Ознакомьтесь с QVAR RediHaler

QVAR® RediHaler - это ежедневный ингалятор для поддержания астмы, а не спасательный (быстрого действия) ингалятор. Пользование им 2 раза в день сможет помочь предотвратить симптомы астмы и обострения при лечении воспаления легких - основной причины симптомов астмы.

Одобренное использование

QVAR® RediHaler™ (беклометазона дипропионат HFA) Ингалятор Аэрозоль - это лекарственное средство, предназначенное для вдыхания и которое срабатывает если есть синхронность между выбросом медикамента и вдохом, и используется для профилактики и контроля астмы у людей в возрасте 4 лет и старше.

Важная информация о безопасном использовании

- Не используйте QVAR RediHaler при вnungных острых приступах астмы. У вас всегда должен быть с собой спасательный ингалятор для облегчения в>Loading more pages due to high content amount.</div>
**Инструкция по хранению**

- Держите белый колпачок на ингаляторе закрытым во время хранения.
- Храните при комнатной температуре от 68 °F до 77 °F (20 °C - 25 °C). Разрешены колебания температуры между 59 °F и 86 °F (15 °C и 30 °C).
- Не используйте и не храните вблизи источники тепла или открытого пламени. Воздействие температуры выше 120 °F (49 °C) может привести к разрыву канистры.
- Не бросайте в огонь или мусоросжигательное устройство.

**Когда заменить**

Когда счетчик доз достигнет 20, цвет цифры изменится на красный, указывая на то, что пришло время для пополнения. (Если вы будете использовать свой ингалятор после того, как счетчик доз достигнет нуля, вы не не получите правильное количество медикамента.)

Выбросьте QVAR® RediHaler™, когда счетчик доз отобразит «0», а фон будет сплошным красным или по истечении срока годности на упаковке, в зависимости от того, что наступит раньше.

Замените QVAR RediHaler до истечения срока его действия. Не используйте ингалятор после истечения срока его действия.

**Чистка вашего ингалятора**

Чистите мундштук ингалятора не реже одного раза в неделю чистой сухой салфеткой или тканью. НЕ МОЙТЕ или НЕ ПОМЕЩАЙТЕ какую-либо часть вашего QVAR RediHaler в воду.

**Важная информация о безопасном использовании (продолжение)**

- Не используйте QVAR RediHaler чаще, чем предписано.
- Сообщите своему врачу о всех лекарствах, которые вы принимаете, и обо всех ваших известных недомоганиях.
- QVAR RediHaler может вызвать серьезные побочные эффекты, в том числе:
  - Грибковые инфекции (молочница) во рту и горле. Прополощите рот водой без проглатывания после использования QVAR RediHaler, чтобы предотвратить инфекцию во рту или горле.
  - Ухудшение астмы или внезапных приступов астмы. После использования вашего спасательного ингалятора немедленно свяжитесь с вашим врачом, если вы не получите облегчения от внезапных приступов астмы.
  - Снижение функции надпочечников (надпочечниковая недостаточность). Это потенциально опасное для жизни состояние может произойти, когда вы прекратите принимать пероральные кортикостероиды и начнёте использовать вдыхаемые кортикостероидные лекарства (например, QVAR RediHaler). Немедленно сообщите своему врачу о любых признаках и симптомах надпочечниковой недостаточности, таких как: чувство усталости или слабости (утомления); недостаток энергии; низкое кровяное давление (гипотония); головокружение или слабость; тошнота и рвота.
  - Ослабление иммунной системы и более высокий шанс инфекционного заражения. Сообщите своему врачу о любых признаках или симптомах инфекции, таких как: лихорадка, озноб, боль, чувство усталости, боли в теле, тошнота или рвота.
  - Увеличение хрипов (бронхоспазм) сразу после использования QVAR RediHaler. Вы должны использовать спасательный ингалятор при наличии свистящего дыхания.

**Вопросы?**

Посетите QVAR.com или позвоните по номеру 1-888-483-8279 за дополнительной поддержкой или информацией о том, как использовать или очищать свой ингалятор.

- Серьезные аллергические реакции. Прекратите использование QVAR RediHaler и позвоните своему поставщику медицинских услуг или немедленно получите неотложную медицинскую помощь, если у вас появились следующие симптомы: крапивница; отек губ, языка или лица; сыть; или проблемы с дыханием.
- Замедленный рост у детей. У детей должен регулярно проверяться рост при использовании QVAR RediHaler.
- Снижение плотности костной ткани. Это может быть проблемой для людей, которые приостановили прием пероральных кортикостероидов.
- Глазные проблемы. Если у вас была глаукома, катаракта или помутнение зрения в прошлом, вам необходимо регулярно проверять зрение при использовании QVAR RediHaler.

**Общие побочные эффекты QVAR RediHaler включают:**
- дрожжевая инфекция во рту (оральный кандидоз);
- холодные симптомы (инфекция верхних дыхательных путей);
- боль в горле (орофарингит);
- раздражение слизистой оболочки (синусит);
- снижение иммунной системы; и более высокий шанс инфекционного заражения.

Обратитесь к сопроводительной полной информации о назначении, включая полные инструкции по использованию.
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. (5.3)
- 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. (5.4)
- 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. (5.5)
- Hypersensitivity reactions: Hypersensitivity reactions, such as urticaria, angioedema, rash, and bronchospasm may occur. Discontinue QVAR REDIHALER if such reactions occur. (5.6)
- 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. (5.7)
- Effects on growth: Monitor growth of pediatric patients. (5.8)
- Decreases in bone mineral density: Monitor patients with major risk factors for decreased bone mineral content. (5.9)
- Eye Disorders: Monitor patients with change in vision or with a history of increased intraocular pressure, blurred vision, glaucoma, and/or cataracts closely. (5.10)

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)

To report SUSPECTED ADVERSE REACTIONS, contact Teva Pharmaceuticals at 1-888-483-8279 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch
See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.
Revised: 3/2018

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use QVAR REDIHALER safely and effectively. See full prescribing information for QVAR REDIHALER.

QVAR® REDIHALER™ (beclomethasone dipropionate HFA) inhalation aerosol, for oral inhalation use
Initial U.S. Approval: 1976

INDICATIONS AND USAGE
QVAR REDIHALER is a corticosteroid indicated for:
- Maintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older. (1)

Important Limitations:
- Not indicated for the relief of acute bronchospasm. (1)

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)

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

CONTRAINDICATIONS
- Maintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older. (1)

Important Limitations:
- Not indicated for the relief of acute bronchospasm. (1)

WARNINGs AND PRECAUTIONS
- Localized infections: Candida albicans infection of the mouth and throat may occur. Advise patients to rinse the mouth with water without swallowing after inhalation to help reduce the risk. (5.1)
- 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)

ADVERSE REACTIONS
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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.

Important Limitations of Use:
- QVAR REDIHALER is NOT indicated for the relief of acute bronchospasm.

2 DOSAGE AND ADMINISTRATION
2.1 Administration Information
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. 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).

Priming: QVAR REDIHALER does not require priming.

Shaking the inhaler prior to use is not necessary. Do not shake the inhaler with the cap open to avoid possible actuation of the device.

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

Cleaning:
- Keep the inhaler clean and dry at all times. Never wash or put any part of the inhaler in water.
- Routine maintenance is not required. If the mouthpiece needs cleaning, gently wipe the mouthpiece with a dry cloth or tissue as needed.

Dose Counter: QVAR REDIHALER has a dose counter attached to the actuator. When the patient receives the inhaler, the number 120 will be displayed. The dose counter will count down each time a spray is released. When the dose counter reaches 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 physician for a prescription refill.

When the dose counter reaches 0, the background will change to solid red. Discard QVAR REDIHALER inhaler when the dose counter displays 0 or after the expiration date on the product, whichever comes first. [See Patient Counseling Information (17)].

2.2 Recommended Dosage
Adults and Adolescents 12 years of age and older
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 12 years of age and older who are not on an inhaled corticosteroid is 40 to 80 mcg twice daily, approximately 12 hours apart. 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

8 USE IN SPECIFIC POPULATIONS
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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 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 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 phenomenon has been demonstrated 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 in the following 2 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 40 mcg is available as a 120-inhalation/10.6-g canister.
- 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 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 beta2-agonist such as QVAR REDIHALER should be used to relieve acute 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 Transferring Patients from Systemic Corticosteroid Therapy

Particular care is needed in patients who are transferred from systematically 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 systematically available inhaled corticosteroids. After withdrawal from systemic 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, clinical signs and symptoms of adrenal insufficiency may be expected after 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.

5.4 Deterioration of Asthma and Acute Episodes

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.

5.5 Paradoxical Bronchospasm

Paradoxical bronchospasm can occur in some patients on QVAR REDIHALER. If these reactions occur [see Contraindications (4.2)].

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 higher doses, the beneficial effects 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 corticosteroid effects and the dose reduced if a more serious or even fatal course in non-immune patients on corticosteroids. Patients who have been withdrawn from corticosteroids (e.g., joint and/or muscular pain, lassitude, and depression, despite maintenance or even improvement of respiratory function.

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 immobilization, famines, history of osteoporosis, 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.

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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)]

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 Patients 4 to 11 Years of Age 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>Number (%) of patients</th>
<th>QVAR REDIHALER</th>
<th>QVAR MDI</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=92</td>
<td>80 mcg N=126</td>
<td>160 mcg N=125</td>
<td>320 mcg N=214</td>
</tr>
<tr>
<td>Oral Candidiasis</td>
<td>0 (0)</td>
<td>2 (2)</td>
<td>7 (3)</td>
<td>15 (7)</td>
</tr>
<tr>
<td>Upper Respiratory Tract Infection</td>
<td>3 (3)</td>
<td>3 (3)</td>
<td>9 (4)</td>
<td>6 (3)</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>4 (4)</td>
<td>2 (2)</td>
<td>3 (1)</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Oropharyngeal Pain</td>
<td>2 (2)</td>
<td>2 (2)</td>
<td>1 (&lt;1)</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Viral Upper Respiratory Tract Infection</td>
<td>3 (3)</td>
<td>0</td>
<td>1 (&lt;1)</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>3 (3)</td>
<td>0</td>
<td>1 (&lt;1)</td>
<td>2 (&lt;1)</td>
</tr>
<tr>
<td>Rhinitis Allergic</td>
<td>0 (0)</td>
<td>3 (3)</td>
<td>0</td>
<td>2 (&lt;1)</td>
</tr>
<tr>
<td><em>QVAR MDI=QVAR Inhalation Aerosol</em></td>
<td></td>
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<td></td>
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</tr>
</tbody>
</table>
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. Results in a lower number of live births relative to controls at doses of beclomethasone dipropionate 6 times that of triamcinolone acetonide, 1.5 times that of beclomethasone dipropionate 25 times that of beclomethasone dipropionate. The clinical significance of these findings is unknown. Studies in patients with asthma have shown a favorable ratio between topical anti-inflammatory activity and systemic corticosteroid effects with recommended doses of QVAR REDIHALER.

12.2 Pharmacokinetics

Absorption

QVAR REDIHALER is a pressurized, breath-actuated, metered-dose aerosol with a valve, no priming actuations are required before use. For both products, an actuation of 80 mcg delivers 80 mcg of beclomethasone dipropionate from the actuator mouthpiece and 100 mcg from the canister valve. Both products deliver 50 microliters of solution formulation as an aerosol from the canister valve. QVAR REDIHALER has not been evaluated.

12.3 Pharmacokinetics

Absorption

The mean peak plasma concentration (C_max) of QVAR MDI (100 mcg) administered every 12 hours was 0.77 pg/mL at 2 hours after inhalation of 200 mcg using QVAR REDIHALER (4 inhalations of the 80 mcg dose strength). The mean peak plasma concentration of the major and most active metabolite, 17-BMP, was 1464 pg/mL at 10 minutes after inhalation of 320 mcg of QVAR REDIHALER.

Distribution

Lung tissue protein binding for 17-BMP was reported to be 94-96% over the concentration range of 1000 to 5000 pg/mL. Protein binding was constant over the concentration range evaluated. There is no evidence of tissue storage of beclomethasone dipropionate or its metabolites.

Excretion

Irrespective of the route of administration (injection, oral or inhalation), beclomethasone dipropionate and its metabolites are mainly excreted in the feces. Less than 10% of the drug and its metabolites are excreted in the urine.

Specific Populations

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

Pediatrics: No pharmacokinetic studies for QVAR REDIHALER have been conducted in children. Use of QVAR REDIHALER in children aged 4 to 17 years has been evaluated.

Metabolism

Three major metabolites are formed via esterases:

- beclomethasone-17-monopropionate (17-BMP)
- beclomethasone-21-monopropionate (21-BMP)
- beclomethasone (BOH)

Lung metabolites beclomethasone dipropionate rapidly to 17-BMP and more slowly to BOH. 17-BMP is the most active metabolite.

12.4 Mechanism of Action

Becloherasa dipropionate is a corticosteroid demonstrating potent anti-inflammatory activity. The precise mechanism of corticosteroid action on asthma is not known. Corticosteroids have been shown to have multiple anti-inflammatory effects, inhibiting both inflammatory cells (e.g., mast cells, eosinophils, basophils, lymphocytes, macrophages, and neutrophils) and release of inflammatory mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines). These anti-inflammatory actions of corticosteroids contribute to their efficacy in asthma. Beclomethasone dipropionate is a prodrug that is rapidly activated by hydrolysis to the active monomer, 17-monopropionate (17-BMP). Beclomethasone-17-monopropionate has been shown in vitro to inhibit a binding affinity for the human glucocorticoid receptor. In vivo, it is a potent inhibitor of the nuclear factor kappa B (NF-κB) pathway, inhibiting both inflammatory cells (e.g., mast cells, eosinophils, basophils, lymphocytes, macrophages, and neutrophils) and release of inflammatory mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines). These anti-inflammatory actions of corticosteroids contribute to their efficacy in asthma. Beclomethasone diproprionate is a prodrug that is rapidly activated by hydrolysis to the active monomer, 17-monopropionate (17-BMP). Beclomethasone-17-monopropionate has been shown in vitro to inhibit a binding affinity for the human glucocorticoid receptor. In vivo, it is a potent inhibitor of the nuclear factor kappa B (NF-κB) pathway, inhibiting both inflammatory cells (e.g., mast cells, eosinophils, basophils, lymphocytes, macrophages, and neutrophils) and release of inflammatory mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines). These anti-inflammatory actions of corticosteroids contribute to their efficacy in asthma.
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 MRHDID 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 MRHDID 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 MRHDID 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 MRHDID 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, inhaled twice daily as 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, reversible bronchoconstriction of at least 10% 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 forced expiratory 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 REDIHALER 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 FEV1, morning PEF, weekly average of daily trough morning FEV1, reduced rescue medication use and improved asthma symptom scores than with placebo. Similar results were demonstrated with QVAR MDI.

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.

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</th>
<th>Placebo</th>
<th>QVAR REDIHALER 320 mcg/day (N=90)</th>
<th>QVAR REDIHALER 640 mcg/day (N=107)</th>
<th>Placebo</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>
<th>p-value Analysis set</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>
<td>0.148</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>0.054, 0.193</td>
<td>0.048, 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>

*QVAR MDI=QVAR Inhalation Aerosol

Pediatric Patients 4 to 11 Years of Age

This randomized, double-blind, parallel-group, placebo-controlled, 12-week, efficacy and safety trial (NCT02040766) compared QVAR REDIHALER 40 or 80 mcg, with short-acting inhaled beta-agonist, to placebo 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, 40-90% predicted normal and reversible bronchoconstriction at or below 12% with short acting inhaled beta agonist entered a 14-21 day run-in period. Patients who met the randomization criteria including asthma symptoms and rescue medication use were randomized equally across treatment groups. Five hundred sixty-eight (568) pediatric patients with symptomatic asthma of which 410 had previously been treated with low dose inhaled corticosteroids with or without a LABA were randomized to receive either 40 mcg or 80 mcg twice daily of QVAR REDIHALER, QVAR MDI or placebo. The primary endpoint was the change from baseline in trough percent predicted FEV1, AUEC (0-12 weeks). While the primary endpoint, was not
QVAR® REDIHALER™ (beclomethasone dipropionate HFA) inhalation aerosol

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 59310-304-40
- **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

Advise 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 beta₂-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, 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.

**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.** 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.

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 mouthpiece. 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. Instruct 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
© 2018 Teva Respiratory, LLC
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.

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.
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.

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.

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 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.

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.

How to store your QVAR REDIHALER
- Store QVAR REDIHALER at room temperature between 68°F to 77°F (20°C - 25°C). Excursions between 59°F and 86°F (15°C and 30°C) 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.

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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