Ipravent Respules

1. **Brand Name**
   Ipravent

2. **Generic name**
   Ipratropium bromide

3. **Dosage Form**
   Pressurized inhalation aerosol (Inhaler): 20 mcg/dose

4. **Indication & Usage**
   Ipravent inhaler is an anticholinergic agent indicated for the regular treatment of reversible bronchospasm associated with chronic obstructive pulmonary disease (COPD).

5. **Dosage & Administration**
   Adults (Including the Elderly)
   Usually 1 or 2 puffs, three or four times daily, although some patients may need up to 4 puffs at a time to obtain maximum benefit during early treatment

   Children (6–12 years)
   1 or 2 puffs (20 or 40 micrograms) two times daily

   Children below 6 years
   1 puff (20 micrograms) three times daily

   Shake well before each use.
   The recommended dose should not be exceeded.

6. **Adverse reactions**

The following side effects have been reported. The frequencies given below are based on clinical trials involving patients who have been treated with ipratropium bromide.

Frequencies	
Very common	≥1/10
Common	≥1/100 < 1/10
Uncommon	≥1/1,000< 1/100
Rare	≥1/10,000< 1/1,000

Very rare	< 1/10,000
Immune system disorders	
Hypersensitivity	Uncommon
Anaphylactic reaction	Uncommon
Angioedema of tongue, lips, face	Uncommon
Nervous system disorders	
Headache	Common
Dizziness	Common
Eye disorders	
Blurred vision	Uncommon
Glaucoma [(1)]	Uncommon
Intraocular pressure increased [(1)]	Uncommon
Eye pain[(1)]	Uncommon
Mydriasis[(1)]	Uncommon
Halo vision	Uncommon
Conjunctival hyperemia	Uncommon
Corneal edema	Uncommon
Accommodation disorder	Rare
Cardiac Disorders	
Increased heart rate	Rare
Palpitations	Uncommon
Supraventricular tachycardia	Uncommon
Atrial fibrillation	Rare
Respiratory, Thoracic and Mediastinal Disorders	
Cough	Common
Pharyngeal oedema	Uncommon
Dry throat	Uncommon

Bronchospasm	Uncommon
Throat irritation	Common
Paradoxical bronchospasm [2]	Uncommon
Laryngospasm	Uncommon
Gastro-intestinal Disorders	
Dryness of mouth	Common
Vomiting	Uncommon
Gastro-intestinal motility disorder e.g. Diarrhoea Constipation	Common Uncommon Uncommon
Nausea	Common
Stomatitis	Uncommon
Skin and Subcutaneous Disorders	
Skin rash	Uncommon
Pruritus	Uncommon
Urticaria	Rare
Renal and Urinary Disorders	
Urinary retention [3]	Uncommon

[1]Ocular complications have been reported when aerosolized ipratropium bromide, either alone or in combination with an adrenergic beta$_2$-agonist, has come into contact with the eyes during nebulizer therapy.

[2]As with other inhalation therapy, inhalation induced bronchoconstriction may occur with an immediate increase in wheezing after dosing. This should be treated straight away with a fast acting inhaled bronchodilator. IPRAVENT inhaler should be discontinued immediately, the patient assessed and, if necessary, alternative treatment instituted.

[3]The risk of urinary retention may be increased in patients with pre-existing urinary outflow tract obstruction.

Other side-effects that have been reported include urticaria including giant urticaria, hypotension, back pain, influenza-like symptoms, dyspepsia, bronchitis, COPD exacerbations, dyspnea, sinusitis and urinary tract infection.

Allergic-type reactions such as skin rash, angioedema including that of tongue, lips and face, urticaria (including giant urticaria), laryngospasm and anaphylactic reactions have been reported, with positive rechallenge in some cases.

7. Contraindications

IPRAVENT Inhaler should not be taken by patients with known hypersensitivity to atropine or its derivatives, or to ipratropium bromide or to any other component of the product.

8. Drug interactions

There is evidence that the administration of ipratropium bromide with beta-adrenergic drugs and xanthine preparations may produce an additive bronchodilatory effect.

9. Warnings & Precautions

IPRAVENT inhaler contains ipratropium,a bronchodilator for the maintenance treatment of bronchospasm associated with COPD and asthma and, is not indicated for the initial treatment of acute episodes of bronchospasm where rescue therapy is required for rapid response.

Caution is advocated in the use of anticholinergic agents in patients predisposed to or with narrow-angle glaucoma, or with pre-existing urinary outflow tract obstruction (e.g. prostatic hyperplasia or bladder-outflow obstruction). As patients with cystic fibrosis may be prone to gastrointestinal motility disturbances, ipratropium bromide, as with other anticholinergics, should be used with caution in these patients.

Ipratropium can produce paradoxical bronchospasm that can be life threatening. If this occurs, treatment with IPRAVENT inhaler should be stopped and other treatments considered.

Hypersensitivity reactions following the use of ipratropium bromide have been seen and have presented as urticaria, angioedema, rash, bronchospasm, oropharyngeal edema and anaphylaxis.

There have been isolated reports of ocular complications (i.e. mydriasis, increased intraocular pressure, narrow-angle glaucoma, eye pain) when aerosolized ipratropium bromide, either alone or in combination with an adrenergic beta2-agonist, has come into contact with the eyes. Thus patients must be instructed in the correct administration of IPRAVENT inhaler and warned against the accidental release of the contents into the eye. Anti-glaucoma therapy is effective in the prevention of acute narrow-angle glaucoma in susceptible individuals and patients who may be susceptible to glaucoma should be warned specifically on the need for ocular protection.

Eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema may be signs of acute narrow-angle glaucoma. Should any combination of these symptoms develop, treatment with miotic drops should be initiated and specialist advice sought immediately.

Patients should be informed when starting treatment that the onset of action of ipratropium bromide is slower than that of inhaled sympathomimetic bronchodilators.

Ipratropiumis an anticholinergic and may cause urinary retention. Therefore caution is advised when administering IPRAVENT inhaler to patients with prostatic hyperplasia, or bladder-neck obstruction.

10. Pregnancy & Lactation

Pregnancy Category B.

No adequate or well-controlled studies have been conducted in pregnant women. Because animal reproduction studies are not always predictive of human response, ipratropium bromide should be used during pregnancy only if clearly needed.

Lactation

It is not known whether ipratropium bromide is excreted in human milk. Although lipid-insoluble quaternary bases pass into breast milk, it is unlikely that the active component, ipratropium bromide, would reach the infant to an important extent, especially when taken in aerosol form. However, because many drugs are excreted in human milk, caution should be exercised when ipratropium bromide is administered to a nursing mother.

11. Storage condition

Store below 25°C.
Do not freeze.
Pressurized canister, keep away from sunlight and heat. Do not puncture, break or burn even when apparently empty.
Keep away from eyes.
Keep out of the sight and reach of children.

12. Packaging

1 inhaler in each pack containing 200 metered doses.

13. License Holder

CIPLA Ltd/ India

14. Marketing Authorization Holder in IRAN

Koushan Pharmed