HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use UCERIS® (budesonide) rectal foam safely and effectively. See full prescribing information for UCERIS® (budesonide) rectal foam.

UCERIS® (budesonide) rectal foam

Initial U.S. Approval: 1997

INDICATIONS AND USAGE

UCERIS rectal foam is a glucocorticoid indicated for the induction of remission in patients with active mild to moderate distal ulcerative colitis extending up to 40 cm from the anal verge. (1)

DOSEAGE AND ADMINISTRATION

• The recommended dosage is 1 metered dose administered twice daily for 2 weeks followed by 1 metered dose administered once daily for 4 weeks. (2.1)
• For rectal administration only. (2.2)
• Warm the canister in the hands while shaking it vigorously for 10 to 15 seconds prior to use. (2.2)

DOSEAGE FORMS AND STRENGTHS

UCERIS rectal foam contains 2 mg budesonide per metered dose. (3)

CONTRAINDICATIONS

Known hypersensitivity to budesonide or any of the ingredients in UCERIS rectal foam. (4)

WARNINGS AND PRECAUTIONS

• Hypercorticism and adrenal suppression: Follow general warnings concerning glucocorticoids. (5.1)
• Impaired Adrenal Function in Patients Transferred from Other Glucocorticoids: Taper slowly from glucocorticosteroids with high systemic effects; monitor for withdrawal symptoms and unmasking of allergies (rhinitis, eczema). (5.2)
• Increased Risk of Infection, including serious and fatal, chicken pox and measles: Monitor patients with active or quiescent tuberculosis infection, untreated fungal, bacterial, systemic viral or parasitic infections, or ocular herpes simplex. (5.3)
• Other Glucocorticosteroid Effects: Monitor patients with other conditions where glucocorticoids may have unwanted effects. (5.4)
• Flammable Contents: The contents of UCERIS rectal foam are flammable. Instruct the patient to avoid fire, flame and smoking during and immediately following administration. (5.5)

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥ 2%) are decreased blood cortisol, adrenal insufficiency, and nausea. (6.1)

DRUG INTERACTIONS

CYP3A4 Inhibitors (e.g. ketoconazole, grapefruit juice): May cause increased systemic corticosteroid effects; avoid concomitant use. (7.1)

USE IN SPECIFIC POPULATIONS

• Pregnancy: Based on animal data, may cause fetal harm. (8.1)
• Hepatic Impairment: Monitor patients for signs and/or symptoms of hypercorticism. (8.6)

Adverse reactions appearing in more than 3% of patients treated

- Decreased blood cortisol
- Adrenal insufficiency
- Nausea

Revised: 09/2016

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5.2 Impaired Adrenal Suppression in Patients Transferred from Other Glucocorticoids

Monitor patients who are transferred from glucocorticoid treatment with higher systemic effects to glucocorticosteroids with lower systemic effects, such as UCERIS rectal foam, since symptoms attributed to withdrawal of steroid therapy, including those of acute adrenal suppression or benign intracranial hypertension, may develop. Adrenocortical function monitoring may be required in these patients and the dose of glucocorticoid treatment with high systemic effects should be reduced cautiously.

Replacement of systemic glucocorticosteroids with UCERIS rectal foam may unmask allergies (e.g., rhinitis and eczema), which were previously controlled by the systemic drug.

5.3 Increased Risk of Infection

Patients who are on drugs that suppress the immune system are more susceptible to infection than healthy individuals. Chicken pox and measles, for example, can have a more serious or even fatal course in susceptible patients or patients on immunosuppressant doses of glucocorticosteroids. In patients who have not had these diseases, particular care should be taken to avoid exposure.

How the dose, route and duration of glucocorticoid administration affect the risk of developing a disseminated infection is not known. The contribution of the underlying disease and/or prior glucocorticoid treatment to the risk is also not known. If exposed, therapy with varicella zoster immune globulin (VZIG) or pooled intravenous immunoglobulin (IVIG), as appropriate, may be indicated. If exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be indicated (see prescribing information for VZIG and IG). If chicken pox develops, treatment with antiviral agents may be considered.

Glucocorticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculosis infection, untreated fungal, bacterial, systemic viral or parasitic infections, or ocular herpes simplex.

5.4 Other Glucocorticoid Effects

Monitor patients with hypertension, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma or cataracts, or with a family history of diabetes or glaucoma, or with any other condition where glucocorticosteroids may have unwanted effects.

5.5 Flammable Contents

The contents of UCERIS rectal foam include n-butane, isobutane and propane as propellants which are flammable. Instruct the patient to avoid fire, flame, and smoking during and immediately following administration. Patients should temporarily discontinue use of UCERIS rectal foam before initiation of bowel preparation for colonoscopy and consult their healthcare provider before resuming therapy.

6 ADVERSE REACTIONS

Serious and important adverse reactions include:

- Hypercorticism and adrenal axis suppression [see Warnings and Precautions (5.1)]
- Symptoms of steroid withdrawal in those patients transferring from systemic glucocorticosteroid therapy [see Warnings and Precautions (5.2)]
- Increased susceptibility to infection [see Warnings and Precautions (5.3)]
- Other glucocorticoid effects [see Warnings and Precautions (5.4)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data described below reflect exposure to UCERIS rectal foam in 332 patients with active mild to moderate distal ulcerative colitis extending up to 40 cm from the anal verge. The median duration of exposure was 42 days. This included 14 patients exposed for at least 6 months.

UCERIS rectal foam was studied primarily in 2 placebo-controlled, 6-week trials in patients with active disease (Study 1 and Study 2). In these trials, 268 patients received UCERIS rectal foam 2 mg twice a day for 2 weeks followed by 2 mg once a day for 4 weeks [see Clinical Studies (14)].

The most common adverse reactions (≥ 2% of the UCERIS rectal foam or Placebo group and at higher frequency in the UCERIS rectal foam group) were decreased blood cortisol, adrenal insufficiency, and nausea (Table 1). Decreased blood cortisol was defined as a morning cortisol level of <5 mcg/dL. Adrenal insufficiency was defined as a cortisol level of <18 mcg/dL at 30 minutes post-challenge with adrenocorticotropic hormone (ACTH).

A total of 10% of UCERIS rectal foam-treated patients discontinued treatment due to an adverse reaction compared with 4% of placebo-treated patients.

Table 1: Summary of Adverse Reactions in 2 Placebo-Controlled Trials* (Studies 1 and 2)

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>UCERIS Rectal Foam</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Decreased blood cortisol†</td>
<td>46 (17)</td>
<td>6 (2)</td>
</tr>
<tr>
<td>Adrenal insufficiency†</td>
<td>10 (4)</td>
<td>2 (1)</td>
</tr>
<tr>
<td>Nausea</td>
<td>6 (2)</td>
<td>2 (1)</td>
</tr>
</tbody>
</table>

* Experienced by ≥ 2% of the UCERIS rectal foam or Placebo group and at higher frequency in the UCERIS rectal foam group.
† Decreased blood cortisol was defined as a morning cortisol level of <5 mcg/dL.

5.6 Other Glucocorticoid Effects

Replacement of systemic glucocorticosteroids with UCERIS rectal foam may unmask allergies (e.g., rhinitis and eczema), which were previously controlled by the systemic drug.

5.7 Adverse Reactions Related to the Device

5.8 Post-Marketing Experience

5.9 Other Glucocorticoid Effects

5.10 Drug Interactions

7 DRUG INTERACTIONS

7.1 CYP3A4 Inhibitors

The active ingredient of UCERIS rectal foam, budesonide, is metabolized by CYP3A4. Inhibitors of CYP3A4 activity (such as ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, erythromycin, cyclosporine and grapefruit juice) can increase systemic budesonide concentrations. Avoid concomitant use of CYP3A4 inhibitors with UCERIS rectal foam [see Clinical Pharmacology (12.3)].
There are no adequate and well controlled studies with UCERIS rectal foam in pregnant women. Animal reproduction studies have been conducted with budesonide. In these studies, subcutaneous administration of budesonide to rats and rabbits at doses 1.2 times and 0.12 times, respectively, the human intrarectal dose of 4 mg/day, produced skeletal abnormalities, fetal loss and decreased pup weight. UCERIS rectal foam should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. All pregnancies, regardless of drug exposure, have a background rate of 2 to 4 percent for major malformations, and 15 to 20 percent for pregnancy loss.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Hypoadrenalism may occur in neonates exposed to glucocorticosteroids in utero. Carefully observe these neonates for signs and symptoms of hypoadrenalism.

Animal Data

Budesonide is teratogenic and embryocidal in rabbits and rats. In subcutaneous embryofetal development studies, fetal loss, decreased pup weights, and skeletal abnormalities were observed at a subcutaneous dose of 25 mcg/kg in rabbits (approximately 0.12 times the recommended human intrarectal dose of 4 mg/day, based on the body surface area) and 500 mcg/kg in rats (approximately 1.2 times the recommended human intrarectal dose of 4 mg/day, based on the body surface area).

8.3 Nursing Mothers

Use of UCERIS rectal foam is likely to result in budesonide in human milk as budesonide delivered by inhalation from a dry powder inhaler is present in human milk at low concentrations. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for UCERIS rectal foam and any potential adverse effects on the breastfed child from UCERIS rectal foam or from the underlying maternal condition. Exercise caution when administering UCERIS rectal foam to a nursing woman.

8.4 Pediatric Use

The safety and effectiveness of UCERIS rectal foam has not been established in pediatric patients.

Children who are treated with corticosteroids by any route may experience a decrease in their growth velocity. This negative impact of corticosteroids on growth has been in the absence of laboratory evidence of hypothalamic-pituitary-adrenal (HPA) axis suppression. The long-term effects of this reduction in growth velocity associated with corticosteroid treatment, including the impact on final adult height, are unknown. Growth velocity may therefore be a more sensitive indicator of systemic corticosteroid exposure in children than some commonly used tests of HPA axis function. The linear growth of children treated with corticosteroids by any route should be monitored (e.g., via stadiometry), and the potential growth effects of prolonged treatment should be weighed against clinical benefits obtained and the availability of other treatment alternatives. In order to minimize the potential growth effects of corticosteroids, children should be titrated to the lowest effective dose.

8.5 Geriatric Use

Clinical studies with UCERIS rectal foam did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently than 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 dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

8.6 Hepatic Impairment

No dosage adjustment is needed for patients with mild (Child-Pugh Class A) hepatic impairment. Patients with moderate to severe hepatic impairment (Child-Pugh Class B or C) should be monitored for increased signs and/or symptoms of hypercorticism. Discontinuing the use of UCERIS rectal foam should be considered in these patients if signs of hypercorticism are observed [see Warnings and Precautions (5.1) and Clinical Pharmacology (12.3)].

10 OVERDOSAGE

Acute overdosage with UCERIS rectal foam is unlikely. However, UCERIS rectal foam is absorbed systemically and chronic overdosage may result in signs/symptoms of hypercorticism [see Warnings and Precautions (5.1)].

11 DESCRIPTION

UCERIS rectal foam contains budesonide, a non-halogenated synthetic glucocorticoid, as the active ingredient. It is a mixture of the 2 epimers (22R and 22S) differing in the position of an acetal chain. Both epimers are active glucocorticoids applied in a mixture of approximately 1:1.

Budesonide is designated chemically as (RS)-11β, 16α, 17α-tetrahydroxyprogna-1, 4-diene-3,20-dione cyclic 16,17-acetal with butyraldehyde. The empirical formula of budesonide is C25H34O6 and its molecular weight is 430.5. Its structural formula is: 

UCERIS rectal foam contains 2 mg budesonide per metered dose. Inactive ingredients: cetyl alcohol, citric acid monohydrate, edetate disodium, emulsifying wax, polyoxyl (10) stearyl ether, propylene glycol, and purified water. Propellant: n-butane, isobutane, and propane.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Budesonide has glucocorticoid (GCS) activity.

12.2 Pharmacodynamics

Treatment with glucocorticosteroids, including UCERIS rectal foam, is associated with a suppression of endogenous cortisol concentrations and an impairment of the hypothalamic-pituitary-adrenal (HPA) axis function. These effects were measured by determination of plasma cortisol concentrations and responses to adrenocorticotropic hormone (i.e., ACTH stimulation test) in 2 placebo-controlled, 6-week trials in patients with active disease [see Clinical Studies (14)]. These trials enrolled subjects with post-ACTH stimulation cortisol levels of >18 mcg/dL at baseline. Subjects received UCERIS rectal foam 2 mg or a placebo twice daily for 2 weeks followed by once daily for 4 weeks. Normal morning serum cortisol levels >5 mcg/dL were maintained in 83% and 84% of UCERIS rectal foam treated subjects during Weeks 1 and 2 (twice daily treatment) and 93% and 94% during Weeks 4 and 6 (once daily treatment), respectively [see Table 3]. At baseline (predose), 84% of subjects in the UCERIS rectal foam group had a normal response to the ACTH challenge and at Week 6, 63% of subjects had a normal response to the ACTH challenge; in the placebo group, these values were 86% and 76%, respectively [see Table 3]. ACTH stimulation test was not performed routinely during the twice daily treatment period (Weeks 1 and 2).

Table 3: Proportion of Subjects with Normal Endogenous Cortisol Levels (>5 mcg/dL) During the Study and Proportion of Subjects with Normal Response to ACTH Challenge

<table>
<thead>
<tr>
<th>Cortisol Parameter</th>
<th>UCERIS Rectal Foam</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2 mg/25 mL</td>
<td>N=268</td>
</tr>
<tr>
<td>Total cortisol &gt;5 mcg/dL</td>
<td>259/268 (96.6)</td>
<td>275/278 (98.9)</td>
</tr>
<tr>
<td>Baseline</td>
<td>224/263 (85.2)</td>
<td>264/269 (98.1)</td>
</tr>
<tr>
<td>Week 1</td>
<td>218/257 (84.0)</td>
<td>263/266 (98.9)</td>
</tr>
<tr>
<td>Week 2</td>
<td>218/235 (92.8)</td>
<td>243/249 (97.6)</td>
</tr>
<tr>
<td>Week 4</td>
<td>211/224 (94.2)</td>
<td>234/241 (97.1)</td>
</tr>
<tr>
<td>Week 6</td>
<td>222/266 (83.5)</td>
<td>238/278 (85.6)</td>
</tr>
</tbody>
</table>

aThe normal response to ACTH challenge included 3 criteria, as defined in the cosyntropin label: 1) morning cortisol level >5 mcg/dL; 2) increase in cortisol level by ≥7 mcg/dL above the morning (pre-challenge) level following ACTH challenge; and cortisol level of >18 mcg/dL following ACTH challenge.

bDenominator includes 20 subjects in the UCERIS rectal foam arm and 2 subjects in the placebo arm who discontinued prior to Week 6 due to adverse events related to low cortisol or abnormal response to ACTH challenge.
12.3 Pharmacokinetics

**Absorption**

Dental Ulcerative Colitis Patients

Based on population pharmacokinetic analysis from sparse PK samples from phase 3 studies, the estimated AUC0-12 following administration of UCERIS rectal foam 2 mg twice a day was 4.31 ng·hr/mL with a CV of 64% in the target patient population.

**Distribution**

The volume of distribution (Vd) of budesonide varies between 2.2 and 3.9 L/kg in healthy subjects and in patients. Plasma protein binding is estimated to be 85 to 90% in the concentration range of 1 to 230 nmol/L, independent of gender. The erythrocyte/plasma partition ratio at clinically relevant concentrations is approximately 0.8.

**Metabolism**

Following absorption, budesonide is subject to first-pass metabolism. In vitro experiments in human liver microsomes demonstrate that budesonide is rapidly and extensively biotransformed, mainly by CYP3A4, to its 2 major metabolites, 6α-hydroxy budesonide and 16α-hydroxy prednisolone. The glucocorticoid activity of these metabolites is negligible (<1/100) in relation to that of the parent compound.

In vivo investigations with intravenous doses in healthy subjects demonstrate that budesonide has a plasma clearance of 0.9-1.8 L/min. These plasma clearance values approach the estimated liver blood flow, suggesting that budesonide is a high hepatic clearance drug.

**Excretion**

Budesonide is excreted in urine and feces in the form of metabolites. After oral as well as intravenous administration of micronized [3H]-budesonide, approximately 60% of the recovered radioactivity is found in urine. The major metabolites, including 6α-hydroxybudesonide and 16α-hydroxyprednisolone, are mainly renally excreted, intact or in conjugated forms. No unchanged budesonide is detected in urine.

**Specific Populations**

**Hepatic Impairment**

The effect of hepatic impairment on the pharmacokinetics of UCERIS rectal foam has not been studied. In a study in patients with mild to moderate hepatic impairment (Child-Pugh Class A and Child-Pugh Class B) dosed with budesonide 4 mg oral capsules, systemic exposure was similar between patients with mild hepatic impairment (Child-Pugh Class A; n=4) and healthy subjects (n=8), and 3.5-fold higher in patients with moderate hepatic impairment (Child-Pugh Class B; n=4) than in healthy subjects. For the intravenous dose, no significant differences in CL or Vd are observed. Patients with severe liver dysfunction (Child-Pugh Class C) were not studied.[see Use in Specific Populations (8.6)].

**Renal Impairment**

The pharmacokinetics of budesonide in patients with renal impairment has not been studied. Intact budesonide is not renally excreted, but metabolites are to a large extent, and might therefore reach higher levels in patients with impaired renal function. However, these metabolites have negligible corticosteroid activity as compared with budesonide.

**Drug-Drug Interactions**

Budesonide is metabolized via CYP3A4. Potent inhibitors of CYP3A4 can increase the plasma concentrations of budesonide. Co-administration of ketonozacine (inhibitor of CYP3A4) results in an 8-fold increase in AUC of oral budesonide, compared to budesonide alone. Grapefruit juice, an inhibitor of gut mucosal CYP3A, approximately 60% of the recovered radioactivity is found in urine. The major metabolites, including 6α-hydroxybudesonide and 16α-hydroxyprednisolone, are mainly renally excreted, intact or in conjugated forms. No unchanged budesonide is detected in urine.

14 CLINICAL STUDIES

The safety and efficacy of UCERIS rectal foam were evaluated in 2 replicate, randomized, double-blind, placebo-controlled, multi-center trials (Studies 1 and 2). Participants in the trials were adult patients with active mild-to-moderate distal ulcerative colitis with disease extending at least 5 cm but no further than 40 cm from the anal verge (confirmed by endoscopy). To be eligible, patients had to have a Modified Mayo Disease Activity Index (MMDAI) score between 5 and 10, inclusive, a rectal bleeding subscore of 2 or 3, and an endoscopy subscore of 2 or 3. The MMDAI score ranges from 0 to 12 and has 4 subscales that are each scored from 0 (normal) to 3 (most severe): stool frequency, rectal bleeding, findings on endoscopy, and physician global assessment. An endoscopy subscore of 2 is defined by marked erythema, lack of vascular pattern, friability, and erosions; an endoscopy subscore of 3 is defined by spontaneous bleeding and ulceration.

Oral and rectal corticosteroids, and rectal 5-aminosalicylic acid (5-ASA) products were prohibited during the course of the trials, but were allowed as rescue therapy. Oral 5-ASA products were allowed at doses ≤ 4.8 grams/day.

In total, 546 subjects were randomized in these trials: 267 subjects to UCERIS rectal foam and 279 subjects to placebo. In each trial (Study 1 and Study 2), patients received UCERIS rectal foam 2 mg or placebo twice daily for 2 weeks followed by once daily for 4 weeks.

The median age was 41 years and 42 years, 5% and 8% were ≥ 65 years of age, and 43% and 45% were male, in Studies 1 and 2, respectively. In each of these trials, 90% were Caucasian, 7-8% were African American, and 3% were Asian or Other. The majority of patients had a baseline diagnosis of proctitis/sigmoiditis (69% and 74%) in Studies 1 and 2, respectively. The remaining patients had a baseline diagnosis of proctitis. Concomitant oral 5-ASA use at baseline was 59% and 51% in Studies 1 and 2, respectively.

Baseline MMDAI total score was 7.8 and 7.9 in the UCERIS rectal foam group and placebo group, respectively, of Study 1; and 7.9 and 8.0 in the UCERIS rectal foam group and placebo group, respectively, of Study 2. The mean stool frequency subscore at baseline was 1.8 and 1.9 in the UCERIS rectal foam group and placebo group, respectively, of Study 1; and 1.7 and 1.8 in the UCERIS rectal foam group and placebo group, respectively, of Study 2.

In each trial (Study 1 and Study 2), the primary endpoint was the proportion of subjects who were in remission after 6 weeks of treatment. Remission was defined as a decrease or no change in the stool frequency subscore from baseline, a rectal bleeding subscore of 0, and an endoscopy score of 0 or 1. (An endoscopy subscore
of zero is defined by normal or inactive disease; an endoscopy subscore of 1 is defined by erythema and decreased vascular pattern."

In each trial (Study 1 and Study 2), a higher proportion of patients in the UCERIS rectal foam group than in the placebo group were in remission at Week 6, and had a rectal bleeding subscore of 0 at Week 6 (Table 4).

### Table 4: Efficacy Results: Studies 1 and 2

<table>
<thead>
<tr>
<th>Efficacy Endpoint</th>
<th>Study 1</th>
<th>Study 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>UCERIS Rectal Foam N=133</td>
<td>Placebo N=132</td>
</tr>
<tr>
<td>Remission at Week 6&lt;sup&gt;b&lt;/sup&gt;</td>
<td>38.3%</td>
<td>25.8%</td>
</tr>
<tr>
<td>Rectal Bleeding subscore = 0 at Week 6</td>
<td>46.6%</td>
<td>28.0%</td>
</tr>
</tbody>
</table>

<sup>a</sup> Remission was defined as an endoscopy subscore of 0 or 1, a rectal bleeding subscore of 0, and a decrease or no change in stool frequency subscore from baseline.

<sup>b</sup> p-values obtained from the Cochran-Mantel-Haenszel (CMH) test.

In Study 1, the percentage of patients with endoscopy subscore of 0 or 1 at Week 6 was 55.6% in the UCERIS rectal foam group versus 43.2% in the placebo group. In Study 2, the percentage of patients with endoscopy subscore of 0 or 1 at Week 6 was 56.0% in the UCERIS rectal foam group versus 36.7% in the placebo group (an endoscopy subscore of 0 is defined by normal or inactive disease; an endoscopy subscore of 1 is defined by erythema and decreased vascular pattern). In patients that met the primary endpoint of remission in Study 1, the mean (SD) decrease in stool frequency subscore was 1.2 (0.9) in the UCERIS rectal foam group and 1.2 (0.8) in the placebo group. In patients that met the primary endpoint of remission in Study 2, the mean (SD) decrease in stool frequency subscore was 1.3 (0.8) in the UCERIS rectal foam group and 1.1 (0.9) in the placebo group.

### 16 HOW SUPPLIED/STORAGE AND HANDLING

UCERIS rectal foam is supplied as a kit containing 2 aerosol canisters with 28 PVC applicators coated with paraffin lubricant for administration of the foam (NDC 65649-651-03). Each canister (NDC 65649-651-02) is labeled with a net weight of 33.4 g and contains 14 metered doses.

#### Storage

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

#### Handling

UCERIS rectal foam contains a flammable propellant. Do not have the canister burned after use and do not spray contents directly towards flames.

- Do not expose to heat or store at temperatures above 120°F (49°C).
- Flammable. Avoid fire, flame, or smoking during and immediately following administration.
- Contents under pressure. Do not puncture or incinerate.

DO NOT REFRIGERATE.
What is UCERIS rectal foam?
UCERIS rectal foam is a prescription corticosteroid medicine used to help get mild to moderate active ulcerative colitis that extends from the rectum to the sigmoid colon under control (induce remission).

It is not known if UCERIS rectal foam is safe and effective in children.

Who should not use UCERIS rectal foam?
Do not use UCERIS rectal foam if you are allergic to budesonide or any of the ingredients in UCERIS rectal foam. See the end of this leaflet for a complete list of ingredients in UCERIS rectal foam.

What should I tell my healthcare provider before using UCERIS rectal foam?
Before you use UCERIS rectal foam, tell your healthcare provider if you:
- have liver problems.
- are planning to have surgery.
- have chicken pox or measles or have recently been near anyone with chicken pox or measles.
- have an infection.
- have or had a family history of diabetes, cataracts or glaucoma.
- have or had tuberculosis.
- have high blood pressure (hypertension).
- have decreased bone mineral density (osteoporosis).
- have stomach ulcers.
- have any other medical condition.
- are pregnant or plan to become pregnant. It is not known if UCERIS rectal foam will harm your unborn baby.
- are breastfeeding or plan to breastfeed. UCERIS rectal foam can pass into your breast milk and may harm your baby. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. UCERIS rectal foam and other medicines may affect each other causing side effects. Especially tell your healthcare provider if you take another medicine that contains corticosteroids for a long period of time (chronic use), the adrenal glands may not make enough steroid hormones (adrenal suppression). Tell your healthcare provider if you are under stress or have any symptoms of adrenal suppression during treatment with UCERIS rectal foam including:
- tiredness
- weakness
- nausea
- vomiting
- low blood pressure

Immune system effects and a higher chance of infections. UCERIS rectal foam may weaken your immune system. Taking medicines that weaken your immune system makes you more likely to get infections. Avoid contact with people who have contagious diseases such as chicken pox or measles while using UCERIS rectal foam.

Tell your healthcare provider about any signs or symptoms of infection during treatment with UCERIS rectal foam including:
- fever
- chills
- aches
- pain
- nausea or vomiting

Worsening of allergies. If you take certain other corticosteroid medicines to treat allergies, switching to UCERIS rectal foam may cause your allergies to come back. These allergies may include eczema (a skin disease) or inflammation inside your nose (rhinitis). Tell your healthcare provider if any of your allergies become worse while using UCERIS rectal foam.

The most common side effects of UCERIS rectal foam include:
- decreased blood cortisol levels
- adrenal insufficiency
- nausea

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 UCERIS rectal foam. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may also report side effects to FDA at 1-800-FDA-1088.
How should I store UCERIS rectal foam?

- Store UCERIS rectal foam at room temperature, between 68°F to 77°F (20° to 25°C).
- Do not store the UCERIS rectal foam container near heat or store at temperatures above 120°F (49°C).
- Do not puncture or burn the UCERIS rectal foam canister.
- Do not refrigerate.

Keep UCERIS rectal foam and all medicines out of the reach of children.

General Information about UCERIS rectal foam

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use UCERIS rectal foam for a condition for which it was not prescribed. Do not give UCERIS rectal foam to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about UCERIS rectal foam. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider or pharmacist for information about UCERIS rectal foam that is written for health professionals.

For more information, go to www.UCERIS.com.

What are the ingredients in UCERIS rectal foam?

Active ingredients: budesonide

Inactive ingredients: cetyl alcohol, citric acid monohydrate, edetate disodium, emulsifying wax, polyoxyl (10) stearyl ether, propylene glycol, and purified water

Propellant: n-butane, isobutane, and propane

This Patient Information has been approved by the U.S. Food and Drug Administration.

Manufactured for:
Salix Pharmaceuticals, a division of Valeant Pharmaceuticals North America LLC
Bridgewater, NJ 08807 USA

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Step 4: Warm and Shake Canister
Warm the canister by holding it in your hands while shaking it vigorously for 10 to 15 seconds (See Figure E).

Step 5: Turn the Canister Upside Down
Place your forefinger on the top of pump dome and then turn the canister upside down (See Figure F).

Step 6: Insert the Applicator into Rectum
Insert the applicator into your rectum as far as it is comfortable.

Step 7: Give a Dose of UCERIS Rectal Foam
To give a dose of UCERIS rectal foam, use your forefinger to fully push down the pump dome one time and hold it for about 2 seconds in that position (See Figure H).

Step 8: Release and Hold
Release finger pressure on the pump dome and hold the applicator in place for 10 to 15 seconds (See Figure I).

Step 9: Remove the Applicator (See Figure J)
The foam will still expand a little and may drop out of the applicator or anus.

Step 10: Remove Applicator from Canister
Remove the applicator from the canister and place the used applicator in the plastic bag provided. (See Figure K). Throw the plastic bag away in your household trash.

Step 11: Twist Notch on Dome Away from Nozzle
To prevent loss of UCERIS rectal foam from the canister between uses, turn the pump dome around so that the semicircular notch faces the opposite direction to the nozzle (See Figure L).

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

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