

Spiriva Respimat (tiotropium bromide) - Drug Summary

Boehringer Ingelheim Pharmaceuticals, Inc.

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Spiriva Respimat
(tiotropium bromide)

THERAPEUTIC CLASS

Anticholinergic

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Chronic Obstructive Pulmonary Disease

Long-Term Maint Treatment of Bronchospasm/Reduction of Exacerbations:

5mcg (2 inh; 2.5mcg/actuation) qd

Max: 1 dose (2 inh)/24 hrs

Asthma

Long-Term Maint Treatment:

2.5mcg (2 inh; 1.25mcg/actuation) qd

Max: 1 dose (2 inh)/24 hrs

Max benefits in lung function may take up to 4-8 weeks of dosing

PEDIATRIC DOSAGE & INDICATIONS

Asthma

Long-Term Maint Treatment:

≥12 Years:
2.5mcg (2 inh; 1.25mcg/actuation) qd

Max: 1 dose (2 inh)/24 hrs

Max benefits in lung function may take up to 4-8 weeks of dosing

ADMINISTRATION

Oral inh route

Priming

First-Time Use:

Actuate the inhaler toward the ground until an aerosol cloud is visible and repeat the process 3 additional times.

If Not Used for >3 Days:

Actuate the inhaler once.

If Not Used for >21 Days:

Actuate the inhaler until an aerosol cloud is visible and repeat the process 3 additional times.

HOW SUPPLIED

Spray, Inh: (Tiotropium) 1.25mcg/actuation [28, 60 actuations], 2.5mcg/actuation [28, 60 actuations]

WARNINGS/PRECAUTIONS

Not for relief of acute symptoms (eg, acute episodes of bronchospasm). Immediate hypersensitivity reactions may occur; d/c and consider alternative treatments if such a reaction occurs. Closely monitor patients w/ a history of hypersensitivity reactions to atropine, or its derivatives. May cause paradoxical bronchospasm; d/c and consider other treatments, and treat immediately w/ an inhaled, short-acting β_2 -agonist. Caution w/ narrow-angle glaucoma; monitor for signs and symptoms. Caution w/ urinary retention; monitor for signs and symptoms, especially in patients w/ prostatic hyperplasia or bladder neck obstruction. Closely monitor for anticholinergic

effects in patients w/ moderate to severe renal impairment (CrCl <60mL/min).

ADVERSE REACTIONS

COPD: Pharyngitis, cough, dry mouth, sinusitis. **Asthma:** Pharyngitis, sinusitis, bronchitis, headache.

DRUG INTERACTIONS

Possible increase in anticholinergic adverse effects w/ other anticholinergic-containing drugs; avoid coadministration.

PREGNANCY AND LACTATION

Pregnancy: Category C.

Lactation: Caution in nursing.

MECHANISM OF ACTION

Anticholinergic (long-acting) bronchodilator; exhibits effects through inhibition of M₃-receptors at the smooth muscle, leading to bronchodilation.

PHARMACOKINETICS

Absorption: Absolute bioavailability (2-3%, oral sol); T_{max}=5-7 min. **Distribution:** (IV) V_d=32L/kg; plasma protein binding (72%). **Metabolism:** Liver (oxidation, conjugation) via CYP2D6 and 3A4. **Elimination:** Urine (74%, unchanged, IV); T_{1/2}=25 hrs (COPD), 44 hrs (asthma).

ASSESSMENT

Assess for hypersensitivity to drug, atropine or its derivatives, narrow-angle glaucoma, urinary retention, prostatic hyperplasia, bladder neck obstruction, renal impairment, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for hypersensitivity reactions, paradoxical bronchospasm, narrow-angle glaucoma, and other adverse reactions. Monitor for urinary retention, especially in those w/ prostatic hyperplasia or bladder neck obstruction.

PATIENT COUNSELING

Advise to d/c if paradoxical bronchospasm occurs. Instruct to consult physician immediately if any signs/symptoms of narrow-angle glaucoma and urinary retention develop. Advise not to allow the aerosol cloud to enter into the eyes. Caution about engaging in activities such as driving a vehicle or operating appliances/machinery. Instruct asthma patients that the max benefits of therapy may only be apparent after 4-8 weeks of therapy. Inform that drug is not for immediate relief of breathing problems. Instruct to administer ud.

STORAGE

25°C (77°F); excursions permitted to 15-30°C (59-86°F). Avoid freezing. After assembly, discard the inhaler at the latest 3 months after 1st use or when the locking mechanism is engaged, whichever comes 1st.

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