Atem® Spray

ipratropium bromide

INTRODUCTION:
Atem® Spray (ipratropium bromide) is supplied as a metered dose inhaler provided with a special actuator. Each canister contains 4.21 mg of ipratropium bromide and yields at least 200 inhalations delivering 20 µg of ipratropium bromide each. Ipratropium bromide is an anticholinergic agent which inhibits vagally mediated reflexes by antagonising the action of acetylcholine. Because of its low systemic absorption, Atem® Spray is well tolerated in the long term treatment of bronchospasm. Moreover ipratropium bromide does not affect ciliary beat frequency and the mucus clearance, nor its volume or viscosity. For this reason Atem® Spray is recommended for the treatment of patients suffering from COPD (chronic obstructive pulmonary disease). In order to be maximally effective, this medicament should be administered regularly according to your doctor prescription, and it is not intended for occasional use.

COMPOSITION
One canister contains:
Active ingredient: Ipratropium bromide monohydrate 4.21 mg equal to Ipratropium bromide 4 mg.
Excipients: sorbitan trioleate, soya lecithin, trichlorofluoromethane, dichlorodifluoromethane.
One actuation delivers 20 µg of ipratropium bromide.

THERAPEUTIC CLASSIFICATION: Antiasthmatic medicament with anticholinergic activity.

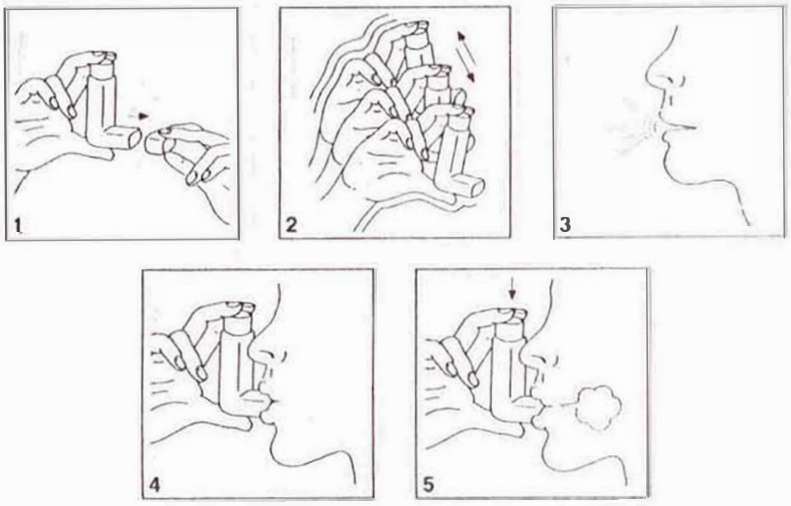
INDICATIONS AND USAGE
Atem® Spray is indicated in the treatment of bronchial asthma and chronic obstructive airways disease (COPD) with asthmatic characteristics.

CONTRAINDICATIONS
This product is not recommended in patients with glaucoma, hypertrophy of the prostate, urinary retention syndrome or intestinal occlusion, hyper-sensitivity towards atropine-like substances or known to be allergic to any of the excipients listed.

PREGNANCY AND LACTATION
There are insufficient data to support the safety of use of ipratropium bromide in pregnant women. Reproduction studies performed in animals have demonstrated no evidence of teratogenic effects as a result of ipratropium bromide. However, because animal reproduction studies are not always predictive of human response, in case of presumed or ascertained pregnancy, Atem® Spray should be administered with caution and under strict medical control. It is not known to what extent ipratropium bromide passes into breast milk. However it is unlikely that the infant would be reached to an important extent especially because Atem® Spray is administered by aerosol into the lungs. Nevertheless caution should be paid in prescribing Atem® Spray to nursing women.

PRECAUTIONS
The prescribed dose should not be modified, the doctor should be informed if the expected improvement is not achieved, so the prescribed dosage can be adjusted accordingly.
Atem® Spray should be administered with cautions in patients suffering from myocardiopathy and coronary artery disease. Should the drug accidentally be sprayed into the eyes, it may give rise to slight and reversible visual accommodation disturbances in rare cases.

DOSAGE AND METHOD OF ADMINISTRATION
Maintenance therapy: 2 puffs 3-4 times a day. In order to obtain a durable effect it is advisable to perform the prescribed actuation at regular intervals of 4 hours.
Asthma attack treatment: 2-3 puffs according to necessity, followed by a further dose after 2 hours.
One should keep in mind that the drug activity becomes evident 3-5 minutes after the administration.



Instructions for use
Efficacy of the treatment depends on the correct use of the product.
For a correct use read and follow carefully the instructions listed below:

1) *remove the protective cap;*
2) *handle the actuator putting your thumb under the mouthpiece and your forefinger and middle finger up on the canister as shown in fig.1.*
3) *shake vigorously without pushing the canister inside the actuator (fig.2);*
4) *perform a complete expiration (fig.3) and then put the mouthpiece in your mouth and close your lips firmly as shown in fig.4;*
5) *keeping the actuator in your mouth (fig. 4), inspire deeply through the mouth only while pushing down the canister with your forefinger at the same time. Be careful to push only once in order to obtain one correctly delivered puff.*
6) *afterwards hold your breath as long as possible.*

The actuator should be kept clean. To clean the device take the canister out of the plastic sleeve and rinse the mouthpiece with warm water. Replace the protective cap on the mouthpiece and the canister inside the plastic sleeve.

UNDESIRABLE EFFECTS
Because of the low therapeutic doses, systemic side effects are extremely unlikely.
The most common adverse reactions recorded are dryness of the oropharynx, cough, nausea, dizziness, blurred vision/difficulty in accommodation. Other adverse reactions possibly due to ipratropium bromide have been less frequently recorded: tachycardia, drowsiness, urinary retention, constipation, mucosal ulcers. If you notice any other unusual or unexpected symptoms you should consult your doctor or tell the pharmacist.

PACKAGING
Pressurised aluminium canister and metering valve provided with a special actuator, for oral use only. Each canister provides at least 200 actuations.

STORAGE
This medicine is contained in a canister under pressure. Do not pierce, do not freeze or expose the canister to the direct sunlight, keep away from heat sources even when empty. To be stored at a temperature below 30°C.

DO NOT USE THIS MEDICAMENT BEYOND THE EXPIRY DATE INDICATED ON THE PACKAGE

THIS DATE REFERS TO THE PRODUCT CORRECTLY STORED IN ITS UNOPENED PACKAGE

TO BE SOLD UNDER MEDICAL PRESCRIPTION ONLY

KEEP OUT OF THE REACH OF CHILDREN