

W=100 mm

Rebreath

Nebulizer Solution

Revefenacin INN

Composition

Each Ampoule of Rebreath contains 3 ml isotonic, transparent nebulizer solution that contains Revefenacin INN 175 mcg.

Pharmacology

Revefenacin is a long acting muscarinic antagonist (LAMA), which is often referred to as an anticholinergic. It has similar affinity to the subtypes of muscarinic receptor M₁ to M₅. In the airways, it exhibits pharmacological effects through inhibition of M₃ receptor at the smooth muscle leading to bronchodilation.

Indication

Rebreath nebulizer solution is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

Dosage and Administration

Route of administration: Inhalation nebulizer Solution

It is for long-term use and should be taken one ampoule once daily with nebulizer to improve symptoms of COPD for better breathing.

OR AS DIRECTED BY THE PHYSICIAN.

Contraindications

Rebreath is contraindicated in patients with hypersensitivity to revefenacin or any component of this product.

Warning and Precautions

Do not initiate Rebreath nebulizer Solution in acutely deteriorating COPD or to treat acute symptoms. If paradoxical bronchospasm occurs, discontinue Rebreath nebulizer solution and institute alternative therapy. Worsening of narrow- angle glaucoma may occur. Use with caution in patients with narrow-angle glaucoma and instruct patients to contact a healthcare provider immediately if symptoms occur.

Worsening of urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction and instruct patients to contact a healthcare provider immediately if symptoms occurs.

Immediate hypersensitivity reactions may occur. If such a reaction occurs, therapy with Rebreath nebulizer solution should be stopped at once and alternative treatments should be considered.

Side effects

Common side effects: Cough, runny nose, upper respiratory tract infection, headache

Serious side effects: Glaucoma, eye pain, blurred vision, painful urination, Rash, swelling of face, mouth and tongue.

Use in Pregnancy and Lactation

Rebreath should be used during labor and delivery only if the potential benefit to the patient justifies the potential risk to the fetus.

Use in Children and Adolescents

Efficacy and safety in children and adolescents under 18 years has not been established

Drug interactions

With medicine: May interact additively with concomitantly used anticholinergic medications. Avoid administration of Rebreath nebulizer solution with other anticholinergic-containing drugs.

Coadministration of Rebreath nebulizer solution with OATP1B1 and OATP1B3 inhibitors (e.g. rifampicin, cyclosporine, etc.) may lead to an increase in exposure of the active metabolite. Therefore, coadministration with Rebreath is not recommended.

With food and others: No sufficient data found.

Overdose

An overdose of Rebreath may lead to anticholinergic signs and symptoms such as nausea, vomiting, dizziness, lightheadedness, blurred vision, increased intraocular pressure (causing pain, vision disturbances, or reddening of the eye), fatigue or difficulties in voiding.

Storage

- Store below 30 °C temperature & in dry place.
- Protect from direct sunlight and temperature.
- Keep all medicines out of reach of children.

Packing

Each box contains 2 x 3 ampoules in blister packs with ampoule breakers.

Pharmaceutical Precaution

- Discard ampoule and other part after use.
- Not for oral administration or injection.

* Further information is available on request.



Manufactured by:
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For Health, Vigour and Happiness

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