Optra®

اوپٹرا

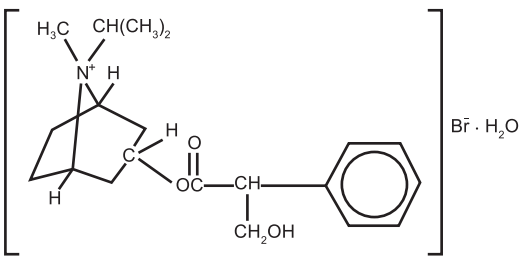
(Ipratropium Bromide)

0.025% Nebuliser Solution
500mcg/2mL

DESCRIPTION

Optra (Ipratropium Bromide) Nebulising Solution is administered by oral inhalation with the aid of a nebuliser.

Optra (Ipratropium Bromide) is a synthetic quaternary ammonium compound, chemically related to atropine. It is chemically described as (1R,3r,5S,8r)-3-[[(2RS)-3-Hydroxy-2-phenylpropanoyl]oxy]-8-methyl-8-(1-methylethyl)-8-azoniabicyclo[3.2.1]octane Bromide monohydrate. Its molecular formula is $C_{20}H_{30}BrNO_3 \cdot H_2O$ and the structural formula is:



Ipratromium Bromide Monohydrate

QUALITATIVE & QUANTITATIVE COMPOSITION

Optra (Ipratropium Bromide) Nebuliser Solution is available for administration as:

Optra Nebuliser Solution 500mcg/2mL
Each 2mL Unit Dose Vial (UDV) contains:
Ipratropium Bromide monohydrate equivalent to Ipratropium Bromide…500mcg

CLINICAL PHARMACOLOGY

Mechanism of Action

Ipratropium Bromide is an anticholinergic (parasympatholytic) agent it appears to inhibits the vagally mediated reflexes by antagonizing the action of acetylcholine, the transmitter agent released from the vagus nerve. Anticholinergics prevent the increases in intracellular concentration of Ca++ which is caused by interaction of acetylcholine with the muscarinic receptor on bronchial smooth muscle. The bronchodilation following inhalation of Ipratropium Bromide is induced by local drug concentrations sufficient for anticholinergic efficacy at the bronchial smooth muscle and not by systemic concentrations.

Pharmacokinetics

Absorption

The therapeutic effect of Ipratropium Bromide is produced by a local action in the airways. Following inhalation, 10 to 30% of a dose is generally deposited in the lungs. The major part of the dose is swallowed and passes through the gastro-intestinal tract. The portion of the dose deposited in the lungs reaches the circulation rapidly (within minutes). Based on these data the total systemic bioavailability of inhaled doses of Ipratropium Bromide is estimated at 7 to 28%.

Distribution

Ipratropium Bromide is minimally bound (less than 20%) to plasma protein. The quaternary amine of the Ipratropium ion does not cross the placental or blood-brain barrier.

Metabolism

After inhalation about 77% of the systemically available dose is metabolized by ester hydrolysis (41%) and conjugation (36%).

Excretion

Ipratropium has a mean total clearance of 2.3L/min and a renal clearance of 0.9L/min.

THERAPEUTIC INDICATIONS

Optra (Ipratropium Bromide) Nebuliser Solution is indicated as:

- The treatment of reversible bronchospasm associated with chronic obstructive pulmonary disease (COPD).
- When used concomitantly with inhaled beta$_2$-agonists, for treatment of reversible airways obstruction as in acute and chronic asthma.

DOSAGE AND ADMINISTRATION

This medicinal product is for inhalation use only. The dosage should be adapted to the individual needs of the patient. In children aged 12 years and under, only Ipratropium Bromide Nebuliser Solution 1 ml should be used. The following doses are recommended:

Adults (including the elderly) and children over 12 years of age:
250mcg – 500mcg 3 to 4 times daily.

For treatment of acute bronchospasm, 500mcg will be used.

Repeated doses can be administered until the patient is stable. The time interval between the doses may be determined by the physician. It is advisable not to exceed the recommended daily dose during either acute or maintenance treatment. Daily doses exceeding 2mg in adults and children over 12 years of age should only be given under medical supervision.

Children 6 - 12 years of age:
250mcg up to a total daily dose of 1mg. The time interval between doses may be determined by the physician.

Children 0 – 5 years of age (for treatment of acute asthma only):
125mcg – 250mcg up to a total daily dose of 1mg.

Ipratropium Bromide should be administered no more frequently than 6 hourly in children under 5 years of age.

For acute bronchospasm, repeated doses may be administered until the patient is stable.

The patient should be instructed that in the case of acute or rapidly worsening dyspnea a doctor should be consulted immediately.

The unit dose vials are intended only for inhalation with suitable nebulizing devices and should not be taken orally or administered parenterally. If necessary, the solution can be diluted with sterile sodium chloride 0.9% solution.

ADVERSE REACTIONS

Following adverse reactions have been reported with the use of Ipratropium Bromide:

Common: Headache, dizziness, cough, throat irritation, nausea, dryness of mouth and gastrointestinal motility disorder.

Uncommon: Blurred vision, mydriasis, intraocular pressure increased, eye pain, halo vision, conjunctival hyperaemia, corneal edema, glaucoma, anaphylactic reactions, hypersensitivity, angioedema of tongue, lips and face, palpitations, supraventricular tachycardia, bronchospasm, dyspnea, bronchitis, laryngospasm, pharyngeal edema, dry throat, diarrhea, constipation, vomiting, stomatitis, rash, pruritus, urinary retention and urinary tract infection.

Rare: Accommodation disorder, atrial fibrillation, heart rate increased and urticaria.

"To report SUSPECTED ADVERSE REACTIONS to Getz Pharma's Pharmacovigilance Section, please contact at dsafety@getzpharma.com or +92-21-38636363"

CONTRAINDICATIONS

Ipratropium Bromide is contraindicated in patients with:

- Hypersensitivity to Ipratropium Bromide or to any excipient of the product.
- Hypersensitivity to atropine or its derivatives.

PRECAUTIONS

Hypersensitivity Reactions, Including Anaphylaxis

Hypersensitivity reactions including urticaria, angioedema, rash, bronchospasm, anaphylaxis and oropharyngeal edema, may occur after the administration of Ipratropium Bromide. If such a reaction occurs, therapy with Ipratropium Bromide should be stopped at once and alternative treatment should be considered.

Paradoxical bronchospasm
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. Ipratropium Bromide should be discontinued immediately, the patient assessed and, if necessary, alternative treatment instituted.

Ocular complications
Caution is advocated in the use of anticholinergic agents in patients predisposed to or with narrow-angle glaucoma. 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. Care must be taken not to allow the solution or mist to enter the eyes.

Renal and urinary effects
Ipratropium Bromide should be used with caution in patients with pre-existing urinary outflow tract obstruction (e.g. prostatic hyperplasia or bladder-outflow obstruction).

Gastro-intestinal motility disturbances
As patients with cystic fibrosis may be prone to gastro-intestinal motility disturbances, Ipratropium Bromide, as with other anticholinergics, should be used with caution in these patients.

Effects on ability to drive and use machines
Patients should be advised that they may experience undesirable effects such as dizziness, accommodation disorder, mydriasis and blurred vision during treatment with Ipratropium Bromide. If patients experience the above mentioned side effects they should avoid potentially hazardous tasks such as driving or operating machinery.

Pregnancy
There are no adequate and well-controlled studies of Ipratropium Bromide in pregnant women. Ipratropium Bromide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers
It is not known whether Ipratropium Bromide is excreted into human milk. Caution should be exercised when Ipratropium Bromide is administered to a nursing mother.

DRUG INTERACTIONS
Following drug interaction have been observed with the use of Ipratropium Bromide:

The chronic co-administration of Ipratropium Bromide inhalation with other anticholinergic drugs has not been studied. Therefore, the chronic coadministration of Ipratropium Bromide with other anticholinergic drugs is not recommended.

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

The risk of acute glaucoma in patients with a history of narrow-angle glaucoma may be increased when nebulised Ipratropium Bromide and $beta_2$-agonists are administered simultaneously.

OVERDOSAGE
No symptoms specific to overdosage have been encountered. Minor systemic manifestations of anticholinergic action, including dry mouth, visual accommodation disturbances and tachycardia may occur.

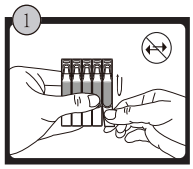
STORAGE
Do not store above 30°C.
Store unused vials in the foil pouch and carton in order to protect from light.
Do not freeze.

For nebulisation only, not to be injected.

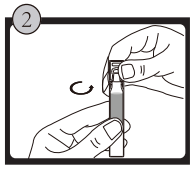
The expiration date refers to the product correctly stored at the required conditions.

HOW SUPPLIED
Optra (Ipratropium Bromide) Nebuliser Solution 500mcg/2mL is available in pack size of 10's.

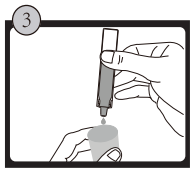
DIRECTIONS FOR USE
The ampoule should be opened immediately before use and any solution remaining after use should be discarded.



Detach a vial from the bottom.



Twist the top firmly to open the vial.



Pour the medicine into nebuliser.

Keep out of reach of children.

To be sold on prescription of a registered medical practitioner only.

Please read the contents carefully before use.
This package insert is continually updated from time to time.

Manufactured by:
Jewim Pharmaceutical (Shandong) Co., Ltd.
West of Peitianman Street, Taian Hi-Tech
Industrial Development Zone,
Shandong Province, China.

Manufactured for:
Getz pharma (PVT) LIMITED
www.getzpharma.com
29-30/27,
K.I.A., Karachi,
Pakistan