BRIEF SUMMARY
Please see full Prescribing Information for full Prescribing Information.

INDICATIONS AND USAGE
GELNIQUE is indicated for the treatment of overactive bladder symptoms of urinary incontinence, urgency, and frequency. GELNIQUE is for topical application only and should not be ingested.

CONTRAINDICATIONS
The use of GELNIQUE is contraindicated in the following conditions:
• Urinary retention
• Gastric retention
• Uncontrolled narrow-angle glaucoma
• Known hypersensitivity to GELNIQUE, including skin hypersensitivity

PRECAUTIONS
Urinary Retention
Administer GELNIQUE with caution in patients with clinically significant bladder outflow obstruction because of the risk of urinary retention.

Patients with Gastrointestinal Disorders
Administer GELNIQUE with caution to patients with gastrointestinal obstructive disorders because of the risk of gastric retention.

GELNIQUE, like other anticholinergic drugs, may decrease gastrointestinal motility and should be used with caution in patients with conditions such as ulcerative colitis or inflammatory bowel GELNIQUE should be used with caution in patients who have gastroesophageal reflux and/or who are concurrently taking drugs (such as bisphosphonates) that can cause or exacerbate esophagitis.

Skin Hypersensitivity
A controlled clinical trial of skin sensitization, 1 of 200 patients (0.5%) demonstrated skin hypersensitivity to GELNIQUE. It is not known whether GELNIQUE should discontinue drug treatment. Since GELNIQUE is for topical application only, patients with skin hypersensitivity to nonactive ingredients of GELNIQUE should discontinue drug treatment.

Flammable Gel
GELNIQUE is a flammable alcohol-based gel and is therefore flammable. Avoid open fire or smoking until gel has dried.

Mastectomy Gravis
Administer GELNIQUE with caution in patients with mastectomy gravis, a disease characterized by decreased cholinergic activity in the muscular junction.

ADVERSE REACTIONS
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 large randomized, double-blind, placebo-controlled 12-week study and in greater than 2% of patients treated with GELNIQUE.

Table 1: Common Adverse Events in the Randomized, Double-Blind, Placeto-controlled 12-Week Study (% > placebo)

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>GELNIQUE</th>
<th>Placebo</th>
</tr>
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<tbody>
<tr>
<td>Dry mouth</td>
<td>29.5%</td>
<td>11.2%</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>21.4%</td>
<td>17.4%</td>
</tr>
<tr>
<td>Application site reactions</td>
<td>21.4%</td>
<td>4.1%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>11.2%</td>
<td>4.1%</td>
</tr>
<tr>
<td>Nausea</td>
<td>11.2%</td>
<td>9.2%</td>
</tr>
<tr>
<td>Constipation</td>
<td>8.0%</td>
<td>1.3%</td>
</tr>
</tbody>
</table>

Includes application site pruritus, dermatitis, papules, anesthesia, erythema, irritation, pain and papules. The most common adverse reactions, defined as adverse events judged by the investigator to be reasonably associated with the use of study drug, that were reported in at least 1% of GELNIQUE-treated patients were dry mouth (8.8%), application site reactions (5.4%), diarrhea (1.5%), headache (1.5%), constipation (1.5%), and pruritus (1.3%). Application site pruritus (2.1%) and application site dermatitis (1.8%) were the most commonly reported application site reactions. A majority of treatment-related adverse events were described as mild or moderate in intensity. There were no serious adverse events in patients who were patients treated with GELNIQUE.

No serious adverse events were judged by the investigator to be drug-related during the randomized, double-blind, placebo-controlled 12-week study. The most common adverse reaction leading to drug discontinuation was application site reaction (0.8% with GELNIQUE versus 0.3% with placebo).

The most common adverse reactions reported during the 14-week open-label extension study were application site reactions (46.1%) and dry mouth (1.5%). The most common reason for premature discontinuation was application site reactions (5 patients or 2.4%). Two of these 9 patients experienced application site reactions of severe intensity (dermatitis, urticaria, and erythema).

DRUG INTERACTIONS
No specific drug interaction studies have been performed with GELNIQUE.

Use With Other Anticholinergics
The concomitant use of GELNIQUE with other anticholinergic (antimuscarinic) agents may increase the frequency and/or severity of dry mouth, constipation, blurred vision, tachycardia, and other anticholinergic pharmacological effects.

USE IN SPECIFIC POPULATIONS
Pregnancy
Pregnancy Category B
There are no adequate and well-controlled studies of topical or oral oxybutynin use in pregnant women. Subcutaneous administration to rats at doses as high as 25 mg/kg/day (approximately 5 times the human exposure based on surface area) and to rabbits at doses up to 0.4 mg/kg/day (approximately 1 times the human exposure) revealed no evidence of harm to the fetus due to oxybutynin administration. The safety of GELNIQUE administration to women who are or who may become pregnant has not yet been established. Therefore, GELNIQUE should be used with caution in pregnant women unless, in the judgment of the physician, the potential clinical benefits outweigh the possible hazards.

Nursing Mothers
It is not known whether oxybutynin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when GELNIQUE is administered to a nursing woman.

Geriatric Use
Of the 496 patients exposed to GELNIQUE in the randomized, double-blind, placebo-controlled 12-week study and the 14-week safety extension study, 188 patients (38%) were 65 years of age or older. The incidence of differences in safety or effectiveness were observed between the 2 patient populations studied. GELNIQUE is not expected to have different effects in elderly and younger patients.

Pediatric Patients
The pharmacokinetics of oxybutynin and N-desethyl oxybutynin have not been evaluated in infants younger than 18 years of age.

Renal Impairment
There is no experience with the use of GELNIQUE in patients with renal impairment.

Hepatic Impairment
There is no experience with the use of GELNIQUE in patients with hepatic impairment.

Race
The effect of race on the pharmacokinetics of GELNIQUE has not been studied.

Gender
Available data suggest that there are no significant differences in the pharmacokinetics of oxybutynin based on gender in healthy volunteers following administration of GELNIQUE.

Use of Sunscreen
The effect of sunscreen on the absorption of oxybutynin when applied 30 minutes before or 30 minutes after GELNIQUE application was evaluated in a single-dose randomized crossover study (N=16). Concomitant application of sunscreen, either before or after GELNIQUE application, had no effect on the systemic exposure of oxybutynin.

Showering
The effect of showering on the absorption of oxybutynin was evaluated in a randomized, steady-state crossover study under conditions of no showering, or showering 1, 2, or 6 hours after GELNIQUE application (N=20). The results of the study indicate that showering after one hour does not affect the systemic exposure to oxybutynin.

OVERDOSAGE
Overdosage with oxybutynin has been associated with anticholinergic effects including central nervous system excitation, agitation, delirium, fever, delirium, cardiac arrhythmia, vomiting, and urinary retention. Oral ingestion of 100 mg oxybutynin chloride in association with alcohol has been reported in a 13-year-old boy who experienced memory impairment, disorientation, and visual hallucinations associated with drowsiness, flushed skin, cardiac arrhythmia, and retention of urine. Both patients recovered fully with symptomatic treatment.

The plasma concentrations of oxybutynin begin to decline 24 hours after GELNIQUE application. If overdose occurs, monitor patients until symptoms resolve.

Keep out of reach of children.

Storage
Store at room temperature, 35°C (77°F). Temporary storage between 15°C and 30°C (59°F and 86°F) is acceptable. Keep GELNIQUE and all medications in a safe, secure place and out of the reach of children.

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