

TOPIUM

Tiotropium Bromide

DESCRIPTION

Topium is a long-acting antimuscarinic bronchodilator, which is indicated as a maintenance treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD).

COMPOSITION

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

DOSAGE AND ADMINISTRATION

The capsules are intended for use with a rotahaler device. While using with the device, the capsule will be pierced and powder will be released on the screen of the device that is to be inhaled by the patient.

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 bromide, atropine or its derivatives e.g. ipratropium or to the excipient lactose.

SIDE EFFECTS

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

USE IN PREGNANCY AND LACTATION

Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the fetus. It is not known whether tiotropium is excreted in human milk, but because many drugs are excreted in human milk, caution should be exercised if this drug is administered to a nursing woman.

PRECAUTIONS

Patients should be instructed about the proper use of Rotahaler to ensure that drug reaches the target areas of the lung. 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.

PRESENTATION

Plastic pot of 30 capsules for use with Rotahaler device.

PHARMACEUTICAL PRECAUTION

Keep all medicines out of reach of children.

Store in a cool and dry place protected from light.

Rotacap is to be used through Rotahaler device.

Rotacap is not to be swallowed.

Do not exceed the recommended dose.

Keep the container tightly closed.

Insert the Rotacap in the Rotahaler just prior to use, as Rotacap exposed to moisture may not be pierced easily.

FOR HEALTH, VIGOUR AND HAPPINESS

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Dhamrai, Dhaka, Bangladesh.