

PACKAGE LEAFLET: INFORMATION FOR USER

TIODAY CAPSAIR 18 mcg inhalation powder

For oral inhalation only.

- **Active ingredient:** Each inhalation dose contains 22 mcg Tiotropium Bromide Anhydrous equivalent to 18 mcg Tiotropium.
- **Excipients:** Lactose

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 more questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *Inform your doctor that you are using this medicine, when you go to a hospital or see a doctor while using this medicine.*
- *Comport all information in this leaflet. Do not use **high** or **low** dose besides the dose recommended for you.*

What is in this leaflet:

- 1. What TIODAY is and what it is used for***
- 2. Before you use TIODAY***
- 3. How to use TIODAY***
- 4. Possible side effects***
- 5. How to store TIODAY***

1. What TIODAY is and what it is used for

- TIODAY contains Tiotropium Bromide Anhydrous as dust particles suitable for inhalation orally (via inhalation).
- TIODAY Capsair 18 mcg inhalation powder containing 30 (3x10), 60 (6x10) or 120 (12x10) capsules is provided in blister with security package, cardboard container and leaflet.
- Tiotropium is a long-acting, specific bronchodilator commonly referred to as anticholinergic in clinical medicine. It helps to open your airways and makes it easier for the air to get in and out of your lungs.
- TIODAY helps people who have chronic obstructive pulmonary disease (COPD) to breathe more easily. COPD is a chronic lung disease that causes shortness of breath and coughing. The term COPD is associated with the conditions chronic bronchitis and emphysema. As COPD is a chronic disease you should take TIODAY every day and not only when you have breathing problems or other symptoms of COPD.

Regular use of TIODAY can also help you when you have on-going shortness of breath related to your disease. It also helps you to be active longer. Daily use of TIODAY will also help to prevent short-term worsening of your COPD symptoms (exacerbation/ attack) which may last for several days.

TIODAY provides selective action on bronchia locally via inhalation when it is applied via inhalation. The bronchodilation following inhalation of Tiotropium is primarily a local effect (on the airways), not a systemic one.

TIODAY reduces the frequency of exacerbations and improves the symptoms and quality of life when it is used regularly in moderate to severe COPD (chronic obstructive pulmonary disease).

The effect of this medicine lasts for 24 hours, so you only need to take it once a day. For correct dosing of TIODAY please see section 3. How to take TIODAY and the instructions for use provided on the leaflet.

2. Before you take TIODAY

Do not use TIODAY:

If,

- You are allergic (hypersensitive) to Tiotropium or any other excipients in the TIODAY formula (See “Excipient” above)
- You are allergic (hypersensitive) to atropine or substances related to it, e.g. ipratropium or oxitropium.
- You are under 18 years.

Take special care with TIODAY in the conditions given below:

- TIODAY is indicated for long-term maintenance treatment of your chronic obstructive pulmonary disease, it should not be used to treat a sudden attack of breathlessness or wheezing (acute bronchospasm episodes).
- Immediate allergic reactions such as rash, swelling, itching, wheezing or breathlessness may occur after administration of TIODAY. If this occurs, please consult your doctor immediately.
- If you suffer from narrow angle glaucoma, prostate problems or have difficulty passing urine, using of TIODAY may result in worsening of these conditions. In this condition, please consult your doctor.
- If you have problems with your kidneys, please consult your doctor.
- Inhaled medicines such as TIODAY 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 as 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 coloured 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, please remember to pay attention to oral hygiene.
- If you have had a heart attack in the past 6 months, or have had a life-threatening / irregular rhythm disturbance in your heart over the past year or if you have severe heart failure, please talk to your doctor. In such a case, it is important to decide whether you can use TIODAY.
- Do not take TIODAY more frequently than once daily.
- You should learn the correct administration of TIODAY.

If any of the above applies to you even in the past, consult your doctor.

Pregnancy

Consult your doctor or pharmacist before using this medicine.

You should not use this medicine unless specifically recommended by your doctor.

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 medicine.

You should not use this medicine unless specifically recommended by your doctor.

Driving and using machines

The occurrence of dizziness, blurred vision, or headache may influence the ability to drive and use machinery. Avoid driving and using machinery if such conditions are present.

Important information about some of the ingredients of TIODAY

Each delivered dose contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before using this medicine.

Other medicines and TIODAY

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 Tiotropium has been taken together with other products used to treat COPD such as reliever inhalers, e.g. salbutamol, methylxanthines, e.g. theophylline and/or oral and inhaled steroids e.g. prednisolone.

Please inform your doctor or pharmacist if you are using, or have recently taken, any other medicines, even those not prescribed.

3. How to use TIODAY

Instructions for proper use, dose and frequency of use:

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 TIODAY at the same time every day. This is important because TIODAY is effective over 24 hours.

Route and method of administration:

The recommended dose is to inhale the contents of 1 capsule (18 micrograms of tiotropium) once a day. Do not use more than the recommended dose.

Use after mouth cleaning and meals.

Do not swallow capsules. Capsules are only used with inhaler device in the box. The inhaler device is specifically designed for inhalation of TIODAY, inhalation capsule.

Inhalation device (TIODAY capsules put into this device) makes a hole in the capsule provide inhalation of powder in the device.

Before use capsules, take from foil package. Make sure your fingers are dry so that the capsules do not get wet.

Do not use the capsules with any device other than the device in the box.

Keep inhalation device with you and you must have learned how to use this device properly.

Detailed information about using of device is available in the attached instruction. Please check the device that is clean and non-damaged before each using.

If you have any problems using the device, ask your doctor, nurse or pharmacist to show you how it works.

When taking TIODAY, take care not to let any of the powder enter your eyes. If any powder does get into your eyes you may get blurred vision, eye pain and/or red eyes, you should wash your eyes in warm water immediately. Then talk to your doctor immediately for further advice.

If you feel that your breathing is worsening, you should tell your doctor as soon as possible.

Different age groups:

Use in children: TIODAY is not recommended for children and adolescents under 18 years due to lack of experience.

Use in elderly: TIODAY can be used at the recommended dose in elderly with normal kidney functions.

Using of medicine should be carried out under the supervision of a wise adult for mentally ill people.

Special conditions:

Kidney failure: Patients with kidney failure can use TIODAY at the recommended dose. As with other drugs which are excreted by kidneys, patients with moderate to severe kidney failure, treated with TIODAY, should be monitored closely.

Liver failure: Patients with liver failure can use TIODAY at the recommended doses.

If you have the impression that the effect of TIODAY is either too strong or too weak, discuss this with your doctor or pharmacist.

If you use more TIODAY than you should

If you have used more TIODAY than you should, talk to your doctor or pharmacist immediately.

If you inhale from more than one dose of TIODAY in a day, you should talk to your doctor immediately. You may be at a higher risk of experiencing a side effect such as dry mouth, constipation, difficulties passing urine, increased heartbeat, or blurred vision.

If you forget to use TIODAY

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 a forgotten dose.

Effects that may occur when treatment with TIODAY is terminated

You should talk to your doctor before you stop taking TIODAY.

If you stop taking TIODAY the signs and symptoms of COPD may worsen.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

If any of the following occurs, stop using TIODAY and tell your doctor immediately and contact the emergency department of your nearest hospital:

Serious side effects include allergic reactions which cause swelling of the face or throat (angioedema) or other hypersensitivity reactions (such as sudden reduction of your blood pressure or dizziness) may occur individually or as part of severe allergic reaction (anaphylactic reaction) after administration of TIODAY. In addition, in common with all inhaled medicines, some patients may experience an unexpected tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation (bronchospasm). If any of these occur, please consult your doctor immediately

These are all very serious side effects. If one of these is present in you, then you have a serious allergy to TIODAY. You may need to be admitted to an emergency medical intervention or hospital.

All of these very serious side effects are very rare.

The incidence rates of side effects are defined as follows:

Very common: more than 1 person in 10 people.

Common: can affect up to 1 person from 10 people.

Uncommon: can affect up to 1 person from 100 people.

Rare: can affect up to 1 person from 1000 people.

Very rare: can affect up to 1 person from 10000 people.

Unknown: It cannot be predicted by moving from the available data.

The following side effects have been reported in the patients taking this medication and are reported in terms of frequency:

Common:

- Dry mouth

Uncommon:

- Dizziness
- Headache
- Disorders of taste
- Blurred vision
- Heart rate irregularities (atrial fibrillation)
- Throat inflammation (pharyngitis)
- Aphonia
- Cough
- Reflux disease
- Constipation
- Mouth infections and throat fungal infections
- Rash
- Difficulty in making urine
- Painful urination

Rare:

- Difficulty in sleeping
- See halos or colored images around lights in relation to eye flushing (Glaucoma)
- High values in eye pressure measurements
- Irregular heartbeats (supraventricular tachycardia)
- Increase in heart rate (tachycardia)
- Feeling of heartbeats (palpitations)
- Coughing, wheezing or breathlessness (bronchospasm) with compression of the chest immediately after inhalation,
- Nose bleeding
- Inflammation of the throat (laryngitis)
- Inflammation of the sinuses (sinusitis)
- Obstruction of intestines or absence of bowel movements
- Inflammation of the gums
- Inflammation of the tongue

- Swallowing difficulty
- Inflammation in the mouth
- Nausea
- Hypersensitivity reactions, including sudden onset
- Serious allergic reaction leading to swelling of face or throat (angioedema)
- Rash
- Itching
- Urinary tract infection

Unknown:

- Discharge water from the body
- Tooth decay
- Severe allergic reaction (anaphylactic reaction)
- Infections or ulcers on skin
- Skin dehydration
- Swelling in joints

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

5. How to store TIODAY

Keep TIODAY out of the reach and sight of children and its package.

Store at room temperature below 25°C.

Use properly according to the expiry date.

Do not use TIODAY after the expiry date.

The expiry date refers to the last day of that month.

If you realize any defect in its package and/or in the product, do not use TIODAY

Manufacturer:

Neutec İnhaler İlaç San. ve Tic. A.Ş.

Sakarya 1. OSB. 2. Yol No:3

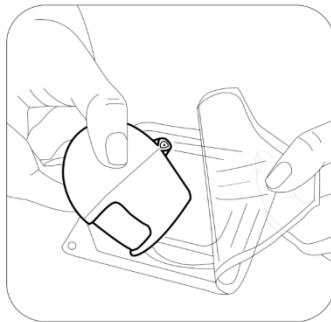
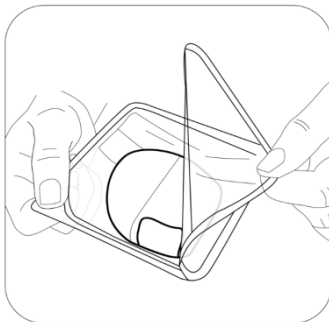
Arifiye / SAKARYA / TURKEY

Instructions for correct use of inhalation device:

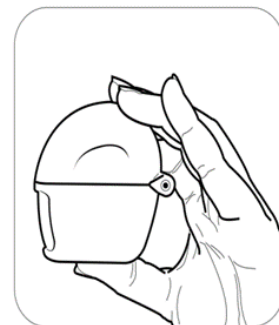
Inhaler device which is launched in the cardboard within the protective packaging for safety purposes.



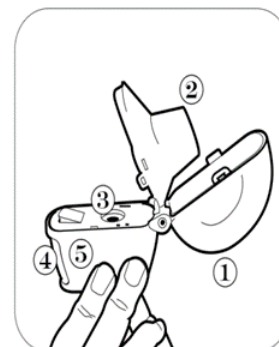
Please take out your device from the package before using as shown at figure.



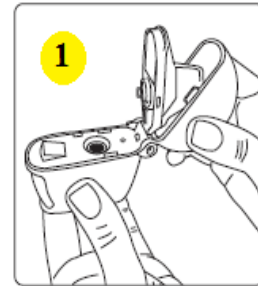
While using TIODAY, please do not forget to follow the instructions of your doctor carefully. The inhaler device is specifically designed for inhalation of TIODAY, inhalation capsule. It should not be used to take another drug.



1. Powder cap
2. Mouthpiece
3. Central reservoir
4. Drill button
5. Bottom reservoir



1. Pulling the dust head up
ensure that the mouthpiece is fully opened.



2. Take a TIODAY inhalation capsule from blister package
(It is important that you take the capsule from the blister pack only immediately before you use it.) and as shown at figure 2, place it in the central reservoir. It does not matter direction of the capsule in the reservoir.



3. Close the mouthpiece tightly until it clicks.
Close as shown figure 3 to avoid pinching when you close the device. Leave the dust cap open.



4. Keep the inhaler device upright and push the drilling button only a single motion and leave. Thus holes will be opened in the capsule and will allow the drug to be released when you breathe.



5. Breathe out fully.

Important: please never breathe into the mouthpiece.



6. Lift the inhalation device up to your mouth and close your lips tightly around the mouthpiece. Take a slow and deep breath by holding your head upright; adjust your breathing rate to hear or feel the capsule vibrating.



Inhale until your lungs are full; hold your breath for a period of time and remove the inhalation device from your mouth.

Then breathe normally. Repeat steps 5 and 6 to empty capsule

7. Open the mouthpiece again. Turn the device and throw the used capsule. To clean dusts in the inside, use a dry soft tissue or a clean soft brush. Close the mouthpiece and dust cap and leave your device.



NOTE: DO NOT USE WATER to clean the inhaler device.

The capsules should not be exposed to extreme temperatures.

TIODAY inhaler capsules contain a small amount of dust, so capsules are only partially filled.

Questions and answers about the application

1. How do I prevent the capsules from breaking into small particles?

During device use, the capsules may break and small particles may escape into your mouth or throat while breathing. You can prevent this by applying the following:

- Holding the capsules in their original packaging (blister packages) before use.
- By storing the capsules at room temperature below 25°C.
- Protect the capsules from moisture.

2. Are capsule particles harmful?

No. The capsule is made of non-harmful edible gelatin. The gelatin particles that slip down to your mouth or throat can be swallowed.

3. How do I remove the capsule stuck in the capsule compartment?

Open the device, turn it upside down, and gently tap the bottom.

4. How do I know if I really took the dose?

- When you breathe through the device, you will detect that the capsule vibrates.
- You will feel the 'sugar taste' from lactose in your mouth. You may feel dust in the back of your throat. This is normal.
- When the dose is taken, the capsule will be empty.

5. How do I clean the dust inside the device?

- Use a dry tissue or a soft brush.
- Keep in mind that you should never wash the device.