

KP-Tiova Inhalation capsules

1. Brand Name

KP-Tiova

2. Generic name

Tiotropium bromide monohydrate

3. Dosage Form

Dry powder for Inhalation in hard capsules: 18 mcg

4. Indication & Usage

Tiotropium is a long-acting, antimuscarinic agent, which is often referred to as an anticholinergic. It has similar affinity to the subtypes of muscarinic receptors, M1 to M5.

KP-Tiova Inhaler is indicated in the maintenance treatment of bronchospasm associated with COPD, including chronic bronchitis and emphysema.

5. Dosage & Administration

The recommended dosage of KP-Tiova is one inhalation capsule once daily, using the Cipla Revolizer.

No dosage adjustment is required for geriatric, hepatically-impaired, or renally-impaired patients. However, patients with moderate to severe renal impairment, who are being treated with No dosage adjustment is required for geriatric, hepatically-impaired, or renally-impaired patients. However, patients with moderate to severe renal impairment, who are being treated with KP-Tiova, should be monitored closely.

KP-Tiova capsules are for inhalation only and must not be swallowed.

Adverse reactions

Many of the listed undesirable effects can be assigned to the anticholinergic properties of tiotropium.

In patients with COPD, the common ($\geq 1/100$ to $< 1/10$) adverse reaction includes dry mouth; the uncommon ($\geq 1/1,000$ to $< 1/100$) adverse reactions include dizziness, headache, taste disorders, blurred vision, atrial fibrillation, cough, pharyngitis, dysphonia, constipation, gastroesophageal reflux disease, oropharyngeal candidiasis, rash, dysuria and urinary retention; rare ($\geq 1/10,000$ to $< 1/1,000$) adverse reactions include insomnia, glaucoma, increased intraocular pressure, supraventricular tachycardia, tachycardia, palpitations, bronchospasm, epistaxis, laryngitis, sinusitis, intestinal obstruction, including ileus paralytic, gingivitis, glossitis, dysphagia, stomatitis, nausea, urticaria, pruritus, hypersensitivity (including immediate reactions), angioedema and urinary tract infection; not known (cannot be estimated from the available data) adverse reactions include: dehydration, dental caries, anaphylactic reaction, skin infection, skin ulcer, dry skin, joint swelling.

In controlled clinical studies, the commonly observed undesirable effects were anticholinergic undesirable effects such as dry mouth which occurred in approximately 4% of patients.

Serious undesirable effects consistent with anticholinergic effects include glaucoma, constipation and intestinal obstruction including ileus paralytic as well as urinary retention.

An increase in anticholinergic effects may occur with increasing age.

6. Contraindications

KP-Tiova is contraindicated in patients with a history of hypersensitivity to tiotropium, atropine or its derivatives, including ipratropium, or to any component of this product.

7. Drug interactions

Although no formal drug interaction studies have been performed, tiotropium bromide has been used concomitantly with other drugs commonly used in COPD and asthma without clinical evidences of drug interactions. These include sympathomimetic bronchodilators, methylxanthines, oral and inhaled steroids, antihistamines, mucolytics, leukotriene modifiers, cromones, anti-IgE treatment. Use of LABA or ICS was not found to alter the exposure to tiotropium.

The co-administration of tiotropium bromide with other anticholinergic containing drugs has not been studied and therefore is not recommended.

8. Warnings & Precautions

KP-Tiova is intended as a once-daily maintenance treatment for COPD and are not indicated for the initial treatment of acute episodes of bronchospasm, i.e. rescue therapy. In the event of an acute attack, a rapid-acting beta2-agonist should be used.

Immediate hypersensitivity reactions may occur after administration of KP-Tiova. If such a reaction occurs, therapy with KP-Tiova should be stopped at once and alternative treatments should be considered. Given the similar structural formula of atropine to tiotropium, patients with a history of hypersensitivity reactions to atropine should be closely monitored for similar hypersensitivity reactions to KP-Tiova. In addition, KP-Tiova should be used with caution in patients with severe hypersensitivity to milk proteins.

Inhaled medicines, including KP-Tiova, may cause paradoxical bronchospasm. If this occurs, treatment with KP-Tiova should be stopped and other treatments considered.

Tiotropium should be used with caution in patients with known cardiac rhythm disorders. Tiotropium should be used with caution in patients with recent myocardial infarction < 6 months; any unstable or life threatening cardiac arrhythmia or cardiac arrhythmia requiring intervention or a change in drug therapy in the past year; hospitalization of heart failure (NYHA Class III or IV) within the past year. These patients were excluded from the clinical trials and these conditions may be affected by the anticholinergic mechanism of action.

KP-Tiova should be used with caution in patients with narrow-angle glaucoma, prostatic hyperplasia or bladder-neck obstruction. Also in general, patients should be cautioned to avoid getting the drug powder into their eyes. They should be advised that this may result in the precipitation or worsening of narrow-angle glaucoma, eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema. In such a case, patients should stop using KP-Tiova and consult a specialist immediately. Prescribers and patients should be alert for signs and symptoms of prostatic hyperplasia or bladder-neck obstruction (e.g., difficulty passing urine, painful urination). Patients should consult a physician immediately should any of these signs or symptoms develop.

As plasma concentration increases with decreased renal function in patients with moderate to severe renal impairment (creatinine clearance \leq 50 ml/min) KP-Tiova should be used only if the expected benefit outweighs the potential risk. There is no long term experience in patients with severe renal impairment. Dry mouth, which has been observed with anti-cholinergic treatment, may in the long term be associated with dental caries.

Tiotropium bromide should not be used more frequently than once daily.

9. Pregnancy & Lactation

Pregnancy Category C.

There are no adequate and well-controlled studies in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity at clinically relevant doses.

As a precautionary measure, it is preferable to avoid the use of KP-Tiova during pregnancy.

Lactation

Clinical data from nursing mothers exposed to tiotropium are not available. Based on studies in lactating rodents, tiotropium is excreted into breast milk only in small amounts. It is not known whether tiotropium is excreted into human milk, but because many drugs are excreted into human milk and given the findings in rats, caution should be exercised if tiotropium bromide is administered to a nursing mother.

10. Storage condition

Keep the container tightly closed.

Store below 25°C.

Protect from heat & moisture.

Keep out of the reach of children.

11. Packaging

Each box contains a bottle of 15 inhalation capsules.

12. License Holder

CIPLA LTD. / India

13. Marketing Authorization Holder in IRAN

Koushan Pharmed