

Norvent Inhaler

Composition

Each single actuation of Norvent[®] provides: 9 micrograms of Tiotropium.

Indication

Norvent is indicated for the long-term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Pharmacology

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. In the airways, it exhibits pharmacological effects through inhibition of M₃-receptors at the smooth muscle leading to bronchodilation. The bronchodilation following inhalation of Tiotropium is predominantly a site-specific effect.

Dosage and Administration

Adults and adolescents 12 years and older:

The recommended dosage of Tiotropium bromide is the inhalation of 2 puffs of Norvent Inhaler once daily.

Contraindication

Tiotropium 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, Tiotropium 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.

As a predominantly renally excreted drug, patients with moderate to severe renal impairment treated with Tiotropium should be monitored closely.

Eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema may be signs of acute narrow angle glaucoma. Should any of these signs and symptoms develop, consult a physician immediately. Miotic eye drops alone are not considered to be effective treatment.

Side Effect

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.

Drug Interaction

Tiotropium has been used concomitantly with other drugs commonly used in COPD without increases in adverse drug reactions. These include sympathomimetic bronchodilators, methylxanthines, and oral and inhaled steroids. However, the co-administration of Tiotropium with other anticholinergic-containing drugs (e.g., ipratropium) has not been studied and is therefore not recommended.

Pregnancy & Lactation:

Pregnancy Category C

Tiotropium should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in Labor and Delivery

The safety and effectiveness of Tiotropium has not been studied during labor and delivery.

Nursing Mothers

Clinical data from nursing women exposed to Tiotropium are not available. Caution should be exercised if Tiotropium is administered to a nursing woman.

Pediatric Use

The safety and effectiveness of Tiotropium in pediatric patients have not been established.

Geriatric Use

No adjustment of Tiotropium dosage in geriatric patients is warranted.

Overdosage

High doses of Tiotropium may lead to anticholinergic signs and symptoms. Acute intoxication by inadvertent oral ingestion of Tiotropium is unlikely since it is not well-absorbed systemically.

PHARMACEUTICALS PRECAUTION

The inhaler should be stored in a dry, cool place away from direct sunlight and heat. The canister should not be broken, punctured or burnt, even when apparently empty. Keep away from eyes. Keep out of reach of children.

HOW SUPPLIED

Norvent[®] MDI

Each puff delivers 9 mcg of Tiotropium, 200 puffs.

Manufactured by:
SQUARE PHARMACEUTICALS LTD.
Bangladesh.