Ultivent™ Cozycap

Dry Powder Inhaler (DPI) Capsule

Glycopyrronium 50 mcg and Indacaterol 110 mcg

Composition

Each **Ultivent**™ Cozycap contains Glycopyrronium Bromide EP equivalent to Glycopyrronium 50 mcg & Indacaterol Maleate INN equivalent to Indacaterol 110 mcg.

Description

Ultivent™ Cozycap is a once daily fixed dose combination of Glycopyrronium, a long acting muscarinic receptor antagonist (LAMA) and Indacaterol, a long acting β2 receptor agonist (LABA). When Glycopyrronium & Indacaterol are administered together, they provide additive efficacy due to their different mode of action targeting different receptors and pathways to achieve bronchial smooth muscle relaxation.

Indication

Ultivent™ is indicated for the long-term once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. It should not be used in acute episodes of bronchospasm. **Ultivent**™ is not indicated for asthma.

Dosage and Administration

Ultivent™ is recommended for once-daily administration at the same time each day. **Ultivent**™ cozycap capsules must be administered only by the oral inhalation route and only using the **revolizer**™ device. **Ultivent**™ cozycap capsules must not be swallowed. If a dose is missed, it should be taken as soon as possible. Patients should not take more than one dose in a day.

Contraindications

It is contraindicated in patients with hypersensitivity to Glycopyrronium or Indacaterol, or to any other component of this combination; Patients with severe hypersensitivity to milk proteins and All LABA are contraindicated in patients with asthma without use of a long-term asthma control medication.

Side Effects

Adverse reactions that have been associated with muscarinic antagonists include cardiovascular effects (atrial arrhythmias and tachycardia), ocular disorders (e.g., blurred vision), urinary retention, gastrointestinal disorders, dry mouth and cough. Adverse reactions that have been associated with β2-agonists include immediate hypersensitivity reactions (urticaria, rash, bronchospasm, edema and angioedema), cardiovascular effects (tachycardia, arrhythmia, palpitations, myocardial ischaemia, hypertension or. hypotension), hypokalemia, hyperglycemia, headache, nervousness, insomnia, muscle spasms, fatigue, malaise and tremor.

The most common adverse drug reactions related to the drug product (reported >3% and greater than placebo) were cough and oropharyngeal pain (including throat irritation).

Use-in Special Populations

Geriatric: **Ultivent**™ can be used at the recommended dose in elderly patients (65 years of age and older).

Pediatric: The safety and efficacy of **Ultivent**™ in pediatric population under 18 years of age have not been established.

Renal impairment: **Ultivent**™ can be used at the recommended dose in patients with mild to moderate renal impairment. In patients with severe renal impairment or end-stage renal disease requiring dialysis (estimated glomerular filtration rate below 30 ml/min/1.73 m2), it should be used only if the expected benefit outweighs the potential risk.

Hepatic impairment: **Ultivent**™ can be used at the recommended dose in patients with mild and moderate hepatic impairment. There are no data available for the use of **Ultivent**™ in patients with severe hepatic impairment, therefore caution should be observed in these patients.

Warning and Precautions

Long-acting β2-adrenergic agonists may increase the risk of asthma-related serious adverse events, including asthma-related deaths, when used for the treatment of asthma. This combination should be used with caution in patients with narrow angle glaucoma or urinary retention. β2-adrenergic agonists may produce significant hypokalemia in some patients, which has the potential to produce adverse cardiovascular effects.

Administration of this combination Cozycap may result in paradoxical bronchospasm that may be life threatening. If paradoxical bronchospasm occurs, this combination Cozycap should be discontinued immediately and alternative therapy instituted. β2 receptor agonists may produce significant hypokalemia is some patients, which has the potential to produce adverse cardiovascular effects. Inhalation of high doses of β2 agonists may produce increases in plasma glucose. Upon initiation of treatment with this combination plasma glucose should be monitored more closely in diabetic patients.

Use in Pregnancy and Lactation

Pregnancy: Pregnancy category C

There are no data from the use of this combination in pregnant women available. Therefore, this combination should only be used during pregnancy if the expected benefit to the patient justifies the potential risk to the foetus.

Lactation: It is not known whether Indacaterol, Glycopyrronium and their metabolites are excreted in human milk. The use of this combination by breast-feeding women should only be considered if the expected benefit to the woman is greater than any possible risk to the infant.

Drug Interactions

No specific interaction studies were conducted for Glycopyrronium and Indacaterol combination. Information on the potential for interactions is based on the potential for each individual component. The concomitant use of Glycopyrronium and Indacaterol with β-adrenergic blockers, anticholinergics or sympathomimetic agents is not recommended.

Sympathomimetic agents may potentiate the adverse events of Indacaterol. Caution is required with the concomitant use of hypokalemic treatment.

Overdosage

There is no information on clinically relevant overdosing with this combination. An overdose could lead to exaggerated effects typical of β2-adrenergic stimulants, i.e. tachycardia, tremor, palpitations, headache, nausea, vomiting, drowsiness, ventricular arrhythmias, metabolic acidosis, hypokalemia & hyperglycaemia or could induce anticholinergic effects such as increased intraocular pressure (causing pain, vision disturbances or reddening of the eye), obstipation or difficulties in voiding.

Supportive and symptomatic treatment is indicated. In serious cases, patients should be hospitalized.

Storage condition

Store below 30ºC, keep away from light & moisture. Keep out of the reach of the children.

Pharmaceutical Precautions

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

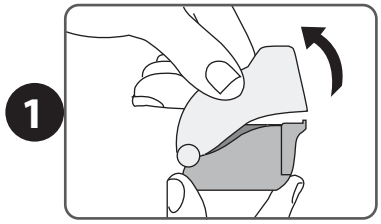
How supplied

Ultivent™ Cozycap: Each box contains 18 Cozycaps in Alu-Alu blister.

Manufactured by

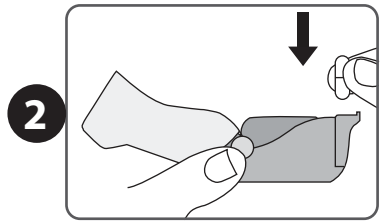
SQUARE PHARMACEUTICALS LTD. BANGLADESH

Instruction for use — revolizer™ — ব্যবহারের নিয়মাবলী



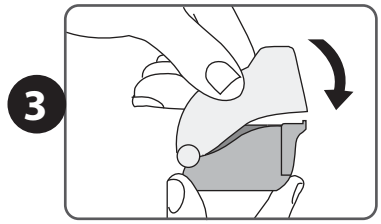
To open the **revolizer**™**,** please hold the base of the **revolizer**™ with one hand, and pull back the mouthpiece as shown.

রেভোলাইজারটি খোলার জন্য নিচের অংশটি একহাতে ধরুন এবং মাউথপিস্‌টি চিত্রানুযায়ী পিছনে টেনে নিন।



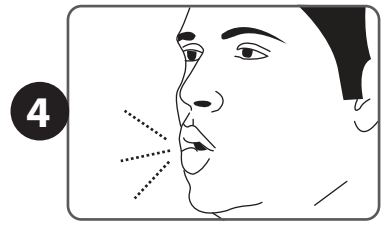
Take a cozycap from the container. Place it in the capsule chamber.

কনটেইনার থেকে একটি কোজিক্যাপ নিন। এরপর এটি ক্যাপসুল চেম্বারে স্থাপন করুন।



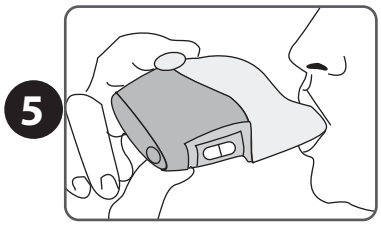
Close the mouthpiece firmly until a click sound is heard which indicates proper locking of the **revolizer**™.

রেভোলাইজারটি খোলার জন্য নিচের অংশটি একহাতে ধরুন এবং মাউথপিস্‌টি চিত্রানুযায়ী পিছনে টেনে নিন।



Breath out completely.

পুরোপুরি শ্বাস ছাড়ুন।



Raise the **revolizer**™ to your mouth and close your lips tightly around the mouthpiece. Keep your head in an upright position.

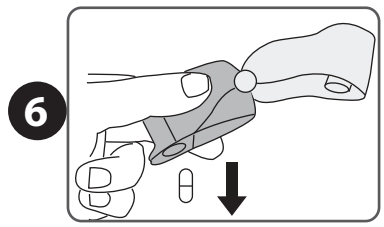
Breathe in through your mouth rapidly and deeply but at a rate sufficient to hear the cozycap vibrate. Hold your breath for 10 seconds and then resume normal breathing.

Repeat step 5 until the cozycap evacuated completely.

রেভোলাইজারটি মুখের কাছে নিন এবং আপনার ঠোঁট মাউথপিসের চারপাশে ভালভাবে বন্ধ করুন। আপনার মাথা সোজাভাবে রাখুন।

আপনার মুখ দিয়ে দ্রুত এবং গভীরভাবে এমন গতিতে শ্বাস নিন যাতে কোজিক্যাপটির কম্পনের শব্দ পাওয়া যায়। শ্বাস ১০ সেকেন্ড ধরে রাখুন এরপর স্বাভাবিকভাবে শ্বাস নিন।

কোজিক্যাপটি পুরোপুরি খালি না হওয়া পর্যন্ত পঞ্চম ধাপ পুনরায় করুন।



Open the mouthpiece again to discard the used cozycap. Close the mouthpiece and store in the pouch provided, for next use.

ব্যবহৃত কোজিক্যাপটি ফেলে দেওয়ার জন্য মাউথপিস্‌টি খুলুন। এরপর মাউথপিস্‌টি বন্ধ করে পরবর্তী ব্যবহারের জন্য সরবরাহকৃত থলেতে রেখে দিন।

Cleaning of **revolizer** ™

Clean the **revolizer**™ by wiping the mouthpiece and the capsule chamber with a dry cloth. If needed, rinse the mouthpiece and capsule chamber with clean running water.
Shake well to remove excess water and leave it to air dry.

রেভোলাইজার পরিস্কার করার নিয়মাবলী

রেভোলাইজারের মাউথপিস্‌ এবং ক্যাপসুল চেম্বারটি একটি শুকনো কাপড় দিয়ে মুছে ফেলুন।
প্রয়োজনে পরিষ্কার পানিতে মাউথপিস্‌টি এবং ক্যাপসুল চেম্বারটি ধুয়ে ফেলুন।
অতঃপর ভালো করে পানি ঝরিয়ে শুকিয়ে নিন।

Cautions :

Please avoid breathing out into your **revolizer**™.
Wash your mouth with water after every use.

সাবধানতা :

রেভোলাইজারে শ্বাস ফেলবেন না এবং ব্যবহারের পর অবশ্যই কুলি করবেন।