

PRESCRIBING ALERT®

Dear Healthcare Professional.

At MPR, we strive to bring you important drug information in a concise and timely manner. In keeping with this goal, we are pleased to provide you with this PRESCRIBING ALERT about QVAR* (beclomethasone dipropionate HFA) Inhalation Aerosol, a product of Teva Respiratory, LLC.

QVAR now has a built-in dose counter that helps patients keep track of their remaining doses and to know exactly when it is time to refill their prescription. PRESCRIBING ALERT highlights helpful features, efficacy information, guideline recommendations, and health plan coverage for QVAR.

Indication

QVAR* (beclomethasone dipropionate HFA) Inhalation Aerosol is indicated in the maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older. QVAR is also indicated for asthma patients who require systemic corticosteroid administration, where adding QVAR may reduce or eliminate the need for systemic corticosteroids.

Important Safety Information

• QVAR is not a bronchodilator and is not indicated for relief of acute bronchospasm

CAUTION: Adrenal insufficiency may occur when transferring patients from systemic steroids (see WARNINGS, Prescribing Information).

- A reduction in growth velocity in growing children and teenagers may occur as a result of inadequate control of chronic diseases such as asthma or from use of corticosteroids for treatment
- Common side effects associated with the use of QVAR and placebo in clinical trials include, but are not limited to, headache (12% and 9%, respectively) and pharyngitis (8% and 4%, respectively)

Please see the full Prescribing Information for QVAR.

More information about QVAR is available in the current edition of MPR.

Sincerely,

Dimpy Mehra, PharmD

Clinical Communications Specialist

Simpy Melira

MPR Custom Programs

REFERENCE

1. QVAR [prescribing information]. Horsham, PA: Teva Respiratory, LLC; May 2014.

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QVAR®

(beclomethasone dipropionate HFA) Inhalation Aerosol



Company: Teva Pharmaceuticals Pharmacologic class: Steroid

Active Ingredient: Beclomethasone dipropionate 40 mcg/inhalation, 80 mcg/inhalation metered-dose inhaler

Indication: Maintenance treatment of asthma as prophylactic therapy in patients 5 years of age or older. Asthma requiring systemic corticosteroid therapy, to reduce or eliminate need for systemic corticosteroids.

Adults: Previously on bronchodilators alone: initially 40-80 mcg twice daily; max 320 mcg twice daily. Previously on inhaled corticosteroids: initially 40-160 mcg twice daily; max 320 mcg twice daily. Rinse mouth after use.

Children: <5yrs: not recommended. 5-11yrs: initially 40 mcg twice daily; max 80 mcg twice daily. Rinse mouth after use.



Contraindications: Not for treatment of acute attacks. Warnings/Precautions: Maintain regular regimen. Infections. If exposed to chickenpox or measles, consider anti-infective prophylactic therapy. If adrenal insufficiency exists following systemic corticosteroid therapy, replacement with inhaled corticosteroids may exacerbate symptoms of adrenal insufficiency (eg, lassitude). Monitor for growth suppression in children. Monitor for hypercorticism and HPA axis suppression (if occur discontinue gradually). Transferring from systemic corticosteroids: see literature. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Adverse Reactions: Headache, pharyngitis, rhinitis, pain; rare: hypersensitivity reactions, psychiatric events and behavioral changes (especially in children).

How Supplied: Inhaler-8.7 g (120 inhalations)



QVAR® now has a dose counter to help patients keep track of remaining doses^{1,2}



OVAR® is the only asthma control inhaler with a built-in dose counter with numbers that turn red when it is time to refill1

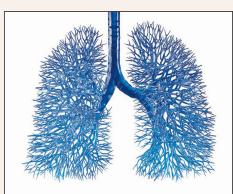
- The dose counter is located on the back of the actuator, and shows the number of actuations of medicine remaining in units of 2
- When the dose counter on the actuator says the number 20, the color of the numbers will change to red. This will remind patients to refill their prescription
- When the dose counter reaches 0, the background color will change to solid red
- The QVAR® inhaler should be thrown away as soon as the dose counter reads 0 or by the expiration date on the QVAR® inhaler package, whichever comes first



Please see full Prescribing Information and Important Safety Information.

Small airways are a vital therapeutic target for achieving asthma control³

- Uncontrolled asthma has been associated with small airway dysfunction4
- Small (distal) airways—those <2 mm in diameter-are significant sites of chronic inflammation3,5
- Inflammation-related structural changes in the small (distal) airways may have a dramatic effect on the pathogenesis and treatment of the disease3
- Chronic inflammation in small and large airways may be associated with3
 - Asthma exacerbations
 - Progressive decline in lung function in adults
 - Airway remodeling



QVAR® is a small-particle inhaled corticosteroid that targets the chronic inflammation in both the large and small airways^{6,7}

The majority of QVAR® (beclomethasone dipropionate HFA) Inhalation Aerosol was deposited in and distributed throughout the lung8,9

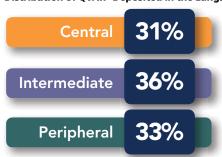
- When tracked by scintigraphy, up to 68% of QVAR® was deposited in the lung^{8,9}
 - Scintigraphy is not a valid surrogate for clinical effect

DISTRIBUTION OF QVAR® IN LUNGS

Lung Regions as Isolated for Imaging*



Distribution of QVAR® Deposited in the Lungs



The relationship of lung deposition to clinical efficacy is unknown.

*Based on an open-label study in 7 patients with mild asthma designed to determine the lung deposition and distribution of radiolabeled HFA-BDP from 2 devices, using coordinated and discoordinated techniques in the P&B inhaler. The distribution shown here is for the P&B on-time group, who were trained to actuate 0.32 sec after start of inspiration.¹⁰

HFA-BDP = hydrofluoroalkane-beclomethasone dipropionate; P&B = press and breathe.

Source: Leach 2005.10

【 VAR® (beclomethasone dipropionate HFA) Inhalation Aerosol helps provide asthma control^{1,7}

■ In a 1-year, observational, retrospective, matched-cohort analysis of the UK's General Practice Research Database for 1319 patients 5 to 60 years of age receiving a first prescription or dose increase of QVAR*11

of patients initiated on QVAR® experienced no exacerbation. The mean daily dose of QVAR® in this study cohort was within the NAEPP-estimated low daily-dose range for youths ≥12 years of age and adults11,12

An exacerbation was defined as the occurrence of one or more of the following interventions during the outcome year¹¹:

- Course of oral corticosteroids
- Hospital admission for asthma
- Emergency department attendance for asthma

[The National Asthma Education and Prevention Program (NAEPP) and the FDA list inhaled corticosteroid (ICS) monotherapy as a first-line treatment in patients with mild to moderate persistent asthma^{12,13}



[√] QVAR® has class-leading preferred health-plan coverage¹⁴

- At 93%, QVAR® has the most preferred formulary coverage among ICSs
- At 96%, QVAR® has the most covered lives among ICSs
- This could mean
 - Fewer pharmacy callbacks
 - Less hassle office staff
 - Lower copays for insured patients

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Please see full Prescribing Information

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