QVAR® RediHaler™ द्रुत की रोजगार देखने के लिए इनहेलर है, न कि संकट की स्थिति में बचाव के लिए (लेंगे से रहते दें दावा) इनहेलर। यदि इसका प्रयोग प्रतिदिन दो बार किया जाता है तो यह इनहेलर दमों के लक्षणों के मूल कारण - फेंट्रिनों के शोष - का इलाज करने के लक्षणों के प्रकट होने तथा असह्य बदने से रोकने में सहायता कर सकता है।

दाखिले के लिए कोई कैनिस्टर नहीं।
किसी चीज़ को दिखाने या भरने की अस्तित्व नहीं।

हवा के निकास

दया तभी बदर आती है जब आप साँस अंदर बीचते हैं।
यह “साँस से शक्ति” होता है।

"स्पेसर-स्कूल" हिटाउन -
स्पेसर के साथ प्रयोग करें न करें।

संग्रह सफेद ढकन

केवल मुंह द्वारा कर लेने के लिए

स्वीकार्य प्रयोग

QVAR® RediHaler™ (बिक्लोमेथासलोन डायप्लोबियलोनेट HFA) इनहेलरसंतान एरलोसलो का प्रयोग अचानक प्कट हलोने वा्े गंभीर जिसके इ्ाज के लिए न करें। अचानक प्रकट होने वाले लक्षणों के इलाज के लिए, इनहेलर के साथ संकटलक्षण इनहेलर करें।

यदि आपके डायट्रीजा में कोई प्रकार का संकट प्रकट होता है तो आपके डायट्रीजा के लिए इनहेलर का प्रयोग करें।

अपने QVAR RediHaler के प्रयोग करने के लिए QVARHowTo.com पर जाएं।

प्रयोग का तरीका

अपने QVAR RediHaler का प्रयोग करने से पहले प्रक्षेपण के नीचे दिए गए चरणों के वाद में पढ़ लें। हमेशा इसका प्रयोग अपने डायट्रीजा के निर्देश के अनुसार करें। यदि आपके मन में कोई प्रकार का संकट प्रकट होता है तो अपने डायट्रीजा के साथ संकटवाला इनहेलर से पूछ।

हर कश लेने से पहले, इनहेलर को तैयार करने के लिए सफेद ढकन को बंद करना जरूरी है अगर आपका आयु दाक्तर निर्देशों के अनुसार करें। अगर आपका चरण न भी जाए, तब तक डायट्रीजा को न बोलें।

1. इनहेलर के माउथिीस को उठाए और साँस से रखें।
2. इनहेलर को उठाए, साँस को 5 से 10 सेकंड के लिए रखें।
3. अपना अगला कश लेने के लिए इनहेलर को तैयार करने के लिए इनहेलर का प्रयोग करें।

यदि आपके डायट्रीजा ने आपका एक खुराक में एक से अधिक दे दी है तो दखल करें। अति उच्च डायट्रीजा को आपकी चरण का उपयुक्त समय तक जांच करना जरूरी है।

अपने डायट्रीजा के संबंध में दो बार QVAR RediHaler का प्रयोग सुनिश्चित करें। QVAR RediHaler का प्रयोग हुआ करने के बाद इसका लाभ महसूस करने में 3 से 4 साल लग सकते हैं। हालांकि कुछ लोग 24 घंटे के अंदर दीने के लक्षणों में बदलाव महसूस कर सकते हैं।

“How-To” वीडियो देखें

अपने इनहेलर के प्रयोग के बारे में विस्तृत जानकारी वीडियो के लिए QVARHowTo.com पर जाएं।
बदलने का समय
जब खुराक काउंटर 20 पर पहुंचेगा तो संभवतः लाल रंग का हो जाएगी जिसका अंत में यह है कि रीफ़र्स का समय आ गया है। (यदि आप बुझाने के लिए खुराक काउंटर के सुन्दर तक पहुंचाएंगे तो हो सकता है कि आपको दर्द की सही भावना न मिलेगी।)

बाद में, खुराक का 'O' दिखाए और पृथ्वी लाल रंग का हो जाए या पेपकिंग के उपर लिखी मिनार ध्वनि पड़े पर, इसमें से जो श्री पहले हों, QVAR® RediHaler™ को फिक्क दें।

QVAR RediHaler की मिनार ध्वनि ध्वनि की तारीख से पहले उसे बदल से।

महत्वपूर्ण सुरक्षा जानकारी (जारी)

- QVAR RediHaler का प्रयोग इंजेक्टर के निदान से अधिक न करें।
- अपने स्वास्थ्य देखभाल दर्जन को आपके दर्जन के अंदर अवश्य बनाएं।
- QVAR RediHaler के कारण गंभीर गौर प्रभा् हो सकते हैं।
- अपने QVAR RediHaler को अथवा उसके कक्षवी भाग को न िोएं और न ही पानी दें।

> गंभीर एलजी प्रतिकारों से निपटने के लिए QVAR RediHaler का प्रयोग बंद करें तथा फैल करें।
> दवा के विकास में कभी कभी आंखों की दिकी, जिसमें QVAR RediHaler के सपाट ज्ञात करने का विकास रूप से ज्ञात बनाए।
> हंगाम का कम ध्वनि ध्वनि है। यह समस्या आपके लिए हो सकती है जिसमें हंगामों के घनत्व के कम होने के (ऑस्टियोपोसिस) की संभावना से ही है।
> आंखों की संभावना। यदि आपने अपने आंखों की रूप से ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंखों की ज्ञात करने का आंक
QVAR® REDIHALER™ (beclomethasone dipropionate HFA) inhalation aerosol is a corticosteroid indicated for:
- Primary treatment of status asthmaticus or other acute episodes of asthma where relief of acute symptoms is required immediately. (2.1)
- Deterioration of asthma and acute episodes: Do not use QVAR REDIHALER for relief of acute symptoms. Patients require immediate re-evaluation during rapidly deteriorating asthma. (5.2)

**INDICATIONS AND USAGE**

QVAR REDIHALER is a corticosteroid indicated for:
- Treatment of asthma in patients 4 to 11 years of age: 40 or 80 mcg twice daily. (2.2)

**DOSAGE AND ADMINISTRATION**

For oral inhalation only. (2.1)
- Starting dosage is based on prior asthma therapy and disease severity. (2.2)
- Treatment of asthma in patients 4 to 11 years of age: 40 or 80 mcg twice daily. (2.2)
- Treatment of asthma in patients 12 years of age and older: 40 mcg, 80 mcg, 160 mcg, or 320 mcg twice daily (2.2)
- Discard QVAR REDIHALER inhaler when the dose counter displays 0 or after the expiration date on the product, whichever comes first. (2.1)
- Do not use a spacer or volume holding chamber. (2.1)

**DOSE FORMS AND STRENGTHS**

Breath-actuated inhalation aerosol: 40 or 80 mcg per actuation. (3)

**CONTRAINDICATIONS**

- Primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required. (4)
- Hypersensitivity to any of the ingredients of QVAR REDIHALER. (4)

**WARNINGS AND PRECAUTIONS**

- Localized infections: Candida albicans infection of the mouth and throat may occur. Advise patients periodically for signs of adverse effects on the oral cavity. Monitor patients with change in vision or with a history of increased intracranial pressure, blurred vision, glaucoma, and/or cataracts closely. (5.10)
- Deterioration of asthma and acute episodes: Do not use QVAR REDIHALER for relief of acute symptoms. Patients require immediate re-evaluation during rapidly deteriorating asthma. (5.2)

**ADVERSE REACTIONS**

Most common adverse reactions (incidence ≥3% and > placebo) include oral candidiasis, upper respiratory tract infection, nasopharyngitis, allergic rhinitis, oropharyngeal pain, and sinusitis. (6.1)

**USE IN SPECIFIC POPULATIONS**

- Pregnancy (8.1)
- Lactation (8.2)
- Females and Males of Reproductive Potential (8.3)
- Pediatric Use (8.4)
- Genitourinary Use (8.5)

**DESCRIPTION**

QVAR REDIHALER (beclomethasone dipropionate HFA) inhalation aerosol is a light, breath-actuated inhalation aerosol. (11)

**FULL PRESCRIBING INFORMATION: CONTENTS**

- 1 INDICATIONS AND USAGE
- 2 DOSAGE AND ADMINISTRATION
- 3 DOSAGE FORMS AND STRENGTHS
- 4 CONTRAINDICATIONS
- 5 WARNINGS AND PRECAUTIONS
- 6 ADVERSE REACTIONS
- 7 USE IN SPECIFIC POPULATIONS
- 8 DESCRIPTION

**FULL PRESCRIBING INFORMATION**

- 1 INDICATIONS AND USAGE
  - QVAR REDIHALER is indicated in the maintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older. (1)
  - QVAR REDIHALER is NOT indicated for the relief of acute bronchospasm. (2.1)

- 2 DOSAGE AND ADMINISTRATION
  - Administer QVAR REDIHALER by the orally inhaled route in patients 4 years of age and older. After inhalation, the patient should rinse his/her mouth with water without swallowing to help reduce the risk of oropharyngeal candidiasis. (2.1)
  - Patients should be instructed on the proper use of their inhaler. Consistent dose delivery is achieved, whether using the 40- or 80-mcg strengths, due to proportionality of the 2 products (i.e., 2 actuations of 40-mcg strength should provide a dose comparable to 1 actuation of the 80-mcg strength). (2.2)

- 3 DOSAGE FORMS AND STRENGTHS
  - Breath-actuated inhalation aerosol: 40 or 80 mcg per actuation. (3)

- 4 CONTRAINDICATIONS
  - Local Effects (5.1)
  - Deterioration of Asthma and Acute Episodes (5.2)
  - Transferring Patients from Systemic Corticosteroid Therapy (5.3)
  - Immunosuppression (5.4)
  - Paradoxical Bronchospasm (5.5)
  - Hypersensitivity Reactions (5.6)
  - Hypertocicism and Adrenal Suppression (5.7)
  - Effects on Growth (5.8)
  - Reduction in Bone Mineral Density (5.9)
  - Eye Disorders (5.10)

- 5 WARNINGS AND PRECAUTIONS
  - Localized infections: Candida albicans infection of the mouth and throat may occur. Advise patients periodically for signs of adverse effects on the oral cavity. Monitor patients with change in vision or with a history of increased intracranial pressure, blurred vision, glaucoma, and/or cataracts closely. (5.10)

- 6 ADVERSE REACTIONS
  - Most common adverse reactions (incidence ≥3% and > placebo) include oral candidiasis, upper respiratory tract infection, nasopharyngitis, allergic rhinitis, oropharyngeal pain, and sinusitis. (6.1)

- 7 USE IN SPECIFIC POPULATIONS
  - Pregnancy (8.1)
  - Lactation (8.2)
  - Females and Males of Reproductive Potential (8.3)
  - Pediatric Use (8.4)
  - Genitourinary Use (8.5)

- 8 DESCRIPTION
  - QVAR REDIHALER (beclomethasone dipropionate HFA) inhalation aerosol is a corticosteroid indicated for:
  - Patients switching to QVAR REDIHALER from another inhaled corticosteroid product, select the appropriate starting dosage strength of QVAR REDIHALER based on the strength of the previous inhaled corticosteroid.
corticosteroid product and disease severity: 40, 80, 160 or 320 mcg twice daily. For patients who do not respond adequately to the initial dosage after 2 weeks of therapy, increasing the dosage may provide additional asthma control. The maximum recommended dosage for patients 4 to 11 years of age is 80 mcg twice daily.

Pediatric Patients 4 to 11 years of age

The starting dosage is based on previous asthma therapy and disease severity, including consideration of the patients’ current control of asthma symptoms and risk of future exacerbation. The recommended starting dosage for patients aged 4 to 11 years of age is 40 mcg twice daily, approximately 12 hours apart. For patients who do not respond adequately to QVAR REDIHALER 40 mcg after 2 weeks of therapy, increasing the dosage to QVAR REDIHALER 80 mcg twice daily may provide additional asthma control. The maximum recommended dosage for patients 4 to 11 years of age is 80 mcg twice daily.

General Dosing Recommendations

The onset and degree of symptom relief will vary in individual patients. Improvement in asthma symptoms can occur within 24 hours of the beginning of treatment and should be expected within the first or second week, but maximum benefit should not be expected until 3 to 4 weeks of therapy. Improvement in pulmonary function is usually apparent within 1 to 4 weeks after the start of therapy. If a dosage regimen of QVAR REDIHALER fails to provide adequate control of asthma, the therapeutic regimen should be re-evaluated and additional therapeutic options (e.g., replacing the current strength of QVAR REDIHALER with a higher strength, or adding additional controller therapies) should be considered.

As with any inhaled corticosteroid, physicians are advised to titrate the dose of QVAR REDIHALER downward over time to the lowest level that maintains proper asthma control. This is particularly important in children since a controlled study has shown that beclomethasone dipropionate has the potential to affect growth in children. The maximum number of inhalations should not exceed 8 per day.

3 DOSAGE FORMS AND STRENGTHS

Inhalation Aerosol. QVAR REDIHALER is a pressurized, breath-actuated, metered-dose aerosol with a dose counter intended for oral inhalation containing beclomethasone dipropionate strengths:

- QVAR REDIHALER 40 mcg is supplied in an aluminum canister contained within a beige plastic actuator with a dose counter and a hinged white cap. Each breath-induced actuation delivers 50 mcg from the valve and 40 mcg from the actuator.
- QVAR REDIHALER 80 mcg is supplied in an aluminum canister contained within a maroon plastic actuator with a dose counter and a hinged white cap. Each breath-induced actuation delivers 100 mcg of beclomethasone dipropionate from the valve and 80 mcg from the actuator. QVAR REDIHALER 80 mcg is available as a 120-inhalation/10.6-g canister.

4 CONTRAINDICATIONS

4.1 Status Asthmaticus

QVAR REDIHALER is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required [see Warnings and Precautions (5.2)].

4.2 Hypersensitivity

QVAR REDIHALER is contraindicated in patients with known hypersensitivity to beclomethasone dipropionate or any of the ingredients in QVAR REDIHALER [see Warnings and Precautions (5.6)].

5 WARNINGS AND PRECAUTIONS

5.1 Local Effects

Localized infections with Candida albicans have occurred in the mouth and pharynx in some patients receiving QVAR REDIHALER. If oropharyngeal candidiasis develops, it should be treated with appropriate local or systemic (i.e., oral) antifungal therapy while still continuing with QVAR REDIHALER therapy, but at times therapy with QVAR REDIHALER may need to be temporarily interrupted under close medical supervision. After inhalation, the patient should rinse his/her mouth with water without swallowing to help reduce the risk of oropharyngeal candidiasis.

5.2 Deterioration of Asthma and Acute Episodes

QVAR REDIHALER is not indicated for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. An inhaled, short-acting beta-2 agonist (QVAR REDIHALER), should be used to relieve insufficiency when such as shortness of breath. Instruct patients to contact their physician immediately if episodes of asthma that are not responsive to bronchodilators occur during the course of treatment with QVAR REDIHALER. During such episodes, patients may require therapy with oral corticosteroids.

5.3 Transferring Patients from Systemic Corticosteroid Therapy

Particular care is needed in patients who are transferred from systemically active corticosteroids to QVAR REDIHALER because deaths due to adrenal insufficiency have occurred in asthmatic patients during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids. After withdrawal from systemic glucocorticoids, a number of months are required for recovery of hypothalamic-pituitary-adrenal (HPA) function. Patients who have been previously maintained on 20 mg or more per day of prednisone (or its equivalent) may be most susceptible, particularly when their systemic corticosteroids have been almost completely withdrawn. During this period of HPA suppression, patients exhibit signs and symptoms of adrenal insufficiency when exposed to trauma, surgery, or infections (particularly gastrointestinal) or other conditions with severe electrolyte loss. Although QVAR REDIHALER may provide control of asthmatic symptoms during these episodes, in recommended doses it supplies less than normal physiological amounts of glucocorticoid systemically and does not provide the mineralocorticoid that is necessary for coping with these emergencies. During periods of stress or a severe asthmatic attack, patients who have been withdrawn from systemic corticosteroids should be instructed to resume oral corticosteroids (in large doses) immediately and to contact their physician for further instruction. These patients should also be instructed to carry a warning card indicating that they may need supplementary systemic steroids during periods of stress or a severe asthma attack. Transfer of patients from oral corticosteroids to less systemically available inhaled corticosteroids can reduce bone mass (e.g., anticonvulsants and corticosteroids) should be monitored for such reactions occur [see Contraindications (4.2)].

5.4 Immunosuppression

In such patients who have not had these diseases or been properly immunized, particular care should be taken to avoid exposure. It is not known how the dose, route of administration, duration of treatment and the underlying clinical condition may influence the development of disseminated infection, and nor is the contribution of the underlying disease and/or prior corticosteroid treatment known. If exposed to chickenpox, prophylaxis with varicella-zoster immune globulin (VZIG) may be indicated. If exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be indicated (See the respective package inserts for complete VZIG and IG prescribing information.) If chickenpox develops, treatment with antiviral agents may be considered.

Inhaled corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculosis infection of the respiratory tract; untreated systemic fungal, bacterial, parasitic or viral infections; or ocular herpes simplex.

5.5 Paradoxical Bronchospasm

Inhaled corticosteroids may produce inhalation-induced bronchospasm with an immediate increase in wheezing after dosing that may be life-threatening. If inhalation induced bronchospasm occurs following dosing with QVAR REDIHALER, it should be treated immediately with an inhaled, short-acting bronchodilator. Treatment with QVAR REDIHALER should be discontinued and alternate therapy instituted.

5.6 Immediate Hypersensitivity Reactions

Hypersensitivity reactions, such as urticaria, angioedema, rash, and bronchospasm, may occur after administration of QVAR REDIHALER. Discontinue QVAR REDIHALER if such reactions occur [see Contraindications (4.2)].

5.7 Hypercorticism and Adrenal Suppression

QVAR REDIHALER will often help control asthma symptoms with less suppression of HPA function than therapeutically equivalent oral doses of prednisone. Since beclomethasone dipropionate is absorbed into the circulation and can be systemically active at low doses, the benefit-to-risk ratio of QVAR REDIHALER in minimizing HPA dysfunction may be expected only when recommended dosages are not exceeded and individual patients are titrated to the lowest effective dose.

Because of the possibility of systemic absorption of inhaled corticosteroids, patients treated with QVAR REDIHALER should be observed carefully for any evidence of systemic corticosteroid effects. In pediatric patients receiving QVAR REDIHALER in minimizing HPA dysfunction may be expected only when recommended dosages are not exceeded and individual patients are titrated to the lowest effective dose.

It is possible that systemic corticosteroid effects such as hypercorticism and adrenal suppression (including adrenal crisis) may appear in a small number of patients, particularly when beclomethasone dipropionate is administered at higher than recommended doses over prolonged periods of time. If such effects occur, the dosage of QVAR REDIHALER should be reduced slowly, consistent with accepted procedures for reducing systemic corticosteroids and for management of asthma symptoms.

5.8 Effects on Growth

Orally inhaled corticosteroids, including QVAR REDIHALER, may cause a reduction in growth velocity when administered to pediatric patients. Monitor the growth of pediatric patients receiving QVAR REDIHALER routinely (e.g., by stadiometry). To minimize the systemic effects of orally inhaled corticosteroids, including QVAR REDIHALER, titrate each patient's dose to the lowest dosage that effectively controls his/her symptoms [see Use in Specific Populations (8.4)].

5.9 Reduction in Bone Mineral Density

Decreases in bone mineral density (BMD) have been observed with long-term administration of products containing inhaled corticosteroids. The clinical significance of small changes in BMD with regard to long-term outcomes, such as fracture, is unknown. Patients with major risk factors for decreased bone mineral content, such as age, low body weight, immobilization, family history of osteoporosis, or chronic use of drugs that can reduce bone mass (e.g., anticonvulsants and corticosteroids) should be monitored and treated with established standards of care.

5.10 Eye Disorders

Decreases in intraocular pressure, blurred vision and cataracts have been reported following the use of long-term administration of inhaled corticosteroids. Therefore, close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, blurred vision, glaucoma, and/or cataracts while using QVAR REDIHALER.
QVAR® REDIHALER™ (beclomethasone dipropionate HFA) inhalation aerosol

6 ADVERSE REACTIONS

Systemic and local corticosteroid use may result in the following:
- *Candida albicans* infection [see Warnings and Precautions (5.1)]
- Immunosuppression [see Warnings and Precautions (5.4)]
- Hypercorticism and adrenal suppression [see Warnings and Precautions (5.7)]
- Growth effects [see Warnings and Precautions (5.8) and Use in Specific Populations (8.4)]
- Eye Disorders [see Warnings and Precautions (5.10)]

6.1 Clinical Trials Experience

A total of 1858 subjects participated in the QVAR REDIHALER clinical development program. Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Adverse reactions that occurred in clinical trials using QVAR REDIHALER with an incidence of 1% to 3% and which occurred at a greater incidence than placebo were back pain, headache, pain, nausea and cough.

Pediatric Patients 4 to 11 Years of Age: The adverse reaction information presented in Table 1 is derived from 3 double-blind, placebo-controlled clinical trials in which 1230 patients (751 female and 479 male adults previously treated with as-needed bronchodilators and/or inhaled corticosteroids) were treated with QVAR REDIHALER (doses of 40, 80, 160, or 320 mcg twice daily) or QVAR (beclomethasone dipropionate HFA) Inhalation Aerosol (QVAR MDI; doses of 160 or 320 mcg twice daily) or placebo. In considering these data, difference in average duration of exposure and clinical trial design should be taken into account.

Table 1: Adverse Reactions Experienced by at Least 3% of Adult and Adolescent Patients in the QVAR REDIHALER or QVAR MDI Groups and Greater Than Placebo by Treatment and Daily Dose

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>QVAR REDIHALER</th>
<th>QVAR MDI</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Candidiasis</td>
<td>0</td>
<td>2 (2)</td>
<td>7 (3)</td>
</tr>
<tr>
<td>Upper Respiratory Tract Infection</td>
<td>3 (3)</td>
<td>3 (3)</td>
<td>9 (4)</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>4 (4)</td>
<td>2 (2)</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Otoryngeal Pain</td>
<td>2 (2)</td>
<td>2 (2)</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Viral Upper Respiratory Tract Infection</td>
<td>3 (3)</td>
<td>0</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>3 (3)</td>
<td>0</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Rhinitis Allergic</td>
<td>0</td>
<td>3 (3)</td>
<td>0</td>
</tr>
</tbody>
</table>

* QVAR MDI=QVAR Inhalation Aerosol

Other adverse reactions that occurred in clinical trials using QVAR REDIHALER with an incidence of 1% to 3% and which occurred at a greater incidence than placebo were influenza, gastroenteritis, viral, ear infection, oral candidiasis, diaphoresis, and myalgia.

6.2 Postmarketing Experience

In addition to the adverse reactions reported from clinical trials with QVAR REDIHALER, the following adverse reactions have been identified during post-approval use of QVAR REDIHALER and other inhaled corticosteroids [see Warnings and Precautions (5.1)]

Psychiatric and Behavioral Changes: Aggression, depression, sleep disorders, psychomotor hyperactivity, and suicidal ideation have been reported (primarily in children).

Eye Disorders: Blurred vision, central serous chorioretinopathy (CSC).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate and well-controlled studies with QVAR REDIHALER or beclomethasone dipropionate in pregnant women. There are clinical considerations with the use of inhaled corticosteroids (ICS), including beclomethasone dipropionate, in pregnant women [see Clinical Considerations]. Also, no published studies, including studies of labor and birth registries, have to date related the use of ICS to any increases in congenital malformations or other adverse perinatal outcomes. Thus, available human data do not establish the presence or absence of drug-associated risk to the fetus.

In animal reproduction studies, beclomethasone dipropionate resulted in adverse developmental effects in mice and rabbits at doses equal and range dose to approximately 0.75 times the maximum recommended human daily inhalation dose (MRHID) in adults (0.64 mg/day) [see Data]. In rats exposed to beclomethasone dipropionate by inhalation, dose-related gross injury to the fetal adrenal glands was observed at doses greater than 180 times the MRHID, but there was no evidence of external or skeletal malformations or embryo lethality at inhalation doses of up to 440 times the MRHID.

The estimated background risk of major birth defects and miscarriage for the indicated population(s) are unknown. In the US general population, the estimated risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

The risk of complications to the mother and developing fetus from inadequate control of asthma must be balanced against the risks from exposure to beclomethasone dipropionate. In women with poorly or moderately controlled asthma, evidence demonstrates that there is an increased risk of preeclampsia in the mother and prematurity, low birth weight, and small for gestational age for the neonate. The level of asthma control should be closely monitored in pregnant women and treatment adjusted to maintain optimal control.

Lactation

There are no specific human data regarding any adverse effects of inhaled beclomethasone dipropionate on labor and delivery.

Data

In an embryofetal development study in pregnant rabbits, beclomethasone dipropionate administration during organogenesis from gestation days 6 to 15 at inhaled doses 180 times the MRHID in adults and higher (on a mg/m² basis at maternal doses of 11.5 and 28.3 mg/kg/day) produced dose-dependent gross injury (characterized by red foci) in the adrenal glands from 3.75 to 10 times the maternal dose and from 0.1 to 10 times the maternal dose at a subcutaneous dose of 20 mcg/kg/day. In a fertility study in female rats, beclomethasone dipropionate administration from gestation days 1 to 18 at subcutaneous doses equal to and greater than 0.75 times the MRHID in adults (on a mg/m² basis at maternal doses of 0.1 mg/kg/day and higher) produced adverse developmental effects (increased incidence of cleft palate). A no-effect dose in mice was not identified. In a second embryofetal development study in pregnant mice, beclomethasone dipropionate administration from gestation days 1 to 19 at subcutaneous doses equal to and greater than 2.3 times the MRHID in adults (on a mg/m² basis at a maternal dose of 0.3 mg/kg/day) produced embryo lethality effects (increased fetal resorptions) and decreased pup survival.

In an embryofetal development study in pregnant rabbits, beclomethasone dipropionate administration during organogenesis from gestation days 7 to 16 at subcutaneous doses equal to and greater than 0.75 times the MRHID in adults (on a mg/m² basis at maternal doses of 0.025 mg/kg/day and higher) produced external and skeletal malformations and embryo lethality effects (increased fetal resorptions). There were no effects in fetuses of pregnant rabbits administered a subcutaneous dose of 0.2 mg/kg/day in adults (on a mg/m² basis at a maternal dose of 0.006 mg/kg/day).

8.2 Lactation

Risk Summary

There are no data available on the presence of beclomethasone dipropionate in human milk; the effects on the breastfed child, or the effects on milk production. However, other inhaled corticosteroids have been detected in human milk. The developmental
8.3 Females and Males of Reproductive Potential

Impairment of fertility was observed in rats and dogs at oral doses of beclomethasone dipropionate corresponding to 250 and 25 times the MRHID for adults on a mg/m² basis, respectively (see Nonclinical Toxicology (13.1)).

8.4 Pediatric Use

Five hundred and one children between the ages of 4 and 11 were treated with at least one dose of QVAR REDIHALER or QVAR MDI in one 12-week clinical trial. The safety and effectiveness of QVAR REDIHALER in children below 4 years of age have not been established.

Do not use QVAR REDIHALER with a spacer or volume holding chamber.

Controlled clinical studies have shown that inhaled corticosteroids may cause a reduction in growth velocity in pediatric patients. A 12-month, randomized, controlled clinical trial evaluated the effects of QVAR MDI versus beclomethasone dipropionate in a GFC-propellant-based formulation (CFC-BDP) on growth in children aged 3 to 11. A total of 529 children were enrolled, of whom 394 received QVAR MDI (100 to 400 mcg/day ex-valve) and 126 received CFC-BDP (200 to 800 mcg/day ex-valve). Similar control of asthma was noted in each treatment arm. When comparing results at month 12 to baseline, the mean growth velocity in children treated with QVAR MDI was approximately 0.5 cm/year less than that noted with children treated with CFC-BDP via large-volume spacer. The long-term effects of the reduction in growth velocity associated with orally inhaled corticosteroids, including the impact on final adult height, are unknown. The potential for “catch-up” growth following discontinuation of treatment with oral corticosteroids has not been adequately studied.

The growth of children and adolescents receiving orally inhaled corticosteroids, including QVAR REDIHALER, should be monitored routinely (e.g., via stadiometry). If a child or adolescent on any corticosteroid appears to have growth suppression, the possibility that he/she is particularly sensitive to this effect should be considered. The potential growth effects of prolonged treatment should be weighed against the clinical benefits obtained and the risks associated with alternative therapies. To minimize the systemic effects of orally inhaled corticosteroids, including QVAR REDIHALER, each patient should be titrated to his/her lowest effective dose (see Dosage and Administration (2.2)).

8.5 Geriatric Use

Clinical studies of QVAR REDIHALER did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be based on clinical judgment and should take into account the following factors: the presence of other concomitant disease or other drug therapy.

11 DESCRIPTION

The active component of QVAR REDIHALER 40 mcg Inhalation Aerosol and QVAR REDIHALER 80 mcg Inhalation Aerosol is beclomethasone dipropionate, USP, a corticosteroid having the chemical name 9-chloro-11β,17α,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-dipropionate. Beclomethasone dipropionate is a diester of beclomethasone, a synthetic corticosteroid chemically related to dexamethasone. Beclomethasone differs from dexamethasone in having a chlorine at the 9-alpha carbon in place of a fluorine, and in having a 16-beta-methyl group instead of a 16-alpha-methyl group. Beclomethasone dipropionate is a white creamy, odorless powder with a molecular formula of C28H26ClO3 and a molecular weight of 521.1. Its chemical structure is:

QVAR REDIHALER is a pressurized, breath-actuated, metered-dose aerosol with a dose counter intended for oral inhalation only. Each unit consists of a sealed breath-actuated inhaler device enclosing a canister containing a solution of beclomethasone dipropionate in propellant HFA-134a (1,1,1,2-tetrafluoroethane) and ethanol (0.85 g). QVAR REDIHALER 40 mcg delivers 40 mcg of beclomethasone dipropionate from the actuator mouthpiece and 50 mcg from the canister valve. QVAR REDIHALER 80 mcg delivers 80 mcg of beclomethasone dipropionate from the actuator mouthpiece and 100 mcg from the canister valve. Both products deliver 50 microliters (59 milligrams) of solution formulation as an aerosol from the canister valve with each actuation. The 40-mcg canisters and the 80-mcg canisters provide 120 inhalations each. Since the QVAR REDIHALER canister is fitted with a primeless system, no priming actuations are required before use. For both products, an actuation was always triggered by a 20 L/min inspiratory flow rate.
Hepatic Impairment: The effect of hepatic impairment on the pharmacokinetics of QVAR REDIHALER has not been evaluated.

**Drug Interaction Studies**
In vitro and in vivo drug interaction studies have not been conducted with QVAR REDIHALER.

**13 NONCLINICAL TOXICOLOGY**

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
The carcinogenicity of beclomethasone dipropionate was evaluated in rats which were exposed for a total of 95 weeks, 12 weeks duration and 1 confirmatory trial of 6 weeks duration in patients 12 years of age and older, and 1 confirmatory trial of 12 weeks duration in patients 4 to 11 years of age. The efficacy of QVAR REDIHALER is based primarily on the confirmatory trials described below.

14.1 Trials in the Maintenance Treatment of Asthma
Adult and Adolescent Patients 12 Years of Age and Older
Two confirmatory Phase 3 clinical trials were conducted comparing QVAR REDIHALER with placebo in adult and adolescent patients with persistent asthma (Trial 1 and Trial 2). Trial 1 (NCT02040779): This randomized, double-blind, parallel-group, placebo-controlled, 12-week, efficacy and safety trial compared QVAR REDIHALER 40 and 80 mcg/day versus 1 inhalation twice daily with placebo in adult and adolescent patients with persistent symptomatic asthma despite low-dose inhaled corticosteroid or non-corticosteroid asthma therapy. Patients aged 12 years and older who met the entry criteria including FEV1 40-85% predicted normal and 15% reversibility met the randomization criteria including asthma symptoms and rescue medication use were discontinued from asthma maintenance medication and randomized equally to treatment with QVAR REDIHALER 80 mcg/day, QVAR REDIHALER 160 mcg/day or placebo. Baseline FEV1 values were similar across treatment groups and asthma symptom scores than with placebo. Similar results were demonstrated with QVAR MDI.

**Figure 2: A 6-Week Dose Response Clinical Trial in Patients with Inhaled Corticosteroid-Dependent Asthma: Mean Change in FEV1, as Percent of Predicted**

- **Difference from Placebo:**
  - Placebo: 0.124, 0.116, 0.144, 0.150, 0.148
  - QVAR REDIHALER 320 mcg/day: 0.0847, 0.2114
  - QVAR MDI 320 mcg/day: 0.144, 0.2066

**Table 3: Primary Analysis of Standardized Baseline-Adjusted Trough Morning FEV1, (L) AUEC from Time Zero to the End of the Treatment Period 12-week Study and 6-week Dose Response Study**

<table>
<thead>
<tr>
<th>Parameter Statistic</th>
<th>Placebo (N=90)</th>
<th>QVAR REDIHALER 80 mcg/day (N=80)</th>
<th>QVAR REDIHALER 160 mcg/day (N=92)</th>
<th>Placebo (N=107)</th>
<th>QVAR REDIHALER 320 mcg/day (N=108)</th>
<th>QVAR REDIHALER 640 mcg/day (N=105)</th>
<th>QVAR MDI* 320 mcg/day (N=105)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difference from Placebo</td>
<td>—</td>
<td>0.124, 0.116</td>
<td></td>
<td>—</td>
<td>0.144</td>
<td>0.150</td>
<td>0.148</td>
</tr>
<tr>
<td>95% CI</td>
<td>0.054, 0.193, 0.185</td>
<td>0.0807, 0.2066</td>
<td>0.0888, 0.2132</td>
<td>0.0847, 0.2114</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure 2:** Side-by-side comparison of the primary analysis of standardized baseline-adjusted trough morning FEV1, from time zero to the end of the treatment period for both studies is shown below in Table 3.

**Figure 1: A 12-Week Clinical Trial in Patients with Asthma: Mean Change in FEV1,**

**Table 2 (NCT02531360):** This randomized, double-blind, parallel-group, placebo-controlled, 6-week, efficacy and safety trial compared QVAR REDIHALER 40 and 80 mcg given as 1 inhalation twice daily and placebo in adult and adolescent patients with persistent symptomatic asthma despite treatment with non-corticosteroid, inhaled corticosteroids (with or without a long acting beta agonist [LABA]), or combination asthma therapy. The study also included a reference treatment group, QVAR. This study was conducted with QVAR MDI. In the study, QVAR MDI was similar. The change from baseline in morning FEV1, during the trial is displayed in Figure 2. Both doses of QVAR REDIHALER were effective in improving asthma control with significantly greater improvements in trough FEV1, morning PEF, weekly average of daily trough morning PEF, reduced rescue medication use and improved asthma symptom scores than with placebo. Similar results were demonstrated with QVAR MDI.
Avoid use as rescue medicine for acute asthma exacerbations. Advise patients to treat acute asthma symptoms with an inhaled, short-acting beta-agonist such as albuterol. Instruct the patient to contact their physicians immediately if there is deterioration of their asthma.

Inform patients that QVAR REDIHALER is not a bronchodilator and is not intended for use as rescue medicine for acute asthma exacerbations. Advise patients to treat acute asthma symptoms with an inhaled, short-acting beta-agonist such as albuterol. Instruct the patient to contact their physicians immediately if there is deterioration of their asthma.

Inform patients that oral inhaled corticosteroids, including QVAR REDIHALER, may cause a reduction in growth velocity when administered to pediatric patients. Physicians should closely follow the growth of adolescents taking corticosteroids by any route.

Inform patients who are pregnant or nursing that they should contact their physician about the use of QVAR REDIHALER.

Use Daily for Best Effect
Patients should use QVAR REDIHALER at regular intervals as directed. The daily dosage of QVAR REDIHALER should not exceed 8 inhalations per day. Advise patients, if they miss a dose, to take their next dose at the same time they normally do. Individual patients will experience a variable time to onset and degree of symptom relief and the full benefit may not be achieved until treatment has been administered for 1 to 2 weeks or longer. Patients should not increase the prescribed dosage but should contact their physicians if symptoms do not improve or if the condition worsens. Instruct patients to not stop use of QVAR REDIHALER abruptly. Patients should contact their physicians immediately if they discontinue use of QVAR REDIHALER.

Caring for and Storing the Inhaler
For normal hygiene, the mouthpiece of QVAR REDIHALER should be cleaned weekly with a clean, dry tissue or cloth. Never wash or put any part of QVAR REDIHALER in water. Patient should replace QVAR REDIHALER if washed or placed in water. Instruct patients to store the inhaler at room temperature and to avoid exposure to extreme heat and cold.

Inform patients that shaking the inhaler prior to use is not necessary. Instruct patients not to shake the inhaler with the cap open to avoid possible actuation of the device.

Inform patients to never take QVAR REDIHALER apart. Instruct patients that QVAR REDIHALER has a dose counter attached to the actuator at the rear of the mouth piece. When the patient receives the inhaler, the number 120 will be displayed. The dose counter will count down each time a spray is released. The dose-counter window displays the number of sprays left in the inhaler in units of two (e.g., 120, 118, 116, etc). When the counter displays 20, the color of the numbers will change to red to remind the patient to contact their pharmacist for a refill of medication or consult their healthcare provider for a prescription refill. When the dose counter reaches 0, the background will change to solid red. Inform patients to discard QVAR REDIHALER when the dose counter displays 0 or after the expiration date on the product, whichever comes first.

Rx only
Marketed by: Teva Respiratory, LLC
Frazer, PA 19355
Developed and Manufactured by:
Norton (Waterford) Limited
Unit 301, IDA Industrial Park, Cork Road, Waterford, Ireland
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U.S. Patent 7,637,260; 8,132,712; 8,931,476
QVARH-002
QVAR® REDIHALER™ (beclomethasone dipropionate HFA) inhalation aerosol

PATIENT INFORMATION
QVAR REDIHALER (kue' var red-ee-haye' ler)
(beclomethasone dipropionate HFA) inhalation aerosol

What is QVAR REDIHALER?
QVAR REDIHALER is a breath-actuated inhaled prescription medicine used as a maintenance treatment for the prevention and control of asthma in people 4 years of age and older.

- QVAR REDIHALER is not used to relieve sudden breathing problems. It is not known if QVAR REDIHALER is safe and effective in children less than 4 years of age.

Who should not use QVAR REDIHALER?
Do not use QVAR REDIHALER:
- to treat sudden severe symptoms of asthma.
- as a rescue inhaler.
- if you are allergic to beclomethasone dipropionate or any of the ingredients in QVAR REDIHALER. See the end of this leaflet for a complete list of ingredients in QVAR REDIHALER.

What should I tell my healthcare provider before using QVAR REDIHALER?
Before using QVAR REDIHALER, tell your healthcare provider about all of your medical conditions, including if you:
- are exposed to chickenpox or measles.
- have or have had tuberculosis (TB) or any untreated fungal, bacterial or viral infections, or eye infections caused by herpes.
- have weak bones (osteoporosis).
- have an immune system problem.
- have or have had eye problems, such as blurred vision, increased pressure in your eye (glaucoma) or cataracts.
- are pregnant or plan to become pregnant. It is not known if QVAR REDIHALER will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if QVAR REDIHALER passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you use QVAR REDIHALER.

Tell your healthcare provider about all of the medications you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use QVAR REDIHALER?
Read the step-by-step instructions for using QVAR REDIHALER at the end of this Patient Information leaflet.
- Use QVAR REDIHALER exactly as your healthcare provider tells you to. Do not use QVAR REDIHALER more often than it is prescribed.
- Do not shake the inhaler before using it. Especially, do not shake the inhaler with the cap open. This could cause the device to accidentally release medicine before you are ready to take it.
- You do not need to prime QVAR REDIHALER.
- If your child needs to use QVAR REDIHALER, watch your child closely to make sure your child uses the inhaler correctly.
- Do not change or stop using QVAR REDIHALER or other asthma medicines used to treat your breathing problems unless your healthcare provider tells you to. Your healthcare provider will change your medicines as needed.
- You must use QVAR REDIHALER regularly. It may take 2 to 4 weeks, or longer, after you start using QVAR REDIHALER for your asthma symptoms to get better. Do not stop using QVAR REDIHALER, even if you are feeling better, unless your healthcare provider tells you to.
- QVAR REDIHALER comes in 2 strengths (40 and 80 mcg). Your healthcare provider has prescribed the strength that is best for you. Pay attention to the differences between QVAR REDIHALER and your other inhaled medicines, including their prescribed use and the way they look.

continued
QVAR® REDIHALER™ (beclomethasone dipropionate HFA) inhalation aerosol

- **Lower bone density.** This may be a problem for people who already have a higher chance for low bone density (osteoporosis).
- **Eye problems.** If you have had glaucoma, cataracts or blurred vision in the past, you should have regular eye exams while using QVAR REDIHALER.

The most common side effects of QVAR REDIHALER include:
- yeast infection in the mouth (oral candidiasis)
- cold symptoms (upper respiratory tract infection)
- pain in the throat (oropharyngeal pain)
- pain or swelling in your nose and throat (nasopharyngitis)
- sinus irritation (sinusitis)
- hay fever (allergic rhinitis)

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of QVAR REDIHALER. Ask your healthcare provider or pharmacist for more information. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### How should I store QVAR REDIHALER?
- Store QVAR REDIHALER at room temperature between 68°F to 77°F (20°C to 25°C).

Your QVAR REDIHALER canister should only be used with the QVAR REDIHALER actuator. Do not use any other medicines in your QVAR REDIHALER actuator.
- The contents of your QVAR REDIHALER canister are under pressure. Do not puncture the QVAR REDIHALER canister.
- Do not store your QVAR REDIHALER canister near heat or a flame. Temperatures above 120°F may cause the canister to burst.
- Do not throw your QVAR REDIHALER canister into a fire or incinerator.

Keep QVAR REDIHALER and all medicines out of the reach of children.

### General information about the safe and effective use of QVAR REDIHALER.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use QVAR REDIHALER for a condition for which it was not prescribed. Do not give QVAR REDIHALER to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about QVAR REDIHALER that is written for health professionals.

### What are the ingredients in QVAR REDIHALER?
- **Active ingredient:** beclomethasone dipropionate
- **Inactive ingredients:** propellant HFA-134a and ethanol

For more information, go to www.QVAR.com or call 1-888-483-8279.

QVARRHIPIL-003
Rev. 3/2018

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**QVAR® REDIHALER™ (beclomethasone dipropionate HFA) inhalation aerosol**

### Instructions for Use

**QVAR REDIHALER (kue' var red-ee-hay' ler)**
(beclo- methasone dipropionate HFA) inhalation aerosol

#### Your QVAR REDIHALER Inhaler

**OVERVIEW**

When you are ready to use your QVAR REDIHALER for the first time, remove the inhaler from the carton.

**Important information:**
- There is no button. You must close the white cap to prepare the inhaler with medicine before each inhalation.
- Do not shake. This breath-actuated device does not need to be shaken. This is not a press-and-breathe inhaler
- QVAR REDIHALER does not need priming.
- Do not use a spacer or volume holding chamber with QVAR REDIHALER.
- Always use the inhaler in the upright position (with the mouthpiece down).
- Once prepared, the inhaler will deliver 1 inhalation of medicine when you breathe in (inhale) through the mouthpiece. Your dose might require more than 1 inhalation.
- Do not open the white cap or leave it open unless you are ready for your next inhalation. If the cap has been opened for more than 2 minutes or left in the open position, you will need to close the white cap before use.
- Do not suddenly stop using your QVAR REDIHALER. Contact your healthcare provider immediately if you stop using your QVAR REDIHALER.

There are 2 main parts of your QVAR REDIHALER including:
- the inhaler body with the mouthpiece. See Figure A.
- the white cap that covers the mouthpiece of the inhaler. See Figure A.

---

**About the Dose Counter**

There is a dose counter in the back of the inhaler with a viewing window that shows you how many inhalations of medicine you have left. See Figure B.
- Your QVAR REDIHALER contains 120 inhalations. See Figure B.
- The counter on the back of your inhaler shows how many inhalations you have left.
- When there are 20 inhalations left, the numbers in the dose counter will change to red and you should refill your prescription or ask your healthcare provider for another prescription.
- When the dose counter shows '0', the background will turn solid red and your inhaler is empty. You should stop using the inhaler and throw it away. Do not put your inhaler into a fire or incinerator. See Figure B.
QVAR® REDIHALER™ (beclomethasone dipropionate HFA) inhalation aerosol

Using your QVAR REDIHALER:

Step 1. Open the white cap
- Open the white cap. See Figure D.
- Breathe out fully.

Step 2. Inhale 1 Time
- Place the mouthpiece in your mouth and close your lips around it so you form a good seal.
- Inhale deeply to release the medicine.
- Remove inhaler, hold breath for 5 to 10 seconds, then, breathe out slowly, away from the inhaler.

Step 3. Close the white cap
- Close the white cap after inhaling to prepare your next inhalation. See Figure F.

Important:
- The white cap must be closed to prepare the inhaler before each inhalation or you will not receive your medicine. See Figure C.
- If the white cap is open, close the white cap to prepare your inhaler and look at the dose counter window to make sure that your inhaler is not empty. See Figure B.
- Do not open the cap until you are ready to take your inhalation.

Remember:
- Do not open the cap until you are ready to take your inhalation.
- Never breathe out into the inhaler mouthpiece.
- Clean the mouthpiece of your QVAR REDIHALER weekly with a clean, dry tissue or cloth.

How to store your QVAR REDIHALER
- Store QVAR REDIHALER at room temperature between 68°F to 77°F (20℃ - 25℃). Excursions between 59°F and 86°F (15℃ and 30℃) are permitted. Do not use or store near heat or open flame. Exposure to temperatures above 120°F (49°C) may cause the canister to burst. Do not throw QVAR REDIHALER into fire or an incinerator.
- Keep the white cap on the inhaler closed during storage.
- Keep your QVAR REDIHALER inhaler dry and clean at all times.
- Keep your QVAR REDIHALER and all medicines out of the reach of children.
- Throw away QVAR REDIHALER when the dose counter displays ‘0,’ or after the expiration date on the package, whichever comes first.

Cleaning your QVAR REDIHALER
- Do not wash or put any part of your QVAR REDIHALER in water.
- Clean the mouthpiece of your QVAR REDIHALER weekly with a clean, dry tissue or cloth.

Support
- If you have any questions about QVAR REDIHALER or how to use your inhaler, go to www.QvarRedihaler.com or call 1-888-483-8279.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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QVARHIFU-002
Rev. 3/2018
QRH-40242