

Vilanterol + Fluticasone Furoate

Composition

Bihale 25/100 Rotacap : Each capsule contains Vilanterol 25 mcg as Vilanterol Trifenatate INN and Fluticasone Furoate BP 100 mcg.

Bihale 25/200 Rotacap : Each capsule contains Vilanterol 25 mcg as Vilanterol Trifenatate INN and Fluticasone Furoate BP 200 mcg.

Pharmacology

Bihale Rotacap is a combination of Vilanterol and Fluticasone Furoate. Vilanterol is a long acting β_2 -agonist (LABA). The pharmacologic effects of beta-adrenoceptor agonist drugs, including Vilanterol are at least in part attributable to stimulation of intracellular adenylyl cyclase, the enzyme that catalyzes the conversion of adenosine triphosphate (ATP) to cyclic 3',5' adenosine monophosphate (cyclic AMP). Increased cyclic AMP levels cause relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from cells, especially from mast cells. Fluticasone Furoate is a synthetic trifluorinated corticosteroid with anti-inflammatory activity. Corticosteroids have been shown to have a wide range of actions on multiple cell types and mediators involved in inflammation. Specific effects of Fluticasone Furoate demonstrated in *in vitro* and *in vivo* models included activation of the glucocorticoid response element, inhibition of pro-inflammatory transcription factors such as NF κ B. These anti-inflammatory actions of corticosteroids may contribute to their efficacy.

Indications

Bihale Rotacap is indicated for-

- Treatment of Asthma in patient aged 12 years and older
- Maintenance treatment of Chronic Obstructive Pulmonary Disease (COPD)

Bihale Rotacap is not indicated for the relief of Acute Bronchospasm.

Dosage and Administration

- **Route of administration** : For oral inhalation only.

The capsule is to be inserted into the ^{ACME}Easyhaler device for use. So, the capsule will be pierced and ready to be used.

- **Special instruction** : Bihale Rotacap should be used at the same time every day. Do not use Bihale Rotacap more than 1 time every 24 hours. After inhalation, the patient should rinse the mouth with water without swallowing to reduce the risk of oropharyngeal candidiasis.

- **Dosage:**

Asthma: 1 Rotacap of Bihale 100/25 or Bihale 25/200 once daily.

Maintenance treatment of COPD: 1 Rotacap of Bihale 25/100 once daily.

OR AS DIRECTED BY THE PHYSICIAN.

Contraindication

This combination is contraindicated in patients with known hypersensitivity to vilanterol and fluticasone furoate or any components of this product. It is also contraindicated in patients with primary treatment of status asthmaticus or other acute episodes of COPD or asthma where intensive measures are required.

Warning & Precaution

- Do not initiate in acutely deteriorating COPD or asthma. Do not use to treat acute symptoms.
- Do not use in combination with an additional medicine containing a LABA because of risk of overdose.
- Increased risk of pneumonia in patients with COPD. Need to monitor patients for signs and symptoms of pneumonia.
- Potential worsening of infections (e.g., existing tuberculosis; fungal, bacterial, viral or parasitic infections; ocular herpes simplex). Use with caution in patients with these infections.
- More serious or even fatal course of chickenpox or measles can occur in susceptible patients. There is risk of impaired adrenal function when transferring from systemic corticosteroids. Taper patients slowly from systemic corticosteroids if transferring to this combination.
- Hypercorticism and adrenal suppression may occur with very high doses or at the regular dose in susceptible individuals. If such changes occur, discontinue this combination slowly.
- If paradoxical bronchospasm occurs, discontinue this combination and institute alternative therapy.
- Use with caution in patients with cardiovascular disorders because of beta-adrenergic stimulation. Assess for decrease in bone mineral density initially and periodically thereafter.

- Glaucoma and cataracts may occur with long term use of ICS. Consider referral to an ophthalmologist in patients who develop ocular symptoms or use this combination long term.

- Use with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus and ketoacidosis. Increased blood glucose levels have been reported. Also be alert to hypokalemia.

Side Effects

Most common side effects are Nasopharyngitis, Upper Respiratory Tract Infection, Headache, Oral Candidiasis, Back Pain, Pneumonia, Bronchitis, Sinusitis, Cough, Oropharyngeal Pain, Arthralgia, Hypertension, Influenza, Pharyngitis, Dysphonia and Pyrexia.

Use in Specific Population

Pregnancy & Lactation: Bihale is not usually recommended for use during pregnancy. It is not known if Bihale may harm unborn baby or not. There is no information available on the presence of fluticasone furoate, or Vilanterol in human milk; the effects on the breastfed child or the effects on milk production.

Use in Children & Adolescents

The safety and efficacy in pediatric patients (aged 11 years and younger) have not been established.

Geriatric use : No adjustment of the dosage of this combination in geriatric patients is necessary, but greater sensitivity in some older individuals cannot be ruled out.

Hepatic impairment : Use this combination with caution in patients with moderate or severe hepatic impairment.

Renal impairment : No dosage adjustment is required in patients with renal impairment.

Drug Interaction

With Medicine : When used with strong cytochrome P450 3A4 inhibitors (e.g., Ketoconazole), it may cause systemic corticosteroid and cardiovascular effects. When used with monoamine oxidase inhibitors and tricyclic antidepressants, use with extreme caution because it may potentiate effect of Vilanterol on vascular system. Use cautiously when used with beta-blockers, because it may block bronchodilatory effects of beta-agonists and produce severe bronchospasm. Electrocardiographic changes and/or hypokalemia associated with non-potassium sparing diuretics may worsen with concomitant beta-agonists.

With food & others : Not applicable.

Overdose

No human overdose data has been reported for this combination. Treatment of overdose consists of discontinuation of this combination together with institution of appropriate symptomatic and/or supportive therapy. The judicious use of a cardioselective beta receptor blocker may be considered, bearing in mind that such medicine can produce bronchospasm. Cardiac monitoring is recommended in cases of overdose.

Pharmaceutical Precautions

- Rotacap is to be used through ^{ACME}Easyhaler.
- Rotacap is not to be swallowed.
- Do not exceed the recommended dose.
- Insert the Rotacap in the ^{ACME}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

Bihale 25/100 Rotacap : Each box contains 3x10 capsules (Rotacap) in Alu-Alu blister.

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* Further information is available on request.



Manufactured by:

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For Health, Vigour and Happiness