

Special use conditions

Renal impairment: Patients with renal impairment can take TIOFIX at recommended doses. However, as all medicines that are eliminated through the kidneys, TIOFIX should be used with caution in patients with moderate to severe kidney insufficiency.

Hepatic impairment: Patients with hepatic impairment can take TIOFIX at recommended doses

If you think that the effect of TIOFIX is too strong or too weak, contact your doctor or pharmacist.

If you take more TIOFIX than you should

If you take more TIOFIX than you should, contact your doctor or pharmacist.

If you inhale more than one inhalation of TIOFIX per day, you should talk to your doctor immediately. This may increase the risk of side effects such as dry mouth, constipation, difficulty urinating, rapid heartbeat or blurred vision.

If you forget to take TIOFIX

If you forget to take a dose, take one as soon as you remember but do not take two doses at the same time or on the same day. Then take your next dose as usual. Do not take a double dose to make up for the missed doses.

If you stop taking TIOFIX

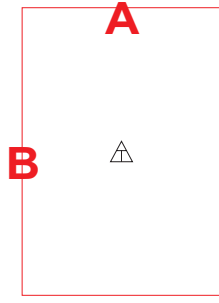
You should talk to your doctor before you stop taking TIOFIX. If you stop taking TIOFIX, your COPD symptoms may worsen. If you have any further questions on the use of this medicine,


ONAYLAR (İsim, Görev, Tarih, İmza)

KONTROL EDEN

YÜRÜRLÜK ONAYI

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ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, TIOFIX can cause side effects in patients who are sensitive to its ingredients, although not everybody gets them.

If you notice any of the following, stop using TIOFIX, tell your doctor IMMEDIATELY or contact the emergency department of your nearest hospital:

Allergic reactions or other hypersensitivity reactions (sudden drop in blood pressure or dizziness), which are serious side effects and cause swelling in your face and throat (angioedema), may occur individually or as part of a severe allergic reaction (anaphylactic reaction) after administration of TIOFIX. may come out. In addition, as with all inhaled drugs, some patients may experience unexpected chest tightness, cough, wheezing or breathlessness immediately after inhalation (bronchospasm). These are all very serious side effects. If you have one of these, it means that you have a serious allergy to TIOFIX. You may need to be admitted to an emergency medical intervention or hospital.

All of these very serious side effects are very rare. Side effects are listed as shown in the categories below:
 Very common : May affect more than 1 in 10 people
 Common : May affect up to 1 in 10 people
 Uncommon : May affect up to 1 in 100 people
 Rare : May affect up to 1 in 1,000 people
 Very rare : May affect up to 1 in 10,000 people
 Unknown : Frequency cannot be estimated from the available data.

Following side effects have been reported in patients taking this drug and are given by frequency:

Common:
 - Dry mouth

Uncommon:
 - Dizziness
 - Headache
 - Taste disturbances
 - Blurred vision
 - Irregularities in heart rate (atrial fibrillation)
 - Inflammation of the throat (pharyngitis)
 - Mute
 - Cough
 - Reflux disease
 - Constipation
 - Fungal infection in the oral cavity and throat
 - Rash
 - Difficulty urinating
 - Painful urination

Rare:
 - Difficulty sleeping
 - Seeing halos or colored images around lights associated with redness of the eye (glaucoma)
 - High values in eye pressure measurements
 - Irregular heartbeats (supraventricular tachycardia)
 - Increased heart rate (tachycardia)
 - Sensation of heartbeats (palpitation)
 - Cough, wheezing or shortness of breath (bronchospasm) with chest tightness immediately after inhalation
 - Nosebleeds
 - Inflammation of the larynx (laryngitis)
 - Inflammation of the sinuses (sinusitis)
 - Blockage of the intestines or absence of bowel movements
 - Inflammation of the gums
 - Inflammation of the tongue
 - Difficulty swallowing
 - Inflammation in the mouth
 - Nausea
 - Hypersensitivity reactions, including sudden onset
 - Severe allergic reaction causing swelling of the face and throat (angioedema)
 - Hives
 - Itching
 - Urinary tract infection

Unknown:
 - Excretion of water from the body
 - Tooth decay
 - Severe allergic reaction (anaphylactic reaction)
 - Infections or ulcers on the skin
 - Dry skin
 - Swelling in the joints

If you notice any other side effects not listed in this leaflet tell your doctor or pharmacist.

5. How to store TIOFIX

Keep TIOFIX out of the sight and reach of children, and in their original package.

Store below 25°C, in dry places.

Use it properly accordance to the expiry date

Do not take TIOFIX after its expiry date. The expiration date is the last day of the stated month. Do not use TIOFIX if you notice any damage to the product and/or package.

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.

Marketing Authorisation Holder:

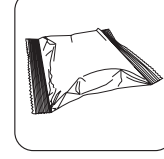
neutec İlaç San. Tic. A.Ş
 Esenler/İSTANBUL/TURKIYE
 Phone: +90 850 201 23 23
 Fax: +90 212 481 61 11
 e-mail: bilgi@neutec.com.tr

Manufacturer:

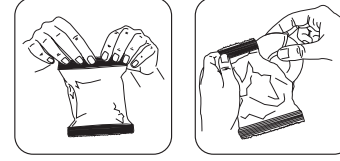
neutec Inhaler İlaç San. Ve Tic. A.Ş.
 Arifiye/SAKARYA/TURKEY

Instructions for use of the inhalation device

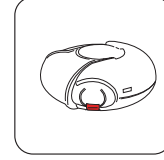
The inhalation device available in the cardboard box, is contained within a protective package for safety purposes.



Before the first use, remove the inhalation device from the package as shown below.



When you unpack the inhalation device, it will be in the closed position.



An unused inhalation device contains 60 individual doses stored separately in a powder formulation. The dose indicator shows how many doses left in the inhaler. Each dose is precisely metered and kept under hygienic conditions. The inhaler does not require maintenance or a refill. The inhalation device is easy to use. The administration process includes three stages, as shown below.

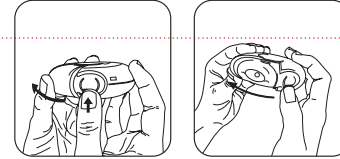
1. Opening
2. Inhalation
3. Closure

How the TIOFIX Inhaler Device Works

The outer cover is pushed away by pushing the red button (child proof). When the outer cover is pushed, a small opening appears in the mouthpiece and one dose of the medicine becomes ready to be inhaled. When the device is closed, the outer cover returns to its original position and is ready for the next use. The outer cover protects the inhalation device, when it is not used.

1. Opening-How should you use the inhalation device

Pushing the red button and pushing the outer cover away is adequate to open the inhalation device and get it ready for inhalation. When you hold the inhaler, the mouthpiece of the inhalation device should point you. Now the inhaler device is ready to use. Every time the outer cover is opened, the inhalation device becomes ready for use. And this is indicated on the dosimeter. Do not unnecessarily open the outer cover in order to not waste the medicine.



2. Breathe in

Please read carefully this section before you breathe in the medicine.

- Hold the inhalation device away from your mouth. Breathe out gently. Remember that you should never breathe out into the inhalation device.



- Place the mouthpiece between your lips. Take a long and deep breath through your mouth (not through your nose), by means of the inhaler



- Remove the inhaler from your mouth.
- Hold your breath for 10 seconds or as long as you can.
- Breathe out slowly.

3. Closure

- Sliding the outer cover back to its original position will be adequate to close the inhalation device.
- Now the inhalation device is ready for use again.



DON'T FORGET!

Keep the inhaler dry. Keep the inhaler closed when it is not used. Never breathe out into the inhalation device. Open the outer cover when you are ready to use it. Do not take more than the recommended dose.

LB-TX1860KT01

ONAYLAR (İsim, Görev, Tarih, İmza)

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