Tioriva® Bexicap

Dry Powder Inhaler

Tiotropium Capsule

Description

Tioriva® Bexicap capsule contains Tiotropium Bromide Monohydrate BP as the active ingredient which is a long-acting, antimuscarinic agent, which is often referred to as an anticholinergic. Tioriva® is indicated as maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Indication

Tioriva® Bexicap is indicated for the long-term treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Dosage

Adult over 18 years: The recommended dose of Tioriva® Bexicap capsule is 18 μg (1 capsule) once-daily, with the device.

The contents of the Tioriva® Bexicap capsules are only for oral inhalation and should only be used with the device.

No dosage adjustment is required for geriatric, hepatically-impaired, or renally-impaired patients. However, patients with moderate to severe renal impairment given Tioriva® Bexicap capsule should be monitored closely for anticholinergic effects.

Pharmacodynamic Properties

Mechanism of Action

Tioriva® Bexicap contains Tiotropium which 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. In the airways, it exhibits pharmacological effects through inhibition of M3-receptors at the smooth muscle leading to bronchodilation. The competitive and reversible nature of antagonism was shown with human and animal origin receptors and isolated organ preparations. In preclinical in vitro as well as in vivo studies, prevention of methacholine-induced bronchoconstriction effects was dose-dependent and lasted longer than 24 hours. The bronchodilation following inhalation of Tioriva® Bexicap is predominantly a site-specific effect.

Contraindication

Tioriva® Bexicap Bromide is contraindicated in patients with a history of hypersensitivity to atropine or its derivatives, including ipratropium, or to any component of this product.

Precaution

As an anticholinergic drug, Tioriva® Bexicap may potentially worsen symptoms and signs associated with narrow-angle glaucoma, prostatic hyperplasia or bladder-neck obstruction and should be used with caution in patients with any of these conditions.

Side Effects

The most commonly reported adverse drug reaction was dry mouth. Dry mouth was usually mild and often resolved during continued treatment. Other reactions reported in individual patients and consistent with possible anticholinergic effects included constipation, increased heart rate, blurred vision, glaucoma, urinary difficulty, and urinary retention.

Pregnancy and Lactation

Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women with Tioriva® Bexicap. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The safety and effectiveness of Tioriva® Bexicap has not been studied during labor and delivery.

Drug Interactions

An interaction study with Tioriva® Bexicap (14.4 μg intravenous infusion over 15 minutes) and cimetidine 400 mg three times daily or ranitidine 300 mg once daily was conducted. Concomitant administration of cimetidine with Tioriva® Bexicap resulted in a 20% increase in the AUC0-4h, a 28% decrease in the renal clearance of Tioriva® Bexicap and no significant change in the C_{max} and amount excreted in urine over 96 hours. Co-administration of Tioriva® Bexicap with ranitidine did not affect the pharmacokinetics of Tioriva® Bexicap.

Overdose

High doses of Tioriva® Bexicap may lead to anticholinergic signs and symptoms. However, there were no systemic anticholinergic adverse effects following a single inhaled dose of up to 282 μg Tioriva® Bexicap in 6 healthy volunteers. In a study of 12 healthy volunteers, bilateral conjunctivitis and dry mouth were seen following repeated once-daily inhalation of 141 μg of Tioriva® Bexicap.

Pharmaceutical Precautions

Bexicap must not be swallowed. Only to be used with Bexihaler®. Avoid storage in direct sunlight or heat.

Store below 30°C.

Keep away from children.

Remove Bexicap capsule from the blister pack only immediately before use it in the Bexihaler as Bexicap capsule exposed to moisture may not be pierced easily.

Commercial Pack

Tioriva® Bexicap Capsule: Each box containing 30 capsules in Alu-Alu blister strips. Each Tioriva® Bexicap Capsule contains Tiotropium Bromide Monohydrate BP equivalent to Tiotropium 18 μg.

BEXIMCO PHARMA

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

TONGI, BANGLADESH 5000664 070113

® Tioriva is a registered trademark of Beximco Pharmaceuticals Ltd.