**Table 1**

<table>
<thead>
<tr>
<th>β</th>
<th>SS</th>
<th>263/266</th>
</tr>
</thead>
</table>

**INDICATIONS AND USAGE**

- For the treatment of active moderate to severe distal rectal ulcerations. UCERIS rectal foam is contraindicated in patients with a history of a known hypersensitivity to budesonide.

**DOSAGE AND ADMINISTRATION**

- **Dose**: 2 mg/25 mL twice daily for 2 weeks followed by 2 mg once daily for an additional 4 weeks. The recommended daily dose of UCERIS should be taken in the morning and evening.

**TREATMENT OF SPECIFIC CONDITIONS**

- **Acute adrenal suppression or benign intracranial hypertension**: UCERIS rectal foam is contraindicated in patients with a history of acute adrenal suppression or benign intracranial hypertension.

**SIDE EFFECTS**

- **Common**: Headache, nausea, vomiting, and diarrhea.

**ALLERGIC REACTIONS**

- **Symptoms**: Skin rash, itching, and swelling.

**PRECAUTIONS**

- **Hypersensitivity**: UCERIS rectal foam is contraindicated in patients with a history of a known hypersensitivity to budesonide.

**ADVERSE REACTIONS**

- **Infections**: Tuberculosis infection, untreated fungal infection.

**CONTRAINDICATIONS**

- **History of adrenal insufficiency**: UCERIS rectal foam is contraindicated in patients with a history of adrenal insufficiency.

**INTERACTIONS**

- **Concomitant Use**: No significant interactions have been reported.

**CLINICAL STUDIES**

- **Summary of Adverse Reactions in 2 Placebo-Controlled Trials**

<table>
<thead>
<tr>
<th>Reaction</th>
<th>UCERIS Rectal Foam N=268</th>
<th>Placebo N=266</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>6 (2)</td>
<td>2 (1)</td>
</tr>
<tr>
<td>Nausea</td>
<td>23 (8)</td>
<td>13 (5)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>15 (5)</td>
<td>12 (4)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>21 (8)</td>
<td>16 (6)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>10 (4)</td>
<td>8 (3)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>11 (4)</td>
<td>7 (2)</td>
</tr>
<tr>
<td>Constipation</td>
<td>11 (4)</td>
<td>8 (3)</td>
</tr>
</tbody>
</table>

**REFERENCES**

- No specific references provided in the image.
Treatment

**Table 4:**

<table>
<thead>
<tr>
<th>Efficacy Endpoint</th>
<th>Rectal Bleeding</th>
<th>Remission at Week 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study 1</td>
<td>36.7%</td>
<td>32.0%</td>
</tr>
<tr>
<td>Study 2</td>
<td>36.7%</td>
<td>33.4%</td>
</tr>
<tr>
<td>Placebo</td>
<td>12.6%</td>
<td>10.0%</td>
</tr>
<tr>
<td>Placebo</td>
<td>17.0%</td>
<td>15.3%</td>
</tr>
</tbody>
</table>

**Table 5:**

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Rectal Foam</th>
<th>Placebo</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea and vomiting</td>
<td>4.5%</td>
<td>2.1%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Headache</td>
<td>3.5%</td>
<td>2.1%</td>
<td>1.4%</td>
</tr>
<tr>
<td>Constipation</td>
<td>3.5%</td>
<td>2.1%</td>
<td>1.4%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>3.5%</td>
<td>2.1%</td>
<td>1.4%</td>
</tr>
<tr>
<td>Hyperactivity</td>
<td>3.5%</td>
<td>2.1%</td>
<td>1.4%</td>
</tr>
<tr>
<td>Nervousness</td>
<td>3.5%</td>
<td>2.1%</td>
<td>1.4%</td>
</tr>
<tr>
<td>Fever</td>
<td>3.5%</td>
<td>2.1%</td>
<td>1.4%</td>
</tr>
</tbody>
</table>

**Package Information:**

- Avoid fire, flame, and smoking during and immediately following treatment.
- Grapefruit juice can increase the level of UCERIS rectal foam in your blood.
- Tell your healthcare provider about any signs or symptoms of infection during treatment with UCERIS rectal foam.
- Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.
- Tell your healthcare provider about all the medicines you take, including if you:
  - have stomach ulcers.
  - have decreased bone mineral density (osteoporosis).
  - have chicken pox or measles or have recently been near anyone with chicken pox or measles.

**Handling:**

- Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F).
- Each applicator is coated with a lubricant. If needed, additional lubrication is recommended.
- The foam will still expand a little and may drop out of the applicator (See Figure J). To avoid accidental expulsion, slow and full finger pressure should be applied on the pump dome for about 1.5 seconds prior to use. (See Figure F).
- To avoid accidental expulsion, slow and full finger pressure should be applied on the pump dome for about 1.5 seconds prior to use. (See Figure F).

**Hypercorticism and Adrenal Suppression:**

- Advise patients to avoid exposure to people with chicken pox or measles and if exposed, to notify their healthcare provider.
- Advise patients that UCERIS rectal foam may cause hypercorticism and adrenal suppression and that they should taper slowly from systemic corticosteroids if necessary.
- Advise female patients that UCERIS rectal foam may cause fetal harm and to inform their healthcare provider if they are pregnant or breastfeeding.

**Precautions:**

- UCERIS rectal foam is flammable. Avoid fire, flame, and smoking during and immediately following treatment.
- Grapefruit juice can increase the level of UCERIS rectal foam in your blood.
- Tell your healthcare provider about any signs or symptoms of infection during treatment with UCERIS rectal foam.
- Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.
- Tell your healthcare provider about all the medicines you take, including if you:
  - have stomach ulcers.
  - have decreased bone mineral density (osteoporosis).
  - have chicken pox or measles or have recently been near anyone with chicken pox or measles.

**What are the possible side effects of UCERIS rectal foam?**

- Nausea and vomiting
- Headache
- Constipation
- Diarrhea
- Hyperactivity
- Nervousness
- Fever

Detailed instructions on the use of UCERIS rectal foam are available in the Patient Information (See Figure C).