

Ultivent -MTM Cozycap

Indacaterol 150 mcg, Glycopyrronium 50 mcg &
Mometasone Furoate 160 mcg

Composition:

Ultivent-MTM Cozycap: Each cozycap contains Indacaterol Acetate INN equivalent to Indacaterol 150 mcg, Glycopyrronium Bromide Ph. Eur. equivalent to Glycopyrronium 50 mcg and Mometasone Furoate BP 160 mcg .

Indication:

It is indicated as a maintenance treatment of asthma, and to reduce asthma exacerbations, in adults not adequately controlled with a maintenance combination of a long-acting β_2 -agonist and an inhaled corticosteroid.

Description:

Ultivent-MTM is an inhalation powder drug product for delivery of a combination of Indacaterol Acetate (an ultra-LABA), Glycopyrronium Bromide (an ultra-LAMA), and Mometasone Furoate (an ICS) to patients by oral inhalation.

Indacaterol:

It is an ultra-LABA. When inhaled, Indacaterol acts locally in the lung as a bronchodilator. Indacaterol is a partial agonist at the human β_2 -adrenergic receptor. In isolated human bronchus, Indacaterol has a rapid onset of action and a long duration of action.

Glycopyrronium:

It is an ultra-LAMA, which works by blocking the bronchoconstrictor action of acetylcholine on airway smooth muscle cells, thereby dilating the airways.

Mometasone Furoate:

Mometasone Furoate is a synthetic corticosteroid with high affinity for glucocorticoid receptors and local anti-inflammatory properties. In vitro, Mometasone Furoate inhibits the release of leukotrienes from leukocytes of allergic patients.

Dosage & Administration:

- For oral inhalation only, to be used with **revolizerTM** device
- One cozycap to be inhaled once daily
- Do not take more than one cozycap in a day

Contraindication:

It is contraindicated in patients with hypersensitivity to any of the active substances or excipients.

Adverse reactions:

The most common adverse reactions over 52 weeks are nasopharyngitis, upper respiratory tract infection and headache.

Manufactured by



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Precautions:

- This should not be used to treat acute asthma symptoms including acute episodes of bronchospasm.
- If any allergic reactions occur, like angioedema, urticaria, this combination should be discontinued immediately and alternative therapy is instructed.
- This combination may produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse rate, blood pressure, or symptoms. If such effects occur, treatment may need to be discontinued.
- Inhalation of high doses of β_2 -adrenergic agonists and corticosteroids may increase plasma glucose. Upon initiation of treatment with this combination, plasma glucose should be monitored more closely in diabetic patients.
- In order to reduce the risk of oropharyngeal candida infection, patients should be advised to rinse their mouth or gargle with water without swallowing it or brush their teeth after inhaling the prescribed dose.

Warning:

Cozycap must not be swallowed. Only to be used with **revolizerTM** device. Remove capsule from the blister pack only immediately before use in the **revolizerTM**.

Drug interactions:

- No specific interaction studies were conducted with this combination.
- This combination, like other medicinal products containing LABA, should be administered with caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants or medicinal products known to prolong the QT interval.
- Concomitant treatment with methylxanthine derivatives, steroids or non-potassium-sparing diuretics may potentiate the possible hypokalemic effect of LABA.
- This combination should not be given together with β_2 -adrenergic blockers.

Use in Pregnancy and Lactation:

Insufficient data on the use of this preparation in pregnant women and lactating mother.

Storage Condition:

Store below 30° C. Keep out of reach of children.

How Supplied:

Ultivent-MTM Cozycap: Each box contains 10 Cozycaps in Alu-Alu blister.