흡입기 알아보기

**QVAR RediHaler**

QVAR® RediHaler™는 응급(바른 완화) 흡입기가 아닌 일상적인 천식 관리를 위한 흡입기입니다. 하루에 2회 사용하면 천식 증상의 근본적인 원인인 폐염증을 치료하여 천식 증상 및 갑작스런 재발을 방지하는 데 도움이 됩니다.

**승인 용도**

QVAR® RediHaler™(beclomethasone dipropionate HFA) Inhalation Aerosol은 만4세 이상의 사람이 천식을 예방 및 제어하기 위한 관리 치료로 사용할 수 있는 흡입 작동성 흡입기 처방 약품입니다.

QVAR RediHaler를 사용하기 전, 아래 단계를 읽으십시오. 항상 의사의 지시대로 사용하십시오.

1. 흡입기의 흡입구를 닫고 있는 백색 마개를 엽니다.
2. 흡입구를 입에 대고 입으로 약제를 흡입하는 경우에만 마개를 열십시오.
3. 숨을 들어 마실 때 약제가 배출되지 않도록 하십시오.

사용 방법

매번 흡입하기 전에 백색 마개가 닫힌 상태로 흡입기를 준비해야 합니다. 그렇지 않으면 약제가 배출되지 않습니다. 흡입제를 흡입할 준비가 될 때까지 마개를 열지 마십시오.

QVAR RediHaler를 사용하기 전, 아래 단계를 읽으십시오. 항상 의사의 지시대로 사용하십시오.

1. 흡입기의 흡입구를 닫고 있는 백색 마개를 엽니다. 흡입제를 흡입하는 경우에만 마개를 열십시오.
2. 빠른 호흡을 가질 준비를 하십시오. 장치를 통한 공기 흐름 차단을 방지하려면 손이 흡입기 상단의 통풍구를 막지 않도록 하십시오. 흡입제 흡입 시에는 흡입기와 흡입구가 똑바로 서도록 잡아야 합니다. 깊게 들이 마셔 약제가 배출되도록 하십시오. 흡입기를 제거하고 5~10초 동안 숨을 참은 후, 흡입기에서 입을 떼고 천천히 숨을 내십시오.
3. 흡입한 이후에는 백색 마개를 닫아 다음 흡입 시 사용할 수 있도록 합니다.

중요 안전 정보

- 갑작스런 심각한 천식 증상을 치료하기 위해 QVAR RediHaler를 사용하지 마십시오. 갑작스런 증상 치료에는 항상 응급 흡입기를 사용하십시오.
- QVAR RediHaler의 beclomethasone dipropionate 또는 성분에 알레르기 증상이 있는 경우에는 QVAR RediHaler를 사용하지 마십시오.

다음 페이지의 추가 중요 안전 정보 및 전체 사용 지침이 포함된 동봉된 전체 처방 정보를 참조하십시오.

“HOW-TO” 비디오 보기

흡입기 사용의 단계별 안내 비디오는 QVARHowTo.com에서 확인할 수 있습니다.
보관 방법
- 보관 중에는 흡입기의 백색 마개를 닫아 두어야 합니다.
- 68°F-77°F(20°C-25°C) 사이의 상온에서 보관하십시오. 단기 외출 시 59°F-86°F(15°C-30°C)에서 사용할 수 있습니다.
- 열 또는 불꽃 근처에서 사용하거나 보관하지 마십시오.
120°F(49°C)를 초과한 온도에 노출되면 용기가 폭발할 위험이 있습니다. 불 또는 소각로로 던지지 마십시오.

흡입기 청소
흡입기의 흡입구를 최소 일주일에 한 번 청결하고 건조한 티슈나 천으로 청소하십시오. QVAR® RediHaler의 일부를 물로 세척하거나 물에 담그지 마십시오.

교체 시기
복용량 카운터가 20에 도달한 경우, 숫자가 적색으로 바뀌어 리필 시점을 알려줍니다. (복용량 카운터가 0에 도달한 이후 흡입기를 사용하는 경우 정확한 양의 약제를 흡입하지 못할 수 있습니다).
순서에 상관없이 흡입기를 사용할 수 있습니다. QVAR® RediHaler™를 폐기하십시오.

질문이 있으십니까?
QVAR.com을 방문하거나 1-888-483-8279번으로 전화하여 흡입기 사용 또는 청소 방법에 대한 추가 지원이나 정보를 받으십시오.

중요 안전 정보(계속)
- QVAR® RediHaler을 처방 횟수보다 자주 사용하지 마십시오.
- 의사에게 복용 중인 의약품 및 모든 건강 상태에 대해 알려십시오.
- QVAR® RediHaler은 다음과 같은 심각한 부작용을 유발할 수 있습니다.
  ○ 심각한 알레르기 반응, 두드러기, 입술, 혀 또는 얼굴의 붓기, 발진, 호흡곤란을 경험하는 경우 QVAR® RediHaler 사용을 중지하고 의사에게 전화하거나 응급 의료진의 지원을 받으십시오.
  ○ 어린이의 성장 저하. QVAR® RediHaler를 사용하는 동안 어린이는 정기적으로 성장 검사를 받아야 합니다.
  ○ 골밀도 감소. 골밀도가 낮은 사람에 대해 발생할 수 있습니다.
  ○ 눈 문제. 과거에 녹내장, 백내장 또는 시력 저하를 경험한 적이 있는 경우에는 정기 시력 검사를 받아야 합니다.
  ○ QVAR® RediHaler의 일반적인 부작용은 다음과 같습니다. 구강 내 효모 감염(구강칸디다증), 감기 증상(상부 기도 감염), 인후통(구강 인두통), 코 및 목의 통증 또는 콧기(비만두염), 부비강염(축농증), 맛각 알레르기(알레르기성 비염)이 있습니다. 이러한 부작용은 QVAR® RediHaler을 사용하는 동안 발생할 수 있습니다.

응급 시 대처
갑작스런 천명에 대비하여 항상 응급 흡입기를 가지고 다니십시오.

동봉된 전체 처방 정보(전체 사용 지침 포함)를 참조하십시오.
HIGHLIGHTS OF PRESCRIBING INFORMATION

QVAR® REDIHALER™ (beclomethasone dipropionate HFA) inhalation aerosol, for oral inhalation use

1 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)
- 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)

For oral inhalation only. (2.1)

- Deterioration of asthma and acute episodes: Do not use QVAR REDIHALER for these episodes. (5.2)
- 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. (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)

2 DOSAGE AND ADMINISTRATION

- Primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required. (4)
- Hyperglycemia: Monitor patients with diabetes mellitus who are receiving any systemic corticosteroids. (5.6)
- Hypersensitivity to any of the ingredients of QVAR REDIHALER. (4)

3 DOSAGE FORMS AND STRENGTHS

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

4 CONTRAINDICATIONS

- Local Effects
- Deterioration of Asthma and Acute Episodes
- Transferring Patients from Systemic Corticosteroid Therapy
- Immunosuppression
- Paradoxical Bronchospasm
- Immediate Hypersensitivity Reactions
- Hypertension and Adrenal Suppression
- Effects on Growth
- Reduction in Bone Mineral Density
- Eye Disorders

5 WARNINGS AND PRECAUTIONS

- 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. (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)

6 ADVERSE REACTIONS

- Local Effects
- Deterioration of Asthma and Acute Episodes
- Transferring Patients from Systemic Corticosteroid Therapy
- Immunosuppression
- Paradoxical Bronchospasm
- Immediate Hypersensitivity Reactions
- Hypertension and Adrenal Suppression
- Effects on Growth
- Reduction in Bone Mineral Density
- Eye Disorders

7 PATIENT COUNSELING INFORMATION

- 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 treatment.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
8.2 Lactation
8.3 Females and Males of Reproductive Potential
8.4 Pediatric Use
8.5 Geriatric Use

9 DESCRIPTION

10 CLINICAL PHARMACOLOGY

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
12.2 Pharmacodynamics
12.3 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

14 CLINICAL STUDIES

14.1 Trials in the Maintenance Treatment of Asthma

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied
16.2 Storage and Handling

17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.
corticosteroid product and disease severity: 40, 80, 160 or 320 mcg twice daily. For patients who do not respond adequately to the initial dosage after 2 weeks of therapy, increasing the dosage may provide additional asthma control. The maximum recommended dosage for patients 4 to 11 years of age is 80 mcg twice daily.

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

General Dosing Recommendations
The onset and degree of symptom relief will vary in individual patients. Improvement in asthma symptoms can occur within 24 hours of the beginning of treatment and should be expected within the first or second week, but maximum benefit should not be expected until 3 to 4 weeks of therapy. Improvement in pulmonary function is usually apparent within 1 to 4 weeks after the start of therapy.

If a dosage regimen of QVAR REDIHALER fails to provide adequate control of asthma, the therapeutic regimen should be re-evaluated and additional therapeutic options (e.g., replacing the current strength of QVAR REDIHALER with a higher strength, or adding additional controller therapies) should be considered.

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

3 DOSAGE FORMS AND STRENGTHS
Inhalation Aerosol. QVAR REDIHALER is a pressurized, breath-actuated, metered-dose aerosol with a dose counter intended for oral inhalation containing beclomethasone dipropionate as the active ingredient.

• QVAR REDIHALER 40 mcg is supplied in an aluminum canister contained within a beige plastic actuator with a dose counter and a hinged white cap. Each breath-induced actuation delivers 50 mcg from the valve and 40 mcg from the actuator.

• QVAR REDIHALER 80 mcg is supplied in an aluminum canister contained within a maroon plastic actuator with a dose counter and a hinged white cap. Each breath-induced actuation delivers 100 mcg of beclomethasone dipropionate from the valve and 80 mcg from the actuator. QVAR REDIHALER 80 mcg is available as a 120-inhalation/10,6-g canister.

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

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

5 WARNINGS AND PRECAUTIONS
5.1 Local Effects
Localized irritation 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 beta2-agonist should be used to relieve reversible bronchospasm, 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 systemically 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, signs or symptoms of adrenal insufficiency may develop 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 physiological amounts of glucocorticoid systemically and does NOT provide the mineralocorticoid that is necessary for coping with these emergencies. When 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 periods of stress or a severe asthma attack, some patients may experience symptoms of systemic corticosteroids 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 on QVAR REDIHALER. If paradoxical bronchospasm occurs following dosing with QVAR REDIHALER, it should be treated immediately with an inhaled, short-acting bronchodilator. Treatment with QVAR REDIHALER should be discontinued and alternate therapy instituted.

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

5.7 Hypercorticism and Adrenal Suppression
QVAR REDIHALER will often help control asthma symptoms with less suppression of HPA function than therapeutically equivalent oral doses of prednisone. Since beclomethasone dipropionate is absorbed into the circulation and can be systemically active at high 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 systemic corticosteroid effects. Baseline heights of pediatric patients treated with QVAR REDIHALER should be observed carefully for any evidence of systemic corticosteroid effects. Particular care should be taken to avoid exposure. It is not known how the dose, route and duration of corticosteroid administration affect the risk of developing growth retardation, although a controlled clinical study has shown that beclomethasone dipropionate has the potential to affect growth in children.

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 malnutrition, 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
Growth of inhaled corticosteroids may cause a decrease in intraocular pressure, blurred vision and cataracts have been reported following the use of long-term administration of inhaled corticosteroids. Therefore, close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, blurred vision, glaucoma, and/or cataracts while using QVAR REDIHALER.
6 ADVERSE REACTIONS

Systemic and local corticosteroid use may result in the following:

- **Candida albicans infection** [see Warnings and Precautions (5.1)]
- Immunosuppression [see Warnings and Precautions (5.4)]
- Hypercorticism and adrenal suppression [see Warnings and Precautions (5.7)]
- Growth effects [see Warnings and Precautions (5.8) and Use in Specific Populations (8.4)]
- Eye Disorders [see Warnings and Precautions (5.10)]

6.1 Clinical Trials Experience

A total of 1,858 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 1,230 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>
<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>Upper Respiratory Tract Infection</td>
<td>6 (4)</td>
<td>3 (3)</td>
<td>9 (4)</td>
<td>6 (3)</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>4 (4)</td>
<td>3 (3)</td>
<td>9 (4)</td>
<td>6 (3)</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>1 (&lt;1)</td>
<td>0</td>
<td>1 (&lt;1)</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Rhinitis Allergic</td>
<td>1 (&lt;1)</td>
<td>0</td>
<td>1 (&lt;1)</td>
<td>3 (1)</td>
</tr>
</tbody>
</table>

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:

- Headache
- Nausea
- Vomiting
- Diarrhea
- Pyrexia

Other adverse reactions that occurred in clinical trials using QVAR REDIHALER with an incidence of 3% or more and which occurred at a greater incidence than placebo were:

- Asthma exacerbation
- Uncontrolled asthma
- Cough
- Dysphonia
- Dysphagia

6.2 Postmarketing Experience

In addition to the adverse reactions reported from clinical trials with QVAR REDIHALER, the following adverse reactions have been identified from 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).

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 fetal 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 drug doses equal and ratio 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.

**Labor or Delivery**

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 from 3 female rabbits. 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 in rats at inhaled doses 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 embryolethal 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.
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 breastfeeding 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 clinical trial.

8.5 Geriatric Use

No pharmacokinetic studies for QVAR REDIHALER have been conducted in elderly patients.

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.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Beclomethasone dipropionate is a corticosteroid that may inhibit cell proliferation, reduce eosinophilic infiltration, and reduce airway edema. It reduces leukocyte infiltration and decreases neutrophil accumulation in bronchiolar brushings in vivo and in vitro.

12.2 Pharmacodynamics

HPA Axis Effects

The effects of QVAR MDI on the hypothalamic-pituitary-adrenal (HPA) axis were evaluated in 40 corticosteroid-naive patients. QVAR MDI, at doses of 80, 160, or 320 mcg twice daily, was compared with placebo and 336 mcg twice daily of CFC-BDP. Active treatment groups showed an expected dose-related reduction in 24-hour urinary-free cortisol (a sensitive marker of adrenal production of cortisol). Patients treated with the highest dose recommended of QVAR MDI (320 mcg twice daily) had a 37.3% reduction in 24-hour urinary-free cortisol compared to a reduction of 47.3% produced by treatment with 336 mcg twice daily of CFC-BDP. There was a 12.2% reduction in 24-hour urinary-free cortisol seen in the group of patients that received 80 mcg twice daily of QVAR MDI and a 24.6% reduction in the group of patients that received 160 mcg twice daily. An open label study of 354 asthma patients given beclomethasone dipropionate for one year assessed the effect of treatment with this product on the HPA axis (as measured by both morning and stimulated plasma cortisol). Less than 1% of patients treated for one year with this product had an abnormal response (peak less than 18 mcg/dL) to a short-cortisoprin test.

12.3 Pharmacokinetics

Beclomethasone dipropionate undergoes rapid and extensive conversion to beclomethasone-17-monopropionate (17-BMP) before biologically active metabolites are released into the systemic circulation. Bioavailability of beclomethasone dipropionate is approximately 4 hours for QVAR REDIHALER.

Distribution

The mean peak plasma concentration (Cmax) of BDP was 6635 pg/mL at 2 minutes after inhalation of 320 mcg using QVAR REDIHALER (4 inhalations of the 80 mcg/inhalation dose).

Metabolism

Three major metabolites are formed via esterases: beclomethasone-17-monopropionate (17-BMP), beclomethasone-21-monopropionate (21-BMP), and beclomethasone (BOH). Lung metabolism beclomethasone dipropionate rapidly to 17-BMP and more slowly to BOH. 17-BMP is the most active metabolite.

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 aged 4 to 17 years. However, the pharmacokinetics of 17-BMP, including dose and strength proportionality, is similar in children and adults using QVAR MDI, although the exposure is highly variable. In children (mean age 10 years), the Cmax of 17-BMP was 787 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 a 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.
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

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 with placebo in adults and adolescents 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 40-90% predicted normal and 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 exhaled forced expiratory volume in 1 second (FEV1) area under the effect curve from time zero to 6 weeks (FEV1; AUC0-6wk). 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 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

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) 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>Statistic</th>
<th>Placebo (N=90)</th>
<th>QVAR REDIHALER 80 mcg/day (N=88)</th>
<th>QVAR REDIHALER 160 mcg/day (N=82)</th>
<th>Placebo (N=107)</th>
<th>QVAR REDIHALER 320 mcg/day (N=108)</th>
<th>QVAR REDIHALER 640 mcg/day (N=108)</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>
<td>0.148</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>—</td>
<td>0.054, 0.193</td>
<td>0.048, 0.185</td>
<td>—</td>
<td>0.0807, 0.097</td>
<td>0.0868, 0.2132</td>
<td>0.0847, 0.2114</td>
<td></td>
</tr>
</tbody>
</table>

*QVAR MDI=QVAR Inhilation Aerosol

Pediatric Patients 4 to 11 Years of Age

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 children aged 4 to 11 years old with persistent symptomatic asthma despite treatment with non-corticosteroid, 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 asthma symptoms and rescue medication use and bronchodilation but were randomized equally across treatment groups. Five hundred sixty-nine (569) pediatric patients with symptomatic asthma of which 410 had previously been treated with low dose inhaled corticosteroids with or without LABA were randomly assigned 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 to trough percent predicted FEV1, AUEC0-6wk. While the primary endpoint, was not...
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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.

16 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
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 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, 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.

QVAR® REDIHALER™ (beclomethasone dipropionate HFA) inhalation aerosol

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.

Inform patients that QVAR REDIHALER has a dose counter attached to the actuator at the rear of the mouth piece. When the patient receives the inhaler, the number 120 will be displayed. The dose counter will count down each time a spray is released. The dose-counter window displays the number of sprays left in the inhaler in units of two (e.g., 120, 118, 116, etc). When the counter displays 20, the color of the numbers will change to red to remind the patient to contact their pharmacist for a refill of medication or consult their healthcare provider for a prescription refill. When the dose counter reaches 0, the background will change to solid red. Inform patients to discard QVAR REDIHALER when the dose counter displays 0 or after the expiration date on the product, whichever comes first.

Rx only
Marketed by: Teva Respiratory, LLC
Frazer, PA 19355
Developed and Manufactured by:
Norton (Waterford) Limited
Unit 301, IDA Industrial Park, Cork Road, Waterford, Ireland
© 2018 Teva Respiratory, LLC
U.S. Patent 7,637,260; 8,132,712; 8,931,476
QVARN-002
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.

• Do not use QVAR REDIHALER 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.

Who should not use QVAR REDIHALER?
Do not use QVAR REDIHALER:
• to treat sudden severe symptoms of asthma.
• as a rescue inhaler.

Who should use 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.
### 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-activated 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.**

**-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.

QVARHPIL-003
Rev. 3/2018

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

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

**The most common side effects of QVAR REDIHALER include:**

- yeast infection in the mouth (oral candidiasis)
- cold symptoms (upper respiratory tract infection)
- pain in the throat (oropharyngitis)
- pain or swelling in your nose and throat (nasopharyngitis)
- sinus irritation (sinusitis)
- hay fever (allergic rhinitis)

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of QVAR REDIHALER. Ask your healthcare provider or pharmacist for more information. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store QVAR REDIHALER?**

- Store QVAR REDIHALER at room temperature between 68°F to 77°F (20°C to 25°C).
- Your QVAR REDIHALER canister should only be used with the QVAR REDIHALER actuator. Do not use any other medicines in your QVAR REDIHALER actuator.
- The contents of your QVAR REDIHALER canister are under pressure. Do not puncture the QVAR REDIHALER canister.
- Do not store your QVAR REDIHALER canister near heat or a flame.
- Temperatures above 120°F may cause the canister to burst.
- Do not throw your QVAR REDIHALER canister.
- 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.

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

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**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**.
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- 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

**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 before inhalation 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.

**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.

**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.

**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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