



# Respimat® Soft Mist™ Inhaler

Your how-to guide

- 1 Turn
- 2 Open
- 3 Press

# Preparing the Respimat® inhaler for first-time use



**1 REMOVE CLEAR BASE**

- Keep the cap closed
- Press the safety catch while pulling off the clear base with your other hand



**2 INSERT CARTRIDGE**

- Insert the cartridge
- Place the inhaler on a firm surface and push down until it clicks into place



**3 TRACK CARTRIDGE**

- Mark the check-box on the inhaler's label to track the number of cartridges
- Put the clear base back into place until it clicks



**4 TURN**

- Keep the cap closed
- Turn the clear base in the direction of the arrows on the label until it clicks (half a turn)



**5 OPEN**

- Open the cap until it snaps fully open



**6 PRESS**

- Point the inhaler towards the ground
- Press the dose-release button
- Close the cap
- Repeat steps 4-6 until a cloud is visible
- Then repeat steps 4-6 three more times

# Daily use of the Respimat® inhaler



**TURN**

- Keep the cap closed
- TURN the clear base in the direction of the arrows on the label until it clicks (half a turn)



**OPEN**

- OPEN the cap until it snaps fully open



**PRESS**

- Breathe out slowly and fully, then close the lips around the mouthpiece
- While taking in a slow, deep breath, PRESS the dose-release button; keep breathing in slowly
- Hold your breath for 10 seconds or for as long as comfortable
- Close the cap

Repeat TURN, OPEN, PRESS for a total of 2 puffs

# When to replace the Respimat® reusable cartridge

The easy-to-read dose indicator shows how many puffs remain in the cartridge:



# Cartridge replacement is straightforward

The cartridge is finished when the dose indicator shows the white arrow on a red background (as shown above). Once the cartridge is finished turn the clear base to loosen it, and remove the clear base. Pull the cartridge out of the inhaler and insert a new one as shown in 'Preparing the Respimat® inhaler for first-time use' section.

The Respimat® reusable inhaler can be used with up to 6 cartridges.

Your patient should be provided with a replacement reusable inhaler after use with 6 cartridges.

If the inhaler has not been used for:



Release one puff towards the ground to make sure the dosing system is full.



Repeat steps 4-6 of the 'Preparing the Respimat® inhaler for first-time use' section until a cloud is visible, then repeat steps 4-6 three more times.

# Reporting side effects

Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

Adverse events should also be reported to Boehringer Ingelheim Drug Safety on 0800 328 1627 (freephone).

Reference: SPIRIVA® Respimat® Summary of Product Characteristics.

## Prescribing Information (UK) SPIRIVA® RESPIMAT® (tiotropium)

Inhalation solution containing 2.5 microgram tiotropium (as bromide monohydrate) per puff. **Indication:** COPD: Tiotropium is indicated as a maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD). **Asthma:** Spiriva Respimat is indicated as add-on maintenance bronchodilator treatment in patients aged 6 years and older with severe asthma who experienced one or more severe asthma exacerbations in the preceding year. **Dose and Administration:** COPD Adults only age 18 years or over: 5 microgram tiotropium given as two puffs from the Respimat inhaler once daily, at the same time of the day. **Asthma** Adults and patients 6 to 17 years of age: 5 microgram tiotropium given as two puffs from the Respimat inhaler once daily, at the same time of the day. In adult patients with severe asthma, tiotropium should be used in addition to inhaled corticosteroids ( $\geq 800 \mu\text{g}$  budesonide/day or equivalent) and at least one controller. In adolescents (12 - 17 years) with severe asthma, tiotropium should be used in addition to inhaled corticosteroids ( $> 800 - 1600 \mu\text{g}$  budesonide/day or equivalent) and one controller or in addition to inhaled corticosteroids (400 - 800  $\mu\text{g}$  budesonide/day or equivalent) with two controllers. For children (6 - 11 years) with severe asthma, tiotropium should be used in addition to inhaled corticosteroids ( $> 400 \mu\text{g}$  budesonide/day or equivalent) and one controller or in addition to inhaled corticosteroids (200 - 400  $\mu\text{g}$  budesonide/day or equivalent) with two controllers. **Contraindications:** Hypersensitivity to tiotropium bromide, atropine or its derivatives, e.g. ipratropium or oxitropium or to any of the excipients; benzalkonium chloride, disodium edetate, purified water, hydrochloric acid 3.6 % (for pH adjustment). **Warnings and Precautions:** Benzalkonium chloride may cause wheezing and breathing difficulties; patients with asthma are at an increased risk for these adverse events. Not for the initial treatment of acute episodes of bronchospasm or for the relief of acute symptoms. Spiriva Respimat should not be used as monotherapy for asthma. Asthma patients must be advised to continue taking anti-inflammatory therapy, i.e. inhaled corticosteroids, unchanged after the introduction of Spiriva Respimat, even when their symptoms improve. Immediate hypersensitivity reactions may occur after administration of tiotropium bromide inhalation solution. Caution in patients with narrow-angle glaucoma, prostatic hyperplasia or bladder-neck obstruction. Inhaled medicines may cause inhalation-induced bronchospasm. Tiotropium should be used with caution in patients with recent myocardial infarction  $< 6$  months; any unstable or life threatening cardiac arrhythmia or cardiac

arrhythmia requiring intervention or a change in drug therapy in the past year; hospitalisation of heart failure (NYHA Class III or IV) within the past year. These patients were excluded from the clinical trials and these conditions may be affected by the anticholinergic mechanism of action. In patients with moderate to severe renal impairment (creatinine clearance  $\leq 50 \text{ ml/min}$ ) tiotropium bromide should be used only if the expected benefit outweighs the potential risk. Patients should be cautioned to avoid getting the spray into their eyes. They should be advised that this may result in precipitation or worsening of narrow-angle glaucoma, eye pain or discomfort, temporary blurring of vision, visual halos or coloured images in association with red eyes from conjunctival congestion and corneal oedema. Should any combination of these eye symptoms develop, patients should stop using tiotropium bromide and consult a specialist immediately. Tiotropium bromide should not be used more frequently than once a day. **Interactions:** Although no formal drug interaction studies have been performed, tiotropium bromide has been used concomitantly with other drugs commonly used in the treatment of COPD and asthma, including sympathomimetic bronchodilators, methylxanthines, oral and inhaled steroids, antihistamines, mucolytics, leukotriene modifiers, cromones, anti-IgE treatment without clinical evidence of drug interactions. Use of LABA or ICS was not found to alter the exposure to tiotropium. The co-administration of tiotropium bromide with other anticholinergic-containing drugs has not been studied and is therefore not recommended. **Fertility, Pregnancy and Lactation:** Very limited amount of data in pregnant women. Avoid the use of Spiriva Respimat during pregnancy. It is unknown whether tiotropium bromide is excreted in human breast milk. Use of Spiriva Respimat during breast feeding is not recommended. A decision on whether to continue/discontinue breast feeding or therapy with Spiriva Respimat should be made taking into account the benefit of breast feeding to the child and the benefit of Spiriva Respimat therapy to the woman. Clinical data on fertility are not available for tiotropium. **Effects on ability to drive and use machines:** No studies have been performed. The occurrence of dizziness or blurred vision may influence the ability to drive and use machinery. **Undesirable effects:** COPD: Common ( $\geq 1/100$  to  $< 1/10$ ) Dry mouth. Uncommon ( $\geq 1/1,000$  to  $< 1/100$ ) Dizziness, headache, cough, pharyngitis, dysphonia, constipation, oropharyngeal candidiasis, rash, pruritus, urinary retention, dysuria. Rare ( $\geq 1/10,000$  to  $< 1/1,000$ ): Insomnia, glaucoma, intraocular pressure increased, vision blurred,

atrial fibrillation, palpitations, supraventricular tachycardia, tachycardia, epistaxis, bronchospasm, laryngitis, dysphagia, gastroesophageal reflux disease, dental caries, gingivitis, glossitis, angioneurotic oedema, urticaria, skin infection/skin ulcer, dry skin, urinary tract infection. Not known (cannot be estimated from the available data): Dehydration, sinusitis, stomatitis, intestinal obstruction including ileus paralytic, nausea, hypersensitivity (including immediate reactions), anaphylactic reaction, joint swelling. **Asthma:** Uncommon ( $\geq 1/1,000$  to  $< 1/100$ ) Dizziness, headache, insomnia, palpitations, cough, pharyngitis, dysphonia, bronchospasm, dry mouth, oropharyngeal candidiasis, rash. Rare ( $\geq 1/10,000$  to  $< 1/1,000$ ): Epistaxis, constipation, gingivitis, stomatitis, pruritus, angioneurotic oedema, urticaria, hypersensitivity (including immediate reactions), urinary tract infection. Not known (cannot be estimated from the available data): Dehydration, glaucoma, intraocular pressure increased, vision blurred, atrial fibrillation, supraventricular tachycardia, tachycardia, laryngitis, sinusitis, dysphagia, gastroesophageal reflux disease, dental caries, glossitis, intestinal obstruction including ileus paralytic, nausea, skin infection/skin ulcer, dry skin, anaphylactic reaction, joint swelling, urinary retention, dysuria. Serious undesirable effects consistent with anticholinergic effects: glaucoma, constipation, intestinal obstruction including ileus paralytic and urinary retention. An increase in anticholinergic effects may occur with increasing age. Prescribers should consult the Summary of Product Characteristics for further information on undesirable effects. **Pack sizes and NHS price:** Single pack: 1 Respimat re-usable inhaler and 1 cartridge providing 60 puffs (30 medicinal doses) £23.00; Single refill pack: 1 cartridge providing 60 puffs (30 medicinal doses) £23.00. **Legal category:** POM. **MA number:** PL 14598/0084. **Marketing Authorisation Holder:** Boehringer Ingelheim International GmbH, D-55216 Ingelheim am Rhein, Germany. Prescribers should consult the Summary of Product Characteristics for full prescribing information. **Prepared in September 2019**

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