**التعريف على جهاز الاستنشاق**

**QVAR RediHaler**

إن QVAR® RediHaler™ هو جهاز يومي للتعامل مع الربو، وهو ليس بديل لجهاز الاستنشاق الفوري (جهاز استنشاق قوي) لكل العملاء الذين يتعاملون مع الربو. قد يساعد في الوقاية من أعراض الربو و trovare الرئة. وهو تطبيق ثابت كإجراء الوقاية أثناء الفترات المريضة.

**طريقة الاستخدام**

قبل البدء في استخدام QVAR RediHaler، اقرأ الخطوات التالية. استخدم الجهاز دائمًا حسب تعليمات الطبيب، وإذا كانت لديك أسئلة، فاطرحها على طبيبك أو الصيدلي.

1. افتح الغطاء الأبيض لتحضير الجهاز قبل كل عملية استنشاق وإلا فلن يقوم الجهاز بتوفير الدواء. لا تفتح الغطاء إلا عندما تكون جاهزًا للاستخدام.
2. افتح الغطاء الأبيض الذي يغطي قطعة الفم في جهاز الاستنشاق، ولا تفتح الغطاء إلا إذا كنت تريد تنظيف الجهاز. تنفس بشكل كامل.
3. ضع قطعة الفم في فمك واحفظ تلك الحالة لحظًا، حتى تتمكن من تنفس الدواء. انزغ جهاز الاستنشاق، واحسب نفسك لمدة 5 إلى 10 ثوان.
4. ثم نفس بطء خارج جهاز الاستنشاق.
5. أغلق الغطاء الأبيض بعد الاستنشاق للتحضير لعملية الاستنشاق التالية.
6. إذا أخبرك طبيبك بالتوقف عن استخدام الجهاز يوميًا، فتأكد من أن استخدام الجهاز يوميًا اختياري.

**لا توجد علبة تضغط عليها!**

**وصفة الجرعة**

**الاستخدام معتمد على الاستخدام الفوري من ماذم الموضوح على المقصد الخاص للجهاز على الربو، والالتباس في الأغراض الأعضوية المذكورة في الجهة الاستنشاقية الفورية.**

**معلومات السلامة الهامة**

لا تستخدم QVAR RediHaler لعلاج أعراض الربو الحادة المفاجئة، ولا استخدم ذات الربح، وتوفر إشارات كافية للجهاز الاستنشاقي بـ QVAR RediHaler. لا تستخدم QVAR RediHaler داهونين أو أي من المكونات الموجودة في جهاز الاستنشاق الاستناثائي.

**شاهد فيديو "كيفية الاستخدام"**

لمشاهدة خطوات تصميم جهاز الاستنشاق، يرجى زيارة QVARHowTo.com.
عندما يصل عدد الجرعات إلى 20، سوف تتغير الأرقام إلى اللون الأحمر، مما يشير إلى أنه قد حان الوقت لإعادة تعبئة الجهاز. (إذا استخدمت الجهاز بعد وصول عدد الجرعات إلى صفر، فقد لا تعمل الإيقاعات الميكانيكية.)

 MessageType not available.

اختصار من QVAR® RediHaler™ عندما يصل عدد الجرعات إلى ‘0’، وأصبحت الخلفية باللون الأحمر، أو بعد تاريخ انتهاء الصلاحية المدون على العبوة، يصح أن يصل إلى تاريخ انتهاء الصلاحية. لا تستخدم جهاز الاستنشاق بعد انتهاء صلاحيته.

أين تستخدم؟: QVAR.com أو الاتصال على الرقم 888-483-2879 للحصول على دعم إضافي أو لمزيد من المعلومات حول كيفية الاستخدام أو تنظيف جهاز الاستنشاق.

Matter of Safety (Follow-up)


لا تستخدم الجهاز ولا تخزنه بالقرب من الحرارة أو مصدر نيران مفتوح، لأنه قد يسبب في انفجار العبوة.

تنظيف جهاز الاستنشاق

نصب عبوة الجهاز الاستنشاق مرة كل أسبوع على الأقل بقطعة قماش أو QVAR® RediHaler تنظيف جهاز الاستنشاق.

QVAR® RediHaler ™ لا تستخدم بعد انتهاء صلاحيته. قد يتسبب استلامك لـ QVAR RediHaler أسرع مقدار الرعاية الصحية للكم عن أية أدوية تتعاطاها وحالات الصحة. قد تحدث هذه الأعراض الخطيرة التشنجات المفاجئة. تواصل مع مقدم الرعاية الصحي مسرع إذا لم تشعر بالراحة بعد نوبات الربو المفاجئة.

لا تستخدم QVAR® RediHaler بعد انتهاء صلاحيته.

هذا ليس الأثر الجانبية الشائعة لـ QVAR® RediHaler™، ولكنه قد يؤدي إلى تشنج قصبي عند التنفس المفاجئ.

أثر التعريض لدرجات حرارة أعلى من 49 درجة مئوية لـ QVAR® RediHaler ™ يمكن أن يؤدي إلى انفجار العبوة. لذا، فإن التعريض لدرجات حرارة أعلى من 120 درجة فهرنهايت (49 مئوية) قد يسبب في انفجار العبوة. لا ت.column the applications as fortunes on the documents. Hopefully, these are coming to terms with the document that naturally reads it. FDA: 888-1088-800.

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Cette page est maintenant disponible en arabe. Contactez-nous si vous souhaitez consulter la version originale en anglais.
QVAR® REDIHALER™ (beclomethasone dipropionate HFA) inhalation aerosol

- Do not use QVAR REDIHALER with a spacer or volume holding chamber.
- Discard QVAR REDIHALER inhaler when the dose counter displays 0 or after the expiration date on the product, whichever comes first.

**Dosage and Administration**

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

**Dosage Forms and Strengths**

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

**Contraindications**

- Localized infections: Candida albicans infection of the mouth and throat may occur.
- Advise patients to rinse the mouth with water after inhalation to help reduce the risk.

**Warnings and Precautions**

- 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.

**Adverse Reactions**

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

**Use in Specific Populations**

- Pregnancy
- Lactation

**Description**

QVAR REDIHALER is a corticosteroid indicated for:

- Maintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older.

**Indications and Usage**

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

**Dosage and Administration**

- For oral inhalation only.
- Starting dosage is based on prior asthma therapy and disease severity.
- Treatment of asthma in patients 4 to 11 years of age: 40 or 80 mcg twice daily.
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**Use in Specific Populations**

- Pregnancy
- Lactation

**Description**

QVAR REDIHALER™ (beclomethasone dipropionate HFA) inhalation aerosol

- Transferring patients from systemic corticosteroids: Risk of impaired adrenal function when transferring from oral steroids. Taper patients slowly from systemic corticosteroids if transferring to QVAR REDIHALER.
- Immunosuppression: Potential worsening of existing tuberculosis, fungal, bacterial, viral, or parasitic infection; or ocular herpes simplex infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients. Use with caution in patients with these infections because of the potential for worsening of these infections.
- Paradoxical bronchospasm: Bronchospasm, with an immediate increase in wheezing, may occur after dosing. Treat bronchospasm immediately with inhaled, short-acting bronchodilator and discontinue QVAR REDIHALER.
- Hypersensitivity reactions: Such as urticaria, angioedema, rash, and bronchospasm may occur. Discontinue QVAR REDIHALER if such reactions occur.
- Hypercorticism and adrenal suppression: May occur with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue QVAR REDIHALER slowly.
- Effects on growth: Monitor growth of pediatric patients.
- Decreases in bone mineral density: Monitor patients with major risk factors for decreased bone mineral content.
- Eye Disorders: Monitor patients with change in vision or with a history of increased intraocular pressure, blurred vision, glaucoma, and/or cataracts.

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corticosteroid product and disease severity: 40, 80, 160 or 320 mcg twice daily. For patients who do not respond adequately to the initial dosages 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 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. Transfer of patients from systemic corticosteroids should be instructed to resume oral corticosteroids (in the primary treatment of status asthmaticus, 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. Transfer of patients from systemic corticosteroids should be instructed to resume oral corticosteroids (in the primary treatment of status asthmaticus, 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.

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 3 mcg/spray in a maroon plastic actuator with a dose counter and a hinged white cap. Each breath-induced actuation delivers 100 mcg of beclomethasone dipropionate.

• 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 Systemic Adrenal Insufficiency

QVAR REDIHALER is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma when intense measures are required [see Warnings and Precautions (5.3)].

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-adrenergic agonist (e.g., QVAR REDIHALER) should be used to relieve symptoms 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 Transfer of 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 systemically active corticosteroids, 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, characteristic signs and symptoms of adrenocortical insufficiency may be masked or delayed in onset following exposure 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 physiologic 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. Patients who have been transferred from oral or systemic corticosteroids, some patients may experience symptoms of systemic active corticosteroid withdrawal, e.g., joint and/or muscular pain, lassitude, and depression, despite maintenance or even improvement of respiratory function.

5.4 Immunosuppression

Patients who are on oral corticosteroids which suppress the immune system are more susceptible to infections than healthy individuals. Chickenpox and measles, for example, can have a more serious or even fatal course in non-immune patients on corticosteroids. 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 administration and underlying disease are related to the risk of opportunistic infection, 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 immunologic package inserts for VZIG and IG prescribing information.) If chickenpox develops, treatment with antiviral agents may be considered. Inhalation 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 in high doses, the benefit/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 HPA suppression effects. Because QVAR REDIHALER is contraindicated in patients with 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 immunologic package inserts for VZIG and IG prescribing information.) If chickenpox develops, treatment with antiviral agents may be considered. Inhalation 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.

5.8 Effects on Growth

Orally inhaled corticosteroids, including QVAR REDIHALER, may cause a reduction in growth rate. To minimize the potential for growth retardation, particularly in young children, the patient's weight should be monitored during therapy and the patient's dose to the lowest dosage that effectively controls his/her symptoms should 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. Transfer of patients from systemic corticosteroid therapy to QVAR REDIHALER may unmask allergic conditions previously suppressed by the systemic corticosteroid therapy, e.g., rhinitis, conjunctivitis, ataxia, arthritis, and eosinophilic conditions. During withdrawal from oral corticosteroids, some patients may experience symptoms of systemically active corticosteroid withdrawal, e.g., joint and/or muscular pain, lassitude, and depression, despite maintenance or even improvement of respiratory function.

5.9 Effect on 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 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

Glaucoma, increased 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.
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)]
- Hypercortisemia 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.

Adults and Adolescent Patients 12 years of Age and Older: 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><strong>80 mcg N=90</strong></td>
<td>0</td>
<td>1 (&lt;1)</td>
<td>0</td>
</tr>
<tr>
<td><strong>160 mcg N=92</strong></td>
<td>0</td>
<td>2 (2)</td>
<td>7 (3)</td>
</tr>
<tr>
<td><strong>320 mcg N=214</strong></td>
<td>15 (7)</td>
<td>15 (7)</td>
<td>15 (7)</td>
</tr>
<tr>
<td><strong>640 mcg N=211</strong></td>
<td>6 (3)</td>
<td>6 (3)</td>
<td>6 (3)</td>
</tr>
<tr>
<td><strong>320 mcg N=212</strong></td>
<td>17 (8)</td>
<td>17 (8)</td>
<td>17 (8)</td>
</tr>
<tr>
<td><strong>640 mcg N=107</strong></td>
<td>4 (4)</td>
<td>4 (4)</td>
<td>4 (4)</td>
</tr>
<tr>
<td><strong>N=304</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<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>3 (3)</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>4 (4)</td>
<td>4 (4)</td>
<td>4 (4)</td>
</tr>
<tr>
<td>Oropharyngeal 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>3 (3)</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>3 (3)</td>
<td>2 (&lt;1)</td>
<td>2 (&lt;1)</td>
</tr>
<tr>
<td>Rhinitis Allergic</td>
<td>0</td>
<td>0</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, diaphrea, 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 MDI and other inhaled corticosteroids. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

**Local Effects:** Localized infections with *Candida albicans* have occurred in patients treated with beclomethasone dipropionate or other orally 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),

6.6 Long-term Use

QVAR REDIHALER is not indicated for the long-term management of asthma, as patients using it long-term may have uncontrolled asthma.

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**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 large 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 to or greater than approximately 0.75 times the maximum recommended human daily inhalation dose (MRHDID) 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 MRHDID, but there was no evidence of external or skeletal malformations or embryolethality at inhalation doses of up to 440 times the MRHDID.

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**

**Animal Data**

In an embryofetal development study in pregnant rats, beclomethasone dipropionate administration during organogenesis from gestation days 6 to 15 at inhaled doses 180 times the MRHDID 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 of fetuses. There were no findings in the adrenal glands of rat fetuses at an inhaled dose that was 40 times the MRHDID in adults (on a mg/m² basis at a maternal dose of 2.4 mg/kg/day). There was no evidence of external or skeletal malformations or embryolethality at inhalation doses of up to 440 times the MRHDID (on a mg/m² basis at maternal doses up to 28.3 mg/kg/day).

In an embryofetal development study in pregnant mice, beclomethasone dipropionate administration from gestation days 1 to 18 at subcutaneous doses equal to and greater than 0.75 times the MRHDID 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 13 at subcutaneous doses equal to and greater than 2.3 times the MRHDID in adults (on a mg/m² basis at a maternal dose of 0.3 mg/kg/day) produced embryolethelial 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 MRHDID in adults (on a mg/m² basis at maternal doses of 0.025 mg/kg/day and higher) produced external and skeletal malformations and embryolethality (increased fetal resorptions). There were no effects in fetuses of pregnant rabbits administered a subcutaneous dose 0.2 times the MRHDID 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
QVAR® REDIHALER™ (beclomethasone dipropionate HFA) inhalation aerosol

and health benefits of breastfeeding should be considered along with the mother's clinical need for QVAR REDIHALER and any potential adverse effects on the breastfed child from beclomethasone dipropionate or from the underlying maternal condition.

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 MRHDID 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 trial of clinical safety. 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 ages 5 to 11. A total of 520 children 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 has not been adequately studied in pediatric patients.

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 inhaled corticosteroids has not been adequately studied in children with asthma. The safety and effectiveness of QVAR REDIHALER in children aged 65 and over to determine whether they respond differently from younger patients. Other reported clinical experience has not identified differences in safety and effectiveness of QVAR REDIHALER compared to younger patients. Because of the lower maximum inhalation dose, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of 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-11,17,21-trihydroxy-16-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 white, odorless powder with a molecular formula of C_{28}H_{37}ClO_{7} and a molecular weight of 521.1. Its structure is:

\[
\text{COC(O)CH}_3 + \text{COC(O)CH}_3 + \text{Cl} + \text{COC(O)CH}_3 + \text{COC(O)CH}_3 + \text{HO} + \text{COC(O)CH}_3 + \text{COC(O)CH}_3
\]

QVAR REDIHALER is a pressurized, breath-activated, metered-dose aerosol with a dose counter intended for oral inhalation only. Each unit consists of a sealed breath-powder with a molecular weight of 521.1. Its structure is:

\[
\text{COC(O)CH}_3 + \text{COC(O)CH}_3 + \text{Cl} + \text{COC(O)CH}_3 + \text{COC(O)CH}_3 + \text{HO} + \text{COC(O)CH}_3 + \text{COC(O)CH}_3
\]

QVAR REDIHALER is a pressurized, breath-activated, metered-dose aerosol with a dose counter intended for oral inhalation only. Each unit consists of a sealed breath-powder with a molecular weight of 521.1. Its structure is:

\[
\text{COC(O)CH}_3 + \text{COC(O)CH}_3 + \text{Cl} + \text{COC(O)CH}_3 + \text{COC(O)CH}_3 + \text{HO} + \text{COC(O)CH}_3 + \text{COC(O)CH}_3
\]

Vapor REDIHALER® is a pressurized, breath-activated, metered-dose aerosol with a dose counter intended for oral inhalation only. Each unit consists of a sealed breath-powder with a molecular weight of 521.1. Its structure is:

\[
\text{COC(O)CH}_3 + \text{COC(O)CH}_3 + \text{Cl} + \text{COC(O)CH}_3 + \text{COC(O)CH}_3 + \text{HO} + \text{COC(O)CH}_3 + \text{COC(O)CH}_3
\]

QVAR REDIHALER (mean age 10 years), the Cmax of 17-BMP was 787 pg/mL at 0.6 hour after inhalation of 80 mcg of beclomethasone dipropionate HFA-134a (1,1,1,2 tetrafluoroethane) and ethanol (0.85 g).

No pharmacokinetic studies for QVAR REDIHALER have been conducted in neonates or elderly subjects.

Age: The influence of sex on the pharmacokinetics of QVAR REDIHALER has not been established. Pediatrics: No pharmacokinetic studies for QVAR REDIHALER have been conducted in children aged 4 to 17 years. However, the pharmacokinetics of QVAR REDIHALER, including dose and strength proportions, are similar in children and adults using QVAR MDI, although the exposure is highly variable. In 17 children (mean age 10 years), the Cmax of 17-BMP was 878 pg/mL at 0.6 hour after inhalation of 160 mcg (4 actuations of the 40 mcg/actuation strength of QVAR MDI). The systemic exposure to 17-BMP from 160 mcg of QVAR MDI administered without spacer was comparable to the systemic exposure to 17-BMP from 336 mcg CFC-BDP administered with a large volume spacer in 14 children (mean age 12 years). This implies that approximately twice the systemic exposure to 17-BMP would be expected for comparable mg doses of QVAR MDI without a spacer and CFC-BDP with a large volume spacer.

Sex: The influence of sex on the pharmacokinetics of QVAR REDIHALER has not been studied.

Race: The influence of race on the pharmacokinetics of QVAR REDIHALER has not been studied.

Renal Impairment: The effect of renal impairment on the pharmacokinetics of QVAR REDIHALER has not been evaluated.
**Inhalation Aerosol** (QVAR MDI) 40 mcg, 4 inhalations twice daily. Patients aged 12 years and older who met the entry criteria including FEV1 50%-90% predicted normal, reversible bronchoconstriction of at least 10% with short-acting inhaled beta-agonist discontinued baseline asthma treatment and entered a 2-4 week run-in period. 425 patients (257 previously treated with ICS with or without LABA) who met all the randomization criteria including FEV1 of 40-85% predicted and 15% reversibility with short-acting inhaled beta-agonist, and asthma symptoms were randomized equally to QVAR REDIHALER 320 mcg/day, QVAR REDIHALER 640 mcg/day, QVAR MDI 320 mcg/day or placebo. Baseline FEV1 values were similar across treatments. The primary endpoint for this trial was the standardized baseline-adjusted trough morning expected respiratory volume in 1 second (FEV1) area under the effect curve from time zero to 6 weeks [FEV1 AUEC(0-6wk)]. Patients in both treatment groups had significantly greater improvements in trough FEV1, compared to placebo (QVAR REDIHALER 320 mcg/day, LS mean change of 0.144 L and QVAR REDIHALER 640 mcg/day, LS mean change of 0.150 L over 6 weeks) (Table 3). Treatment with QVAR MDI was also 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 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.

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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Placebo (N=107)</th>
<th>QVAR REDIHALER 320 mcg/day (N=105)</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>0.124</td>
<td>0.116</td>
<td>0.144</td>
<td>0.150</td>
</tr>
<tr>
<td>95% CI</td>
<td>0.054, 0.193</td>
<td>0.048, 0.185</td>
<td>0.0807, 0.206</td>
<td>0.0888, 0.2132</td>
</tr>
<tr>
<td>Difference from placebo</td>
<td>0.048, 0.185</td>
<td>0.0807, 0.206</td>
<td>0.0888, 0.2132</td>
<td>0.0847, 0.2114</td>
</tr>
</tbody>
</table>

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

**Figure 1: A 12-Week Clinical Trial in Patients with Asthma: Mean Change in FEV1, mg/m2 basis.**

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

**Hepatic Impairment:** The effect of hepatic impairment on the pharmacokinetics of QVAR REDIHALER has not been evaluated.

**Drug Interaction Studies:** In vivo and in vitro 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. 13 weeks at inhalation doses up to 0.4 mg/kg/day and the remaining 82 weeks at combined oral and inhalation doses up to 2.4 mg/kg/day. There was no evidence of treatment-related increases in the incidence of tumors in this study at the highest dose, which is approximately 37 and 72 times the MRHID in adults and children, respectively, on a mg/m2 basis. Beclomethasone dipropionate did not induce gene mutation in bacterial cells or mammalian Chinese hamster ovary (CHO) cells in vitro. No significant clastogenic effect was seen in cultured CHO cells in vitro or in the mouse micronucleus test in vivo.

In rats, beclomethasone dipropionate caused decreased conception rates at an oral dose of 16 mg/kg/day (approximately 250 times the MRHID in adults on a mg/m2 basis). Impairment of fertility, as evidenced by inhibition of the estrous cycle in dogs, was observed following treatment by the oral route at a dose of 0.5 mg/kg/day (approximately 25 times the MRHID in adults on a mg/m2 basis). No inhibition of the estrous cycle in dogs was seen following 12 months of exposure to beclomethasone dipropionate by the inhalation route at an estimated daily dose of 0.33 mg/kg (approximately 17 times the MRHID in adults on a mg/m2 basis).

**14 CLINICAL STUDIES**

The safety and efficacy of QVAR REDIHALER were evaluated in 1,858 patients with asthma. The development program included 2 confirmatory trials of 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 to placebo (inhaled twice daily with placebo in adult and adolescent patients with persistent symptomatic asthma despite low-dose inhaled corticosteroid therapy) with short-acting inhaled beta-agonist, and asthma symptoms were randomized equally to QVAR REDIHALER 80 mcg/day, QVAR REDIHALER 160 mcg/day or placebo. Baseline FEV1, values were similar across treatments. The primary endpoint for this trial was the standardized baseline-adjusted trough morning forced expiratory volume in 1 second (FEV1 AUEC(0-12wk)) area under the effect curve from time zero to 12 weeks. Patients in both treatment groups had significantly greater improvements in trough FEV1 and morning PEF when compared to placebo. Reduction in asthma symptoms was also supportive of the efficacy of QVAR REDIHALER.

**Table 3: Primary Analysis of Standardized Baseline-Adjusted Trough Morning FEV1, mg/m2 Basis.**

<table>
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*QVAR MDI=QVAR Inhalation Aerosol*

**Pediatric Patients 4 to 11 Years of Age**

This randomized, double-blind, parallel-group, placebo-controlled, 12-week, global efficacy and safety trial (NCT02040766) compared QVAR REDIHALER 40 or 80 mcg, QVAR MDI 40 or 80 mcg or placebo given as 1 inhalation twice daily in pediatric patients aged 4 through 11 years old with persistent symptomatic asthma despite treatment with non-corticosteroid or low dose inhaled corticosteroid (with or without a long acting beta-agonist [LABA]). Patients aged 4 to 5 years who were technically unable to complete spirometry participated in the safety population. Patients who met the entry criteria including FEV1 of 40-85% predicted and 15% reversibility with short-acting inhaled beta-agonist, and asthma symptoms were randomized equally to QVAR REDIHALER 80 mcg/day, QVAR REDIHALER 160 mcg/day or placebo. Baseline FEV1 values were similar across treatments. The primary endpoint for this trial was the standardized baseline-adjusted trough morning forced expiratory volume in 1 second (FEV1 AUEC(0-6wk)) area under the effect curve from time zero to 6 weeks. Patients in both treatment groups had significantly greater improvements in trough FEV1, compared to placebo (QVAR REDIHALER 320 mcg/day, LS mean change of 0.144 L and QVAR REDIHALER 640 mcg/day, LS mean change of 0.150 L over 6 weeks) (Table 3). Treatment with QVAR MDI was also 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 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.

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

**Figure 1: A 12-Week Clinical Trial in Patients with Asthma: Mean Change in FEV1, mg/m2 Basis.**

**Trial 2 (NCT02513160):** 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.
QVAR® REDIHALER™ (beclomethasone dipropionate HFA) inhalation aerosol

statistically significant, change in weekly average of daily morning peak expiratory
flow (PEF, L/min) over the 12 week treatment period was 11.3 [95% CI: 5.58, 17.06]
and 8.5 [95% CI: 2.71, 14.24] for the 80 mcg/day and 160 mcg/day doses of QVAR
REDIHALER, respectively, at nominal significance. Similar results were seen with
evening PEF.

18 HOW SUPPLIED/STORAGE AND HANDLING
16.1 How Supplied
QVAR REDIHALER is supplied in 2 strengths:
- **QVAR REDIHALER 40 mcg** is supplied in a box of one 10.6-g canister containing
120 actuations which is enclosed within a sealed beige plastic actuator with a
dose counter and hinged white cap, and Patient Information and Instructions
for Use; box of one; 120 Actuations – NDC 59310-302-40
- **QVAR REDIHALER 80 mcg** is supplied in a box of one 10.6-g canister containing
120 actuations which is enclosed within a sealed maroon plastic actuator with a
dose counter and hinged white dust cap, and Patient Information and
Instructions for Use; box of one; 120 Actuations – NDC 59310-304-80

The correct amount of medication in each inhalation cannot be assured after 120
actuations from the 10.6-g canister even though the canister is not completely
empty. Patients should be informed to discard the QVAR REDIHALER when the dose
counter displays 0 or after the expiration date on the product, whichever comes first.

16.2 Storage and Handling

**Store at 25°C (77°F).**

Excursions between 15° and 30°C (59° and 86°F) are permitted (see USP Controlled
Room Temperature). For optimal results, QVAR REDIHALER should be at room
temperature when used.

**CONTENTS UNDER PRESSURE**

Do not use or store near heat or open flame. Exposure to temperatures above 49°C
(120°F) may cause bursting. Never throw QVAR REDIHALER into fire or incinerator.

Keep out of reach of children.

17 PATIENT COUNSELING INFORMATION

Advising the patient to read the FDA-Approved Patient Labeling (Patient Information
and Instructions for Use).

Patients should be given the following information:

**Local Effects**

Inform patients that localized infections with *Candida albicans* occurred in the mouth
and pharynx in some patients. If oropharyngeal candidiasis develops, treat it with
appropriate local or systemic (i.e., oral) antifungal therapy while still continuing
therapy with QVAR REDIHALER, but at times therapy with QVAR REDIHALER may
need to be temporarily interrupted under close medical supervision. Rinsing
the mouth with water without swallowing after inhalation is advised to help reduce
the risk of thrush.

**Status Asthmaticus and Acute Asthma Symptoms**

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.

**Immunosuppression**

Warn patients who are on immunosuppressant doses of corticosteroids to avoid
exposure to chickenpox or measles and, if exposed, to consult their physicians
without delay. Inform patients of potential worsening of existing tuberculosis; fungal,
bacterial, viral, or parasitic infections; or ocular herpes simplex.

**Hypercorticism and Adrenal Suppression**

Advise patients that QVAR REDIHALER may cause systemic corticosteroid effects of
hypercorticism and adrenal suppression. Additionally, instruct patients that
deaths due to adrenal insufficiency have occurred during and after transfer
from systemic corticosteroids. Patients should taper slowly from systemic corticosteroids
if transferring to QVAR REDIHALER.

**Immediate Hypersensitivity Reactions**

Advise patients that immediate hypersensitivity reactions (e.g., urticaria, angioedema,
rash, bronchospasm, and hypotension), including anaphylaxis, may occur after
administration of QVAR REDIHALER. Patients should discontinue QVAR REDIHALER
if such reactions occur and contact their healthcare provider or get emergency
medical help.

**Reduction in Bone Mineral Density**

Advise patients who are at an increased risk for decreased BMD that the use of
corticosteroids may pose an additional risk.

**Reduced Growth Velocity**

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

**Ocular Effects**

Long-term use of inhaled corticosteroids may increase the risk of some eye problems
(cataracts, glaucoma or blurred vision); consider regular eye examinations.

**Pregnancy**

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. Patients 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.

**Instruct 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. If 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

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**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 or 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.

*What should I avoid while taking QVAR REDIHALER?*

If you have not had, or have not been vaccinated against, chickenpox or measles, you should stay away from people who are infected.

*What are the possible side effects of QVAR REDIHALER?*

QVAR REDIHALER may cause serious side effects, including:

- **fungal infections (thrush) in your mouth and throat.** You may develop a yeast infection (Candida albicans) in your mouth and throat. Tell your healthcare provider if you have any redness or white colored patches in your mouth or throat. Rinse your mouth with water **without swallowing** after using QVAR REDIHALER to help prevent an infection in your mouth or throat.
- **worsening asthma or sudden asthma attacks.** You should contact your healthcare provider right away if you do not get relief from your sudden asthma attacks, after using your rescue inhaler, during your treatment with QVAR REDIHALER.
- **reduced adrenal function** (adrenal insufficiency). Adrenal insufficiency that can lead to death can happen when you stop taking oral corticosteroid medicines and start using inhaled corticosteroid medicines. Adrenal insufficiency can also happen in people who take higher doses of QVAR REDIHALER than recommended over a long period of time. When your body is under stress such as from fever, trauma (such as a car accident), infection, or surgery, adrenal insufficiency can get worse. Signs and symptoms of adrenal insufficiency may include:
  - feeling tired or exhausted (fatigue)
  - lack of energy
  - low blood pressure (hypotension)
  - dizziness or feeling faint
  - nausea and vomiting
  - weakness
- **immune system effects** and a higher chance for infections. Tell your healthcare provider about any signs or symptoms of infection such as:
  - fever
  - chills
  - pain
  - feeling tired
  - body aches
  - nausea
  - vomiting
- **increased wheezing (bronchospasm)** right after using QVAR REDIHALER. Always have a rescue inhaler with you to treat sudden wheezing.

**serious allergic reactions.** Stop using QVAR REDIHALER and call your healthcare provider or get emergency medical help right away if you get any of the following signs or symptoms of a serious allergic reaction:
  - hives
  - swelling of your lips, tongue or face
  - rash
  - breathing problems

**slowed growth in children.** Children should have their growth checked regularly while using QVAR REDIHALER.
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.

QVAR® REDIHALER™ (beclomethasone dipropionate HFA) inhalation aerosol

Instructions for Use

QVAR REDIHALER (kue’ var red-ee-haye’ ler)
(beclomethasone 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.
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.

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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