Beviprex™

HFA Inhaler 120 puffs

Glycopyrronium Bromide EP & Formoterol Fumarate EP

Composition
Beviprex™ HFA inhaler: Each puff delivers Glycopyrronium Bromide EP 9 mcg and Formoterol Fumarate EP 4.8 mcg through the actuator & Glycopyrronium Bromide EP 10.35 mcg and Formoterol Fumarate EP 5.52 mcg through the valve.

Indication
It is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

Pharmacology
This preparation contains two bronchodilators: Glycopyrronium is a long-acting muscarinic antagonist (LAMA) and Formoterol is a long-acting β_2-adrenergic agonist (LABA) with a rapid onset of action. Glycopyrronium has similar affinity to the subtypes of muscarinic receptors M1 to M5. In the airways, it exhibits pharmacological effects through inhibition of the M3 receptor at the smooth muscle leading to bronchodilation. Formoterol causes direct relaxation of airway smooth muscle as a consequence of the increase in cyclic AMP through activation of adenylyl cyclase.

Dosage & administration
Adults: Should be administered as 2 puffs twice daily, in the morning and in the evening.

Contraindication
All LABAs are contraindicated in patients with asthma without use of a long-term asthma control medication. This preparation is also contraindicated in patients with hypersensitivity to glycopyrronium bromide, formoterol fumarate or to any component of the product.

Adverse reactions
The most common adverse reactions include cough and urinary tract infection.

Side effects
Possible side effects are sudden breathing problems, headache, tremor, nervousness, rash, swelling of the face, mouth and tongue, hives, increase blood pressure, chest pain, irregular heartbeat, muscle spasm, muscle weakness, eye pain or discomfort and urinary retention.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH

Drug interactions
- Other adrenergic drugs may potentiate effect. Use with caution.
- Xanthine derivatives, steroids, diuretics or non-potassium sparing diuretics may potentiate hypokalemia or EDG changes. Use with caution.
- Diuretics: Use with caution.
- Monoamine oxidase inhibitors and tricyclic antidepressants: Use with extreme caution. May potentiate effect of formoterol fumarate on cardiovascular system.
- Beta-Blockers: Use with caution and only when medically necessary.
- Anticholinergics: May interact additively with concomitantly used anticholinergic medications. Avoid administrations of this combination with other anticholinergic-containing drugs.

Use in pregnancy and lactation
There are no data on the use of this preparation in pregnant women.

Warnings & precautions
- This combination should not be used with an additional medicine containing a LABA because of risk of overdose.
- Not indicated for the relief of acute bronchospasm
- Do not initiate in acutely deteriorating COPD or to treat acute symptoms
- If paradoxical bronchospasm occurs, discontinue this combination and institute alternative therapy
- Use with caution in patients with cardiovascular disorders
- Use with patients with convulsive disorders, thyrotoxicosis, diabetes mellitus and ketoacidosis.
- Be alert to hypokalemia and hyperglycemia
- Worsening of narrow angle glaucoma may occur. Use with caution with patients with narrow-angle glaucoma
- Worsening of urinary retention may occur. Use with caution with patients with prostatic hyperplasia or bladder-neck obstruction.

Use in specific population
Use in patients with severe renal impairment should be considered if the potential benefit of the treatment outweighs the risk.

Storage
Do not store above 30°C. Do not expose to temperatures higher than 50°C. Do not pierce the pressurized container. Keep out of the reach of the children.

How supplied
Beviprex™ HFA Inhaler: Each Inhaler delivers 120 puffs.