



Tio-Toriva[®]

Tiotropium 18 mcg

◆ What Tio-Toriva[®] is and what it is used for

Chronic obstructive pulmonary disease (COPD) is an irreversible obstruction of the respiratory airways, causing progressive and persistent airflow limitation in the lungs. It is the most common cause of death and disability related to respiratory diseases and ranks as the fourth leading cause of mortality worldwide. COPD is a widespread disease, expanding in various parts of the world each year.

Tio-toriva[®] dry powder inhaler capsule (DPI) contains tiotropium bromide, which is a long-acting bronchodilator (long-acting anticholinergic) used as a maintenance treatment for bronchospasm in COPD, including chronic bronchitis and emphysema.

Furthermore, Tiotropium is a long-acting antimuscarinic agent (LAMA) widely recognized as an anticholinergic in the respiratory tract. This medication administered its pharmacological effects by inhibiting M3 receptors in smooth muscles, leading to bronchodilation.

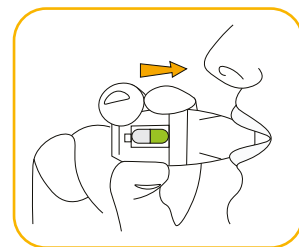
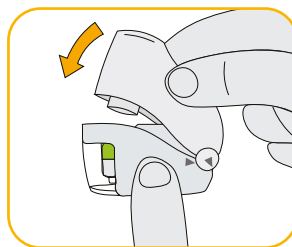
The bronchodilation that occurs after inhaling tiotropium is a localized, site-specific mechanism.

Pharmacokinetics: The drug is partially absorbed from the gastrointestinal tract. The bioavailability of the drug following inhalation of the dry powder is approximately 19.5% and it binds to plasma proteins to an extent of about 72%. The half-life of the drug is 5-6 days.

◆ Dosage and administration

Tio-toriva[®] is intended for oral inhalation only and is available as a dry powder inside capsules (DPI). It should be administered using a specialized powder inhaler device (Capsulizer[®]).

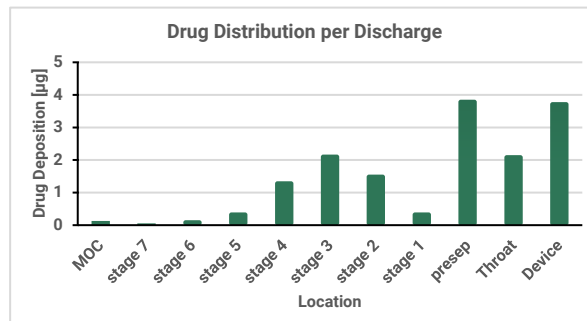
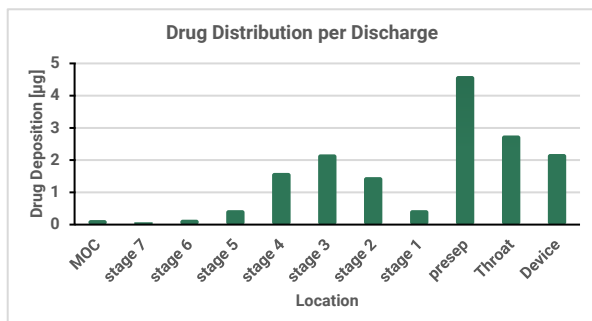
The recommended dosage of tiotropium bromide is inhaling the content of one capsule (18 micrograms of tiotropium) using the specialized powder inhaler device (Capsulizer[®]) once daily at a specific time.



◆ Clinical studies

In-vitro lung deposition study

The lung deposition of tiotropium from Spiriva capsule (as the brand product) and Tio-toriva[®] dry powder inhaler capsule was evaluated by NGI apparatus in in-vitro environment. The results of this study have been shown in the figure.



Trough (pre-dose) FEV1 Mean Values at Each Time point

The results of the aerosolization index analysis have been shown in the table.

No.	Tio-Toriva [®]			Spiriva		
	1	2	3	1	2	3
FPD (µg)	4.97	4.3	4.84	4.54	4.39	4.08
FPF (%)	35.89	35.38	33.48	38.04	25.96	39.19
MMAD (µm)	3.35	3.56	3.56	3.57	3.65	3.27
GSD	1.78	1.71	1.69	1.69	1.61	1.87

Results of Aerosolization Indexes Analysis

◆ Special features of Tio-toriva®

Tiotropium is considered a gold standard and the primary target for COPD treatment compared to other drugs in this category. Tio-toriva® DPI capsules are packaged in the HDPE bottle. The tin lid of the Tio-toriva® inhalation capsule packaging contains silica gel. Silica gel acts as a potent moisture absorbent, preventing the least moisture from penetrating the capsules, ensuring that the remaining formulation remains in the form of dry powder, which ensures the drug dosage is delivered properly and completely. The capsule shells are designed to be moisture-resistant, making them usable in any climate, including humid and moist regions. In the formulation of Tio-toriva®, the minimum volume of excipients is used compared to the brand sample, resulting in minimal patient sensitivity to these excipients.

◆ Contraindications

If you are sensitive to atropine, its derivatives, ipratropium, or any of the drug formulation components in the Tio-toriva® spray, it may cause blurred vision. Therefore, make sure you are alert before driving or operating machinery. Avoid consuming alcohol during the course of treatment with this medication. The use of Tio-toriva® is not recommended for children under six years of age.

◆ Drug interactions

Tio-toriva® may interact with other anticholinergics such as atropine and ipratropium.

◆ Side effects

After using Tio-toriva® capsules, you may experience dry mouth, constipation, or dizziness. If these side effects persist or worsen, please inform your relevant physician.

◆ Precautions and warnings

If you have glaucoma, kidney problems, prostate issues, or difficulty urinating, use Tio-toriva® with caution and consult a doctor. Air Travel: Patients with COPD may experience hypoxia during air travel. Any patient with a blood oxygen saturation level above 92% and an FEV1 greater than 50% can tolerate air travel; otherwise, they should be referred for further evaluation at higher altitudes.

◆ Pregnancy and lactation

During pregnancy, Tio-toriva® is classified as Category C, meaning there is limited information available about its safety during pregnancy. As for breastfeeding, it is unclear whether tiotropium is excreted in breast milk or if it affects nursing infants. Therefore, if you are breastfeeding, it should be used with caution. It is essential to consult with your healthcare provider before using this medication during pregnancy or while breastfeeding to weigh the potential risks and benefits.

◆ Storage condition

Tio-toriva® should always be stored in the HDPE bottle and removed immediately before use. The drug should be used immediately after the packaging over an individual Tio-toriva® DPI capsule is opened.

◆ Packaging

The packaging contains a bottle with 30 inhalation capsules of tiotropium bromide dry powder. It is essential to store the medication properly to maintain its effectiveness and safety.

◆ Product code

Tamin: 04189
Salamat: 70262

**First Iranian
Dry Powder Inhaler (DPI)
Manufacturer**



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