

## Tiotropium (Bromide Monohydrate) BP 18 mcg

**COMPOSITION**

Each capsule contains 22.5 mcg Tiotropium Bromide Monohydrate BP equivalent to 18 mcg Tiotropium.

**PHARMACOLOGY**

Tiotropium is a long acting muscarinic receptor antagonist (LAMA). It has a similar affinity to the subtypes of muscarinic receptors M<sub>1</sub>-M<sub>5</sub>. It inhibits M<sub>3</sub>-receptors at the smooth muscle in the lung resulting in relaxation of the airways.

**INDICATIONS**

Topium is indicated as a maintenance treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD).

**DOSAGE AND ADMINISTRATION**

**Route of administration :** Oral inhalation

The capsule is to be inserted into the <sup>ACME'S</sup> Easyhaler device for use. So, the capsule will be pierced and ready to be used.

**Adults:** One Rotacap once daily.

**Children:** Safety and effectiveness of Tiotropium in patients under 18 years of age has not been established.

**OR AS DIRECTED BY THE PHYSICIAN.**

**CONTRAINDICATIONS**

Tiotropium is contraindicated in patients with hypersensitivity to Tiotropium, atropine or its derivatives e.g. Ipratropium or to the excipient lactose.

**WARNING & PRECAUTIONS**

Patients should be instructed with the proper use of <sup>ACME'S</sup> Easyhaler to ensure that the drug reaches the target areas within the lungs. A capsule should only be inserted into the <sup>ACME'S</sup> Easyhaler immediately prior to use. This drug should be used with caution in patients with narrow-angle glaucoma, prostatic hyperplasia or bladder-neck obstruction. Care should also be taken in patients with moderate to severe renal or hepatic impairment.

**SIDE EFFECTS**

**Common side effects :** The side effects of Tiotropium include dry mouth, nausea, constipation, increased heart rate, blurred vision, glaucoma, urinary difficulty and headache.

**Rare side effects :** Abnormal Liver Function, angina, atrial fibrillation.

**USE IN PREGNANCY AND LACTATION**

Administration of tiotropium during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the fetus. As many drugs are excreted in human milk, caution should be exercised if this drug is administered to a nursing woman.

**USE IN CHILDREN & ADOLESCENTS**

This preparation is not indicate for children under 18 years of age.

**DRUG INTERACTION**

**With medicine:** No formal drug interaction studies have been performed. Tiotropium bromide has been used with other drugs commonly used in the treatment of COPD including sympathomimetic bronchodilators, methylxanthines, and oral and inhaled steroids without clinical evidence of drug interactions. The chronic co-administration of tiotropium with other anticholinergic-containing drug has not been studied.

**With food & others :** No data is found on interaction with food of this medicine.

**OVERDOSE**

Overdosage of Tiotropium may lead to constipation, vision disturbances or reddening of eyes.

**PHARMACEUTICAL PRECAUTIONS**

- Rotacap is to be used through <sup>ACME'S</sup> Easyhaler.
- Rotacap is not to be swallowed.
- Do not exceed the recommended dose.
- Insert the Rotacap in the <sup>ACME'S</sup> Easyhaler just prior to use, as Rotacap exposed to moisture may not be pierced easily.

**STORAGE**

Keep all medicines out of reach of children.

Store below 30° C and dry place, protected from light.

**PACKING**

Each box contains 3x10 capsules (Rotacap) in Alu-Alu blister strips.

\* Further information is available on request.



Manufactured by:

**The ACME Laboratories Ltd.**  
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For Health, Vigour and Happiness

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