Yuav Tau Paub Txog Koj Lub Nqus Tshuaj

Raug raws li QVAR RediHaler

QVAR® RediHaler™ yog ib yam tshuaj nqus pab txhawb rau mob hawb pob, tsis yog tshuaj kho tau (tshuaj kho ntaug mob ib pliag). Siv 2X hauv ib hnub, nws yuav pab tiv thaij mob hawb pob thiab kho ntsws o vim yog los ntawm cov yeeb yam mob hawb pob.

1. Qhib lub hau npog dawb uas npog lub npuav ntawm qhov ncauj nqus. Tsis txhob qhib lub hau npog kom mus txog thauj koj nqus ib zaug. Ua pa tawm tag nrho.


3. Kaw lub hau npog dawb tom qab nqus tag thiaj yuav siv tau zaum txuas mus ntxiv.

Yog koj tus kws kho mob qhia kom kox nqus ntau dua ib zaug hauv ib lub tshuaj, lub hau npog dawb yuav tsis kaw thiab rov qab ua ntxiv li khauj ruam 1-3. Tsis txhob siv lwv cov tshuaj ntxiv lossis ts tseg tsis siv QVAR RediHaler yog tsis tau sab laj nrog koj tus kws ko mob.

Tom qab siv koj cov tshuaj nqus tag, siv dej yaug koj lub qhov ncauj thiab yuav pal qhov uas rau kis mob (thrush) nyob hauv kox jug lub qhov ncauj.

Nco ntsoov siv QVAR RediHaler 2X txhua hnub, raws li koj tus kws kho mob hais. Yuav siv sijawm ntev li 3 txog 4 vij tom qab pib siv QVAR RediHaler thiab yuav hnw ntxim, txawm tias qee tus neeg yeej pom tias tus mob hawb pob muaj kev txawv txav rau hauv lub sijawm 24 teev los xij.

SAIB DAIM VIS DIS AUS “YUAV SIV LI CAS”

Daim duab vis dis aus yuav qhia siv lub nqus ib qho rau ib qho, saib hauv QVARHowTo.com.

Yuav Siv Licas


Tsis muaj qhov nias; tsis tas yoj lossis yeej siv tau lawm

Yuav cov tshuaj us yuav tau siv

Spacer-siv li cas los tau” tawm gauv–tsis siv nrog lub spacer

Muab lub hau dawb loog rau

Qhib lub hau npog dawb uas npog lub npuav ntawm qhov ncauj nqus. Tsis txhob qhib lub hau

Yuav Tau Paub Txog Koj Lub Nqus Tshuaj

Raug Tso Cai Siv

QVAR® RediHaler™ (beclomethasone dipropionate HFA) Tshuaj Nqus Aerosol yog ib yam tshuaj nqus pab txhawb ua pa los tiv thiab tswj xyaws tus mob hawb pob rau cov menyuum muaj 4 xyooos thiab siab dua.

QVAR RediHaler Inhalation Aerosol tsis raug siv ntauq tus mob ua pa nyuaj thiab tsis siv hloov rau yam tshuaj nqus pa.

Cov Ntaub Ntawv Nyab Xeeb

Tseem Ceeb

- Tsis txhob siv QVAR RediHaler los kho cov mob hawb pob. Yuav tsim muaj lub pal nqo pa nrog koj thiab kho tau cov mob tshwm sim kiaj tam sim.
- Tsis txhob siv QVAR RediHaler yog koj fab tshuaj beclomethasone dipropionate lossis ib qho dab tsi xyaws hauv QVAR RediHaler.

Thov saib Cov Ntaub Ntawv Nyab Xeeb Tseem Ceeb ntawm nplooj ntawv txuas mus ntxiv thiab Cov Ntaub Ntawv Hais Qhia Txog Tshooj Cai uas tau muab tuaj nrog ua ke no suav nrog Cov Lus Qhia Siv.

Yuav Tau Paub Txog Koj Lub Nqus Tshuaj

Raug raws li QVAR RediHaler

QVAR® RediHaler™ yog ib yam tshuaj nqus pab txhawb rau mob hawb pob, tsis yog tshuaj kho tau (tshuaj kho ntaug mob ib pliag). Siv 2X hauv ib hnub, nws yuav pab tiv thaij mob hawb pob thiab kho ntsws o vim yog los ntawm cov yeeb yam mob hawb pob.

1. Qhib lub hau npog dawb uas npog lub npuav ntawm qhov ncauj nqus. Tsis txhob qhib lub hau npog kom mus txog thauj koj nqus ib zaug. Ua pa tawm tag nrho.


3. Kaw lub hau npog dawb tom qab nqus tag thiaj yuav siv tau zaum txuas mus ntxiv.

Yuav Siv Licas


Tsis muaj qhov nias; tsis tas yoj lossis yeej siv tau lawm

Yuav cov tshuaj us yuav tau siv

Spacer-siv li cas los tau” tawm gauv–tsis siv nrog lub spacer

Muab lub hau dawb looj rau

*Tsuaas yog siv nqus pab hauv qhov ncauj xwb.

Raug Tso Cai Siv

QVAR® RediHaler™ (beclomethasone dipropionate HFA) Tshuaj Nqus Aerosol yog ib yam tshuaj nqus pab txhawb ua pa los tiv thiab tswj xyaws tus mob hawb pob rau cov menyuum muaj 4 xyooos thiab siab dua.

QVAR RediHaler Inhalation Aerosol tsis raug siv ntauq tus mob ua pa nyuaj thiab tsis siv hloov rau yam tshuaj nqus pa.

Cov Ntaub Ntawv Nyab Xeeb

Tseem Ceeb

- Tsis txhob siv QVAR RediHaler los kho cov mob hawb pob. Yuav tsim muaj lub pal nqo pa nrog koj thiab kho tau cov mob tshwm sim kiaj tam sim.
- Tsis txhob siv QVAR RediHaler yog koj fab tshuaj beclomethasone dipropionate lossis ib qho dab tsi xyaws hauv QVAR RediHaler.

Thov saib Cov Ntaub Ntawv Nyab Xeeb Tseem Ceeb ntawm nplooj ntawv txuas mus ntxiv thiab Cov Ntaub Ntawv Hais Qhia Txog Tshooj Cai uas tau muab tuaj nrog ua ke no suav nrog Cov Lus Qhia Siv.

SAIB DAIM VIS DIS AUS “YUAV SIV LI CAS”

Daim duab vis dis aus yuav qhia siv lub nqus ib qho rau ib qho, saib hauv QVARHowTo.com.
Yuav Kaws Cia Li Cas

- Khaws lub haub npog dawb rau ntawm lub nqus thauamb lub sihjham khaws tseg.
- Khaws tseg rau qhov chav nyob uas kub txog li ntawd thaj tsam 68°F txog 77°F (20°C - 25°C). Nyob thaj tsam ntawm 59°F thiaib 86°F (15°C thiaib 30°C) raws li qhov pub ua tau.
- Tsis txhob siv lossis khaws cia ze tej yam kub lossis ze nplaim taws. Raug qhov kub tshaj 120°F (49°C) yuav ua rau lub kaus poom tawg tau. Tsis txhob cuam rau hauv qhov cub lossis cuam rau ntawm lub qhov cub hlawv ub no.

KEV TU KOJ LUB NQUS TSHUAJ

Yuav tsum tu koj lub npuav ntawm qhov ncauj tsawg kawg yog tu ib zaum hauv ib lub vij, siv ntawv qhuv lossis ntuaq qhuv so kom huv si. TSIS TXHOB ntxuav lossis tso ib qo ntawm lub QVAR RediHaler ntxuav dej.

Cov Ntaub Ntawv Nyab Xeeb Tseem (Txuas ntxiv)

- Tsis txhob siv lub QVAR RediHaler ntau tshaj qhov pub siv.
- Ali Qhia koy tus kws kuaj mob txog txhua cov tshuaj kbo mob uas koy noj thiaib qhia txog koy txhua yam muaj mob.
- Tej zaum QVAR RediHaler yuav ua rau muaj lob loj, xws li:
  - Kev tuaj pwm (thrush) rau hauv koy lub qhov ncauj thiaib lub qa. Yaug deej rau koy lub qhov ncauj kom qhuv tsis txhob nqos dej tom qab siv QVAR RediHaler pab tiv thai mob rau koy lub qhov ncauj lub qa.
  - Qhov mohbawb pob pheej tsis zoo lossis mob hawb pob loj nthawv nthav nthim sim. Tom qab siv koy lub nqus pa, hu rau koy tus kws saib xyus koy noj qab haus huv kiaj tam sim ntawd yoj koy lub qhov mob hawb pob nthawv nthav kiaj tam sim tsis zoo.
  - Kev lub qog mob (lub qog mob tsis zoo). Qhov no tuaj yeem txaus ntshai rau txoj sia thauam koy jooj tsis siv cov tshuaj khomob thiaib piv sib cov cov tshuaj nqus corticosteroid (kws li QVAR RediHaler). Qhia koy tus kws kuaj mob kiaj tam sim txog cov yam nthxw mob thiaib cov yeeb yam mob ntaub lub qog mob tsis zoo xws li: hnov sab heev lossis nkees (sab heev); tsis muaj zog; nthshav qis (nthshav tsis xaus); kiv tuaj hauv lossis tsis meej pem dab tsi li lawm; xeev siab thiaib ntawv; lossis nkees heev.
  - Txheej txheem tiv thai mob koy nthawm lub cev muaj teeb meem thiaib muaj pheej hmoo kis mob tao zoo. Qhia rau koy tus kws kuaj mob txog tus yeem yam ob lossis qhov muaj lob xws li: ua npaws, mob nthsiv, sab heev, no tshee, mob ib ce, xeev siab, lossis ntawv.
  - Txham heev zuz (bronchospasm) kiaj tam sim tom qab siv QVAR RediHaler. Yuav tsum muaj lub lub nqus pa rau koy thiaj li lub tau thauam ua pa hawb mob.

THAUM YUAV HLOOV

Thaum siv tshuaj txog 20, cob nay npawb yuav hloov ua tsos liab, qhia tau tias txog lub sihjham yuav tshuaj tshib lawm. Yoj koy siv koy lub nqus pa tom qab lub ntsuas nyem zero, tej zaum koy yuav tis tau txais kev kho cov tshuaj khomob kom raug.

Muab cov tshuaj QVAR® RediHaler™ pov tseg thauamb tshwm sim ‘0’ thiaib sab tom qab tshwm sim tsos liab, lossis tom qab piav qhia hnuab daim nthawv ntim.

Hloov cov QVAR RediHaler ua ntej tag sihjham. Tsis txhob siv ib yam tshuaj nqus tom qab nws tag sihjham.

PUAS MUAJ LUS NUG?

Mus saib QVAR.com lossis hu 1-888-483-8279 yog xav tau kev pab ntxiv lossis xav paub seb yuav siv lub nqus lossis tu koy lub koy nqus li cas.

- Fab tshuaj loj. Tso tseg tsis siv QVAR thib hu rau koy tus kws kuaj mob lossis thov kev pab khomob kis xwm txheej kub nxov ceev kiaj tam sim ntaub yoj koy muaj tej qho mob raws li nram no: raug cua phem; koy daim di ncauj o loj, tus nplaig o, lossis ntej muaj o; yaub xox o; lossis uas pa nyuaq;
- Cov menyam yaus loj hloob qeeb. Yuav tsum nquag coj cov menyam yaus mus kuaj mob tas li thauam siv QVAR RediHaler.
- Pob txha tsis khov. Tej zaum yuav tu teeb meem rau cov neeg uas twb muaj pheej hmoo muaj yam mob pb txha tsis khov (osteooporosis).
- Teeb meem qhov muag. Yog yav dhau los koy yeej muaj mob qhov muag tawm lossis lub ntsiab qhov muag lossis tsis pom kev zo, koy yuav tsum nquag muaj xyus thauam siv QVAR RediHaler.

- Kev fab tshuaj QVAR RediHaler muaj xws li: tuaj pwm rau lub qhov ncauj (qhov ncauj ua pob xoo dawb to); los nthswg (mob rau theem siab hauv lub qhov nthswg); mob rau lub pob qa (mob oropharyngeal); mob lossis o liab hauv koy lub qhov nthswg thiaib lub qa (nasopharyngitis); mob khaus (sinusitis); thiaib ua npaws (allergic rhinitis).

Thov saib Cov Ntaub Ntawv Piav Qhia tag nrho txhua yam, suav txogTag Nrho Cov Lus Qhia Siv.
Breath-actuated inhalation aerosol: 40 or 80 mcg per actuation. (3)

- Treatment of asthma in patients 12 years of age and older: 40 mcg, 80 mcg, 160 mcg.
- Treatment of asthma in patients 4 to 11 years of age: 40 or 80 mcg twice daily. (2.2)

Starting dosage is based on prior asthma therapy and disease severity. (2.2)

For oral inhalation only. (2.1)

- Deterioration of asthma and acute episodes: Do not use QVAR REDIHALER for relief of acute symptoms. Patients require immediate re-evaluation during rapidly deteriorating asthma. (5.2)
- Localized infections: Candida albicans infection of the mouth and throat may occur. Advise patients to rinse the mouth with water after swallowing 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)

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

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

WARNINGS AND PRECAUTIONS

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

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

To report SUSPECTED ADVERSE REACTIONS, contact Teva Pharmaceuticals at 1-888-682-3759 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

FULL PRESCRIBING INFORMATION: CONTENTS*
QVAR® REDIHALER™ (beclomethasone dipropionate HFA) inhalation aerosol

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 12 years of age and older is 320 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 for 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 in two 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 while still continuing with QVAR REDIHALER therapy, but at times therapy with QVAR REDIHALER may need to be temporarily interrupted under close medical supervision. After inhalation, the patient should rinse his/her mouth with water without swallowing to help reduce the risk of oropharyngeal candidiasis.

5.2 Deterioration of Asthma and Acute Episodes

QVAR REDIHALER is not indicated for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. An inhaled, short-acting beta-agonist (QVAR REDIHALER, 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 systemically active corticosteroids to QVAR REDIHALER because deaths due to adrenal insufficiency have occurred in asthmatic patients during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids. After withdrawal from systemic 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, withdraw other signs and symptoms of adrenal insufficiency may become apparent, such as weakness, nausea and vomiting, and hypotension. Transfer of patients from systemic corticosteroid therapy to QVAR REDIHALER may unmask allergic conditions previously suppressed by the systemic corticosteroid therapy, e.g., rhinitis, conjunctivitis, aczema, arthritis, and eosinophilic conditions. 

5.4 Immunosuppression

QVAR REDIHALER should be discontinued and alternate therapy instituted.

5.5 Paradoxical Bronchospasm

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

5.6 Immediate Hypersensitivity Reactions

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

5.7 Hypercorticism and Adrenal Suppression

QVAR REDIHALER will often help control asthma symptoms with less suppression of HPA function than therapeutically equivalent oral doses of prednisone. Since beclomethasone dipropionate is absorbed into the circulation and can be systemically active in higher doses, the benefits 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 systemically absorbed inhaled corticosteroids, patients treated with QVAR REDIHALER should be observed carefully for any evidence of systemic corticosteroid effects. The potential adverse effects of QVAR REDIHALER in minimizing HPA dysfunction may be expected only after prolonged periods of time. If such effects occur, the dosage of QVAR REDIHALER should be reduced slowly, consistent with accepted procedures for reducing systemic corticosteroids and for management of asthma symptoms.

5.8 Effects on Growth

Orally inhaled corticosteroids, including QVAR REDIHALER, may cause a reduction in growth velocity when administered to pediatric patients. Monitor the growth of pediatric patients receiving QVAR REDIHALER routinely (e.g., via 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, famly 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

Increases 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 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 as-needed bronchodilators and/or inhaled corticosteroids) were treated with QVAR REDIHALER (doses of 40, 80, 160, or 320 mcg twice daily) or QVAR (beclomethasone dipropionate HFA) Inhalation Aerosol (QVAR MDI; doses of 160 or 320 mcg twice daily) or placebo. In considering these data, difference in average duration of exposure and clinical trial design should be taken into account.

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

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>Placebo</th>
<th>QVAR REDIHALER</th>
<th>QVAR MDI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Candidiasis</td>
<td>0 (2)</td>
<td>2 (3)</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Upper Respiratory Tract Infection</td>
<td>3 (1)</td>
<td>9 (4)</td>
<td>6 (3)</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>4 (4)</td>
<td>2 (3)</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Oropharyngeal Pain</td>
<td>2 (2)</td>
<td>2 (2)</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Viral Upper Respiratory Tract Infection</td>
<td>3 (3)</td>
<td>0 (&lt;1)</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>3 (3)</td>
<td>0 (&lt;1)</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Rhinitis</td>
<td>0 (&lt;1)</td>
<td>20 (2)</td>
<td>1 (&lt;1)</td>
</tr>
</tbody>
</table>

*QVAR MDI=QVAR Inhalation Aerosol

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

Pediatric Patients 4 to 11 Years of Age: The adverse reaction information presented in Table 2 concerning QVAR REDIHALER and QVAR MDI is derived from one 12-week placebo-controlled study in pediatric patients 4 to 11 years of age with persistent asthma.

### Table 2: 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>Placebo</th>
<th>QVAR REDIHALER</th>
<th>QVAR MDI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Respiratory Tract Infection</td>
<td>3 (2.4)</td>
<td>1 (0.8)</td>
<td>6 (4.8)</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>5 (4.0)</td>
<td>11 (8.8)</td>
<td>6 (4.8)</td>
</tr>
<tr>
<td>Viral Upper Respiratory Tract Infection</td>
<td>5 (4.0)</td>
<td>5 (4.0)</td>
<td>3 (2.4)</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>4 (3.2)</td>
<td>3 (3.2)</td>
<td>4 (3.2)</td>
</tr>
<tr>
<td>Cough</td>
<td>1 (0.8)</td>
<td>3 (2.4)</td>
<td>9 (7.2)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>2 (1.6)</td>
<td>2 (1.6)</td>
<td>4 (3.2)</td>
</tr>
<tr>
<td>Headache</td>
<td>2 (1.6)</td>
<td>5 (4.0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>1 (0.8)</td>
<td>4 (3.2)</td>
<td>2 (1.6)</td>
</tr>
</tbody>
</table>

*QVAR MDI=QVAR Inhalation Aerosol

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

6.2 Postmarketing Experience

In addition to the adverse reactions reported from clinical trials with QVAR REDIHALER, the following adverse reactions have been identified during post-approval use of QVAR MDI and other inhaled corticosteroids. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

**Local Effects:** Localized infections with *Candida albicans* have occurred in patients treated with beclomethasone dipropionate or other orally inhaled corticosteroids [see Warnings and Precautions (5.1)].

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

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

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 late-labour births, 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 inhalation dose that was 20 or greater than approximately 0.75 times the maximum recommended human daily inhalation dose (MRHDID) in adults (0.64 mg/day) [see Data]. In rats exposed to beclomethasone dipropionate by inhalation, dose-related gross injury to the fetal adrenal glands was observed at doses greater than 180 times the MRHDID, but there was no evidence of external or skeletal malformations or embryolethality at inhalation doses of up to 440 times the MRHDID. The estimated background risk of major birth defects and miscarriage for the indicated population(s) are unknown. In the US general population, the estimated risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

**Clinical Considerations**

**Disease-Associated Maternal and/or Embryo/Fetal Risk**

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

**Lactation**

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

**Data**

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 adrenal glands from 3 days of gestation at inhalation doses of 180 times the MRHDID in adults (on a mg/m² basis at a maternal dose of 2.4 mg/kg/day). There was no evidence of external or skeletal malformations or embryolethality at inhaled doses up to 440 times the MRHDID (on a mg/m² basis at maternal doses up to 28.3 mg/kg/day).

**Animal Data**

In an embryofetal development study in pregnant mice, beclomethasone dipropionate administration from gestation days 2 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 rabbits, beclomethasone dipropionate administration from gestation days 1 to 18 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 embryolethical 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 embryolethical effects (increased fetal resorptions). There were no effects in fetuses of pregnant rabbits administered a subcutaneous dose 0.2 times the MRHDID in adults (on a mg/m² basis at a maternal dose of 0.006 mg/kg/day).

8.2 Lactation

Risk Summary

There are no data available on the presence of beclomethasone dipropionate in human milk; the effects on the breastfed child, or the effects on milk production. However, other inhaled corticosteroids have been detected in human milk. The developmental
QVAR® REDIHALER™ (beclomethasone dipropionate HFA) inhalation aerosol

and health benefits of breastfeeding should be considered along with the mother's clinical need for QVAR REDIHALER and any potential adverse effects on the breastfed and health benefits of breastfeeding should be considered along with the mother's

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 Preclinical 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. Selected safety and effectiveness data for QVAR REDIHALER in children 6 years of age or younger have not been established.

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

Controlled clinical studies have shown that inhaled corticosteroids may cause a reduction in growth velocity in pediatric patients. A 12-month, randomized, controlled clinical trial evaluated the effects of QVAR MDI versus beclomethasone dipropionate in a CFC propellant-based formulation (CFC-BDP) on growth in children ages 5 to 11. A total of 520 children were enrolled, of whom 394 received QVAR MDI (100 to 400 mcg/day ex-valve) and 126 received CFC-BDP (200 to 800 mcg/day ex-valve). Similar control of asthma was noted in each treatment arm. When comparing results at month 12 to baseline, the mean growth velocity in children treated with QVAR MDI was approximately 0.5 cm/year less than that noted with children treated with CFC-BDP via large-volume spacer. The long-term effects of the reduction in growth velocity associated with orally inhaled corticosteroids, including the impact on final adult height, are unknown. The potential for “catch-up” growth following discontinuation of treatment with QVAR MDI has not been adequately studied.

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

8.5 Geriatric Use

Clinical studies of QVAR REDIHALER did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the recommended adult dose range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

11 DESCRIPTION

The active component of QVAR REDIHALER 40 mcg Inhalation Aerosol and QVAR REDIHALER 80 mcg Inhalation Aerosol is beclomethasone dipropionate. USP, a corticosteroid having the chemical name 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione 17,21-dipropionate. Beclomethasone dipropionate is a diester of beclomethasone, a synthetic corticosteroid chemically related to dexamethasone. Beclomethasone differs from dexamethasone in having a chlorine at the 9-alpha carbon in place of a fluoro, and in having a 16-beta-methyl group instead of a 16-alpha-methyl group. Beclomethasone dipropionate is a white to creamy white, odorless powder with a molecular formula of C_{31}H_{35}ClO_6 and a molecular weight of 521.1. Its chemical structure is:

\[
\text{COC}_{2}H_{5} + O \quad \text{COC}_{2}H_{5} + O
\]

QVAR REDIHALER is a pressurized, breath-actuated, metered-dose aerosol with a dose counter intended for oral inhalation only. Each unit consists of a sealed breath-counter mouthpiece and 50 mcg from the canister valve. QVAR REDIHALER 80 mcg delivers 80 mcg of beclomethasone dipropionate from the actuator mouthpiece and 100 mcg from the canister valve. Both products deliver 50 microliters (59 milligrams) of solution formulation as an aerosol from the canister valve with each actuation. The 40-mcg canisters and the 80-mcg canisters provide 250 inhalations each. Since the QVAR REDIHALER canister is fitted with a primeless valve, no priming actuations are required before use. For both products, an actuation was always triggered by a 20 L/min inspiratory flow rate.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Beclomethasone 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, 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 exhibit a binding affinity for the human glucocorticoid receptor that is approximately 6 times that of triamcinolone acetonide, 1.5 times that of budesonide and 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 Pharmacodynamics

HQA Axis Effects

The effects of QVAR MDI on the hypothalamic-pituitary-adrenal (HPA) axis were assessed in 40 corticosteroid-naïve 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 inhaled beclomethasone at recommended doses 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-cosyntropin test.

12.3 Pharmacokinetics

Beclomethasone dipropionate undergoes rapid and extensive conversion to beclomethasone-17-monopropionate (17-BMP) during absorption. The pharmacokinetics of beclomethasone dipropionate and 17-BMP were studied in subjects given single doses.

Absorption

The mean peak plasma concentration (C_{max}) of 6635 pg/mL at 2 minutes after inhalation of 320 mcg using QVAR REDIHALER (4 inhalations of the 80 mcg/inhalation 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

In vitro 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.

Elimination

The major route of elimination of inhaled beclomethasone dipropionate appears to be via hydrolysis. More than 90% of inhaled beclomethasone dipropionate is found as 17-BMP in the systemic circulation. The mean terminal half-life of 17-BMP is approximately 4 hours for QVAR REDIHALER.

Metabolism

Three major metabolites are formed via esterases:

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

Lung dose metabolizes 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 pediatric subjects aged 4 to 17 years. However, the pharmacokinetics of 17-BMP, including dose and strength proportionalities, is similar in children and adults using QVAR MDI, although the exposure is highly variable. In 17 children (mean age 10 years), the C_{max} 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.
**QVAR® REDIHALER™ (beclomethasone dipropionate HFA) inhalation aerosol**

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

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

**13 NONCLINICAL TOXICOLOGY**

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

The carcinogenicity of beclomethasone dipropionate was evaluated in rats which were exposed for a total of 95 weeks, 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 vivo 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 estrus 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/day given 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% percent of predicted normal, reversible bronchoconstriction of at least 12% with short-acting inhaled beta-agonist, and asthma symptoms were randomized equally to treatment with QVAR REDIHALER 320 mcg/day, QVAR REDIHALER 640 mcg/day, QVAR MDI 40 mcg/day or placebo. Baseline FEV1, values were similar across treatments. The primary endpoint for this trial was the standardized baseline-adjusted trough morning expiratory volume in 1 second (FEV1) area under the effect curve from time zero to 12 weeks [FEV1 AUEC(0-12wk)] (Table 3). 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 over 6 weeks; QVAR REDIHALER 640 mcg/day, LS mean change of 0.150 L over 6 weeks) (Table 3). Treatment with QVAR MDI was also similar. The change from baseline in morning FEV1 during the trial is displayed in Figure 2. Both doses of QVAR REDIHALER were effective in improving asthma control with significantly greater improvements in FEV1, morning PEF, weekly average of daily trough morning PEF, reduced rescue medication use and improved asthma symptom scores than with placebo. Similar results were demonstrated with QVAR MDI.

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

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 Statistic</th>
<th>Placebo (N=90)</th>
<th>QVAR REDIHALER 80 mcg/day (N=80)</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 MDI 40 mcg/day (N=105)</th>
<th>QVAR MDI* 320 mcg/day (N=105)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difference from placebo</td>
<td>—</td>
<td>0.124</td>
<td>0.116</td>
<td>—</td>
<td>0.144</td>
<td>0.150</td>
<td>0.148</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, 0.2066</td>
<td>0.0888, 0.2132</td>
<td>0.0847, 0.2114</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, global efficacy and safety trial (NCT02040766) compared QVAR REDIHALER 40 or 80 mcg, QVAR MDI 40 or 80 mcg or placebo given as 1 inhalation twice daily in pediatric patients aged 4 through 11 years old with persistent symptomatic asthma despite treatment with non-corticosteroid or low dose inhaled corticosteroid (with or without a long acting beta agonist [LABA]). Patients aged 4 to 5 years who were technically unable to complete spirometry participated in the safety population. Patients aged 4 to 5 years who were technically unable to complete spirometry participated in the safety population. 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.
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 cloth. Ne ver 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 and 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
Frazier, 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

18 HOW SUPPLIED/STORAGE AND HANDLING
18.1 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 HOW SUPPLIED/STORAGE AND HANDLING
16.1 How Supplied
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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 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 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. Similar results were seen with evening PEF.
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.
- have had chickenpox or measles.
- have or have had eye problems, such as blurred vision, increased pressure in your eye (glaucoma) or cataracts.
- are pregnant or plan to become pregnant. It is not known if QVAR REDIHALER will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if QVAR REDIHALER passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you use QVAR REDIHALER.

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

How should I use QVAR REDIHALER?
Read the step-by-step instructions for using QVAR REDIHALER at the end of this Patient Information leaflet.

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

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

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

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

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

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

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

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

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

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

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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.**
- Do not shake. This breath-actuated device does not need to be shaken. This is **not** a press-and-breathe inhaler
- QVAR REDIHALER does not need priming.
- Do not use a spacer or volume holding chamber with QVAR REDIHALER.
- Always use the inhaler in the upright position (with the mouthpiece down).
- Once prepared, the inhaler will deliver 1 inhalation of medicine when you breathe in (inhale) through the mouthpiece. Your dose might require more than 1 inhalation.
- Do not open the white cap or leave it open unless you are ready for your next inhalation. If the cap has been opened for more than 2 minutes or left in the open position, you will need to close the white cap before use.
- Do not suddenly stop using your QVAR REDIHALER. Contact your healthcare provider immediately if you stop using your QVAR REDIHALER.

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

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

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

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

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

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

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

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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