

Triomid®

Tiotropium
Inhalation Aerosol

INDICATIONS AND USAGE

Triomid® 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 Triomid® inhaler once daily.

CONTRAINDICATIONS

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

PRECAUTIONS

As an anticholinergic drug, Triomid® 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 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 AND LACTATION

Pregnancy Category C. Triomid® 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 Triomid® has not been studied during labor and delivery.

NURSING MOTHER

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

GERIATRIC USE

Based on available data, 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 Bromide unlikely since it is not well-absorbed systemically.

PHARMACEUTICAL PRECAUTION

The inhaler should be stored below 30°C, protected 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.

COMMERCIAL PACK

Triomid® Inhalation Aerosol : Each canister contains 120 metered doses for inhalation aerosol, single actuation delivers Tiotropium Bromide Monohydrate INN equivalent to Tiotropium 9 µg.



Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

Tongi, Bangladesh

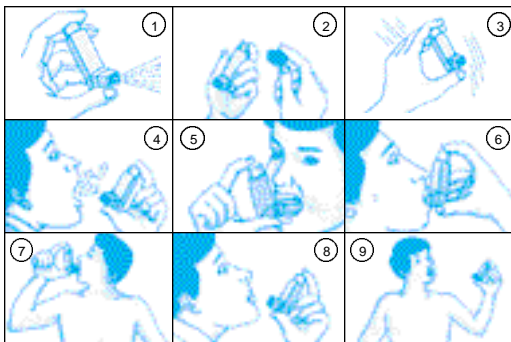
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Before using your inhaler, please read this part and follow the instructions carefully

HOW TO USE YOUR INHALER CORRECTLY



- Before using your inhaler for the first time, or if it has not been used for a week or more, 'test fire' it, i.e. release one puff into the air (Pic-1).
- Remove the mouthpiece cover, and check the mouthpiece thoroughly to see that it is clean. Shake the inhaler vigorously (Pic-2&3).
- Hold the inhaler as shown between index finger and thumb. Breathe out gently through your mouth and immediately place the mouthpiece in your mouth between your teeth (Do not bite it) (Pic-4&5).
- Grip the mouthpiece firmly with your lips. Tilt your head slightly backwards. Start breathing in slowly through your mouth. At the same time press the canister as shown, to release one dose while continuing to breathe in steadily and deeply (Pic-6&7).
- Remove the inhaler from your mouth. Hold the breath at least for 10 seconds, or as long as it is comfortable. Breathe out slowly (Pic-8&9).
- If another dose is required, wait for at least 1 minute and repeat the whole process. After use, place the cover to close the mouthpiece.

SHAKE WELL BEFORE EACH USE

How to clean your inhaler :

1. Gently pull the metal canister out of the plastic body of the inhaler, remove the mouthpiece cover.
2. Rinse the plastic body and the mouthpiece cover in warm water but do not put the metal canister into water.
3. Leave to dry in warm place, avoid excessive heat.
4. Replace the canister and the mouthpiece cover correctly.

CLEAN YOUR INHALER AT LEAST ONCE A WEEK