

**GELNIQUE- oxybutynin chloride gel**  
**Actavis Pharma, Inc.**

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**HIGHLIGHTS OF PRESCRIBING INFORMATION**

**GELNIQUE®**

**(oxybutynin chloride) gel 10 %**

**Rx only**

**These highlights do not include all the information needed to use GELNIQUE safely and effectively. See full prescribing information for GELNIQUE.**

**GELNIQUE (oxybutynin chloride) 10 % gel**

**Initial U.S. Approval: 1975**

----- **RECENT MAJOR CHANGES** -----

WARNINGS AND PRECAUTIONS, Central Nervous System Effects (5.5) 07/2015

----- **INDICATIONS AND USAGE** -----

GELNIQUE is a muscarinic antagonist indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. (1)

----- **DOSAGE AND ADMINISTRATION** -----

- Apply contents of one sachet of GELNIQUE once daily to dry, intact skin on the abdomen, upper arms/shoulders, or thighs. (2)
- Rotate application sites, avoiding use of the same site on consecutive days. (2)
- GELNIQUE is for topical application only and should not be ingested. (2)

----- **DOSAGE FORMS AND STRENGTHS** -----

Gel: 10% (3)

----- **CONTRAINDICATIONS** -----

- Urinary retention (4)
- Gastric retention (4)
- Uncontrolled narrow-angle glaucoma (4)
- Known serious hypersensitivity reaction to GELNIQUE, oxybutynin, or to any of the components of GELNIQUE (4)

----- **WARNINGS AND PRECAUTIONS** -----

- Urinary Retention: Use caution in patients with clinically significant bladder outflow obstruction because of the risk of urinary retention. (5.1)
- Gastrointestinal Disorders: Use caution in patients with gastrointestinal obstructive disorders or decreased intestinal motility because of the risk of gastric retention. Use caution in patients with gastroesophageal reflux and/or those taking drugs that can cause or exacerbate esophagitis. (5.2)
- Angioedema: Angioedema has been reported with oral oxybutynin use. If symptoms of angioedema occur, discontinue GELNIQUE and initiate appropriate therapy. (5.3)
- Skin Hypersensitivity: Discontinue GELNIQUE in patients with skin hypersensitivity. (5.4)
- Central Nervous System Effects: Somnolence has been reported with GELNIQUE. Advise patients not to drive or operate heavy machinery until they know how GELNIQUE affects them. (5.5)
- Skin Transference: Advise patients to cover the application site with clothing if skin-to-skin contact at the application site is anticipated. Wash hands immediately after product application. (5.6)
- Flammable Gel: Contains alcohol-based gel. Avoid open fire or smoking until the gel has dried. (5.7)

----- **ADVERSE REACTIONS** -----

The most common adverse reactions (incidence > 5% and > placebo) were dry mouth, urinary tract infection, and application site reactions. (6)

**To report SUSPECTED ADVERSE REACTIONS, contact Actavis, Inc. at 1-800-272-5525 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)**

----- **DRUG INTERACTIONS** -----

**Other Anticholinergics (muscarinic antagonists):** Concomitant use with other anticholinergic agents may increase the frequency and/or severity of dry mouth, constipation, blurred vision and other anticholinergic pharmacological effects.

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\* Sections or subsections omitted from the full prescribing information are not listed.

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**FULL PRESCRIBING INFORMATION**

**1 INDICATIONS AND USAGE**

GELNIQUE is a muscarinic antagonist indicated for the treatment of overactive bladder with symptoms

of urge urinary incontinence, urgency and frequency [*see Clinical Studies (14)*].

## **2 DOSAGE AND ADMINISTRATION**

The contents of one sachet of GELNIQUE should be applied once daily to dry, intact skin on the abdomen, upper arms/shoulders, or thighs. Application sites should be rotated. Application of GELNIQUE should not be made to the same site on consecutive days [*see Clinical Pharmacology (12.3)*].

GELNIQUE is for topical application only and should not be ingested.

## **3 DOSAGE FORMS AND STRENGTHS**

Gel: 10%

## **4 CONTRAINDICATIONS**

The use of GELNIQUE is contraindicated in the following conditions:

- Urinary retention
- Gastric retention
- Uncontrolled narrow-angle glaucoma
- Known serious hypersensitivity reaction to GELNIQUE, oxybutynin, or to any of the components of GELNIQUE [*see Warnings and Precautions (5.3, 5.4)*].

## **5 WARNINGS AND PRECAUTIONS**

### **5.1 Urinary Retention**

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

### **5.2 Use in 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 intestinal atony. 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.

### **5.3 Angioedema**

Angioedema requiring hospitalization and emergency medical treatment has occurred with the first or subsequent doses of oral oxybutynin. In the event of angioedema, oxybutynin-containing product should be discontinued and appropriate therapy promptly provided.

### **5.4 Skin Hypersensitivity**

In a controlled clinical trial of skin sensitization, 1 of 200 patients (0.5%) demonstrated skin hypersensitivity to GELNIQUE. Patients who develop skin hypersensitivity to GELNIQUE should discontinue drug treatment.

### **5.5 Central Nervous System Effects**

GELNIQUE is associated with anticholinergic central nervous system (CNS) effects. A variety of CNS anticholinergic effects have been reported, including headache, dizziness, somnolence, confusion and

hallucinations. Patients should be monitored for signs of anticholinergic CNS effects, particularly after beginning treatment. Advise patients not to drive or operate heavy machinery until they know how GELNIQUE affects them. If a patient experiences anticholinergic CNS effects, drug discontinuation should be considered.

## 5.6 Skin Transference

Transfer of oxybutynin to another person can occur when vigorous skin-to-skin contact is made with the application site. To minimize the potential transfer of oxybutynin from GELNIQUE-treated skin to another person, patients should cover the application site with clothing after the gel has dried if direct skin-to-skin contact at the application site is anticipated [see *Clinical Pharmacology (12.3)*]. Patients should wash their hands immediately after application of GELNIQUE.

## 5.7 Flammable Gel

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

## 5.8 Myasthenia Gravis

Administer GELNIQUE with caution in patients with myasthenia gravis, a disease characterized by decreased cholinergic activity at the neuromuscular junction.

# 6 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 clinical trial of another drug and may not reflect the rates observed in practice.

## 6.1 Clinical Studies Experience

The safety of GELNIQUE was evaluated in 789 patients (389 randomized to GELNIQUE 1 g and 400 randomized to placebo) during a randomized, placebo-controlled, double-blind, 12-week clinical efficacy and safety study. A subset of these 789 patients (N = 216) participated in the 14-week open-label safety extension that followed the placebo-controlled study. Of 216 patients in the safety extension, 107 were randomized to placebo gel during the double-blind, placebo-controlled 12-week study. In the combined double-blind, placebo-controlled study and the open-label safety extension, a total of 496 patients were exposed to at least one dose of GELNIQUE. Four hundred thirty-one (431) patients received at least 12 weeks of GELNIQUE treatment and 85 patients received 26 weeks of GELNIQUE treatment. The study population primarily consisted of Caucasian women (approximately 90%) with an average age of 59 years who had overactive bladder with urge urinary incontinence.

Table 1 lists adverse reactions that were reported in the randomized, double-blind, placebo-controlled 12-week study in greater than 2% of patients treated with GELNIQUE and at an incidence greater than placebo.

**Table 1: Common Adverse Reactions in the Randomized, Double-blind, Placebo-controlled 12-Week Study (> 2% and > placebo)**

<b>Adverse Reaction</b>	<b>GELNIQUE 1 gram N = 389 n (%)</b>	<b>Placebo N = 400 n (%)</b>
Dry mouth	29 (7.5)	11 (2.8)
Urinary tract infection	27 (6.9)	17 (4.3)
Application site reactions*	21 (5.4)	4 (1.0)
Upper respiratory tract infection	21 (5.4)	20 (5.0)

Dizziness	11 (2.8)	4 (1.0)
Nasopharyngitis	11 (2.8)	9 (2.3)
Fatigue	8 (2.1)	4 (1.0)
Gastroenteritis viral	8 (2.1)	7 (1.8)

\* Includes application site pruritus, dermatitis, papules, anesthesia, erythema, irritation, pain and papules

Other common adverse reactions that were reported in  $\geq 1\%$  of GELNIQUE-treated patients were headache (1.5%), constipation (1.3%), 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 adverse reactions were described as mild or moderate in intensity, except for two patients reporting severe headache.

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 (6.0%) and dry mouth (1.9%). The most common reason for premature discontinuation was application site reactions (9 patients or 4.2%). Two of these 9 patients experienced application site reactions of severe intensity (dermatitis, urticaria, and erythema).

## 6.2 Postmarketing Experience

The following adverse reactions have been identified during post approval use of GELNIQUE. 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.

Nervous System Disorders: dizziness, somnolence, confusion

Psychiatric Disorders: hallucinations

## 7 DRUG INTERACTIONS

No specific drug-drug interaction studies have been performed with GELNIQUE.

### 7.1 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, somnolence and other anticholinergic pharmacological effects.

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 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 up to 25 mg/kg (approximately 50 times the human exposure based on surface area) and to rabbits at doses up to 0.4 mg/kg (approximately 1 times the human exposure) revealed no evidence of harm to the fetus due to oxybutynin chloride. The safety of GELNIQUE administration to women who are or who may become pregnant has not been established. Therefore, GELNIQUE should not be given to pregnant women unless, in the judgment of the physician, the probable clinical benefits outweigh the possible hazards.

### 8.3 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.

#### 8.4 Pediatric Use

The safety and effectiveness of GELNIQUE 10% have not been established in pediatric patients.

#### 8.5 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 and older. No overall differences in safety or effectiveness were observed between these patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out [see *Clinical Pharmacology (12.3)*].

#### 8.6 Renal Impairment

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

#### 8.7 Hepatic Impairment

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

### 10 OVERDOSAGE

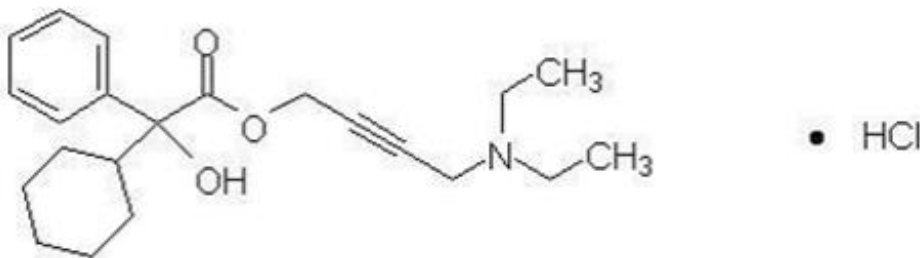
Overdosage with oxybutynin has been associated with anticholinergic effects including central nervous system excitation, flushing, fever, dehydration, cardiac arrhythmia, vomiting, and urinary retention. Oral ingestion of 100 mg oxybutynin chloride in association with alcohol has been reported in a 13-year-old boy who experienced memory loss, and in a 34-year-old woman who developed stupor, followed by disorientation and agitation on awakening, dilated pupils, dry skin, cardiac arrhythmia, and retention of urine. Both patients recovered fully with symptomatic treatment.

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

### 11 DESCRIPTION

Oxybutynin is an antispasmodic, antimuscarinic agent. GELNIQUE (oxybutynin chloride) is a clear and colorless hydroalcoholic gel containing 100 mg oxybutynin chloride per gram of gel. GELNIQUE is available in a 1 gram (1.14 mL) unit dose. Each dose contains 100 mg oxybutynin chloride. Oxybutynin is delivered as a racemate of R- and S- isomers. Chemically, oxybutynin chloride is d, l (racemic) 4-(Diethylamino)-2-butynyl ( $\pm$ )- $\alpha$ -phenylcyclohexanecarboxylate hydrochloride.

The empirical formula of oxybutynin is  $C_{22}H_{31}NO_3 \cdot HCl$ . Its structural formula is:



Oxybutynin chloride is a white powder with a molecular weight of 393.95.

Inactive ingredients in GELNIQUE are alcohol, USP; glycerin, USP; hydroxypropyl cellulose, NF; sodium hydroxide, NF; and purified water, USP.

## 12 CLINICAL PHARMACOLOGY

### 12.1 Mechanism of Action

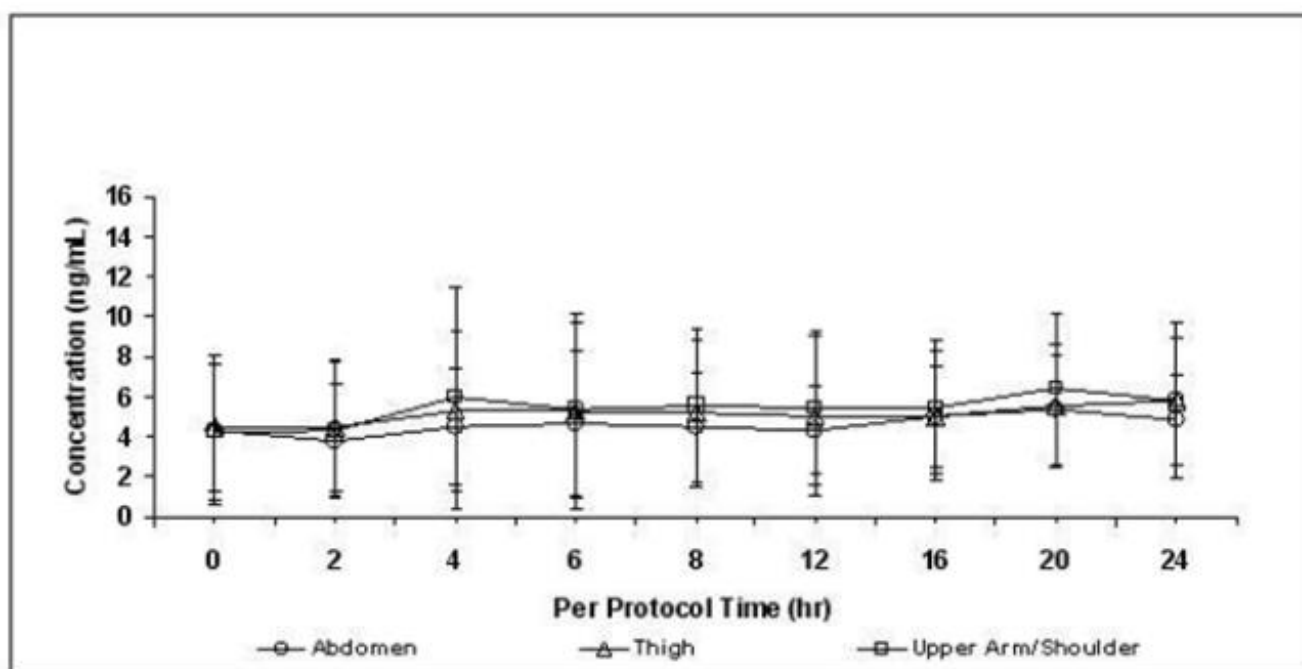
Oxybutynin acts as a competitive antagonist of acetylcholine at postganglionic muscarinic receptors, resulting in relaxation of bladder smooth muscle. Oxybutynin is a racemic (50:50) mixture of R- and S-isomers. Antimuscarinic activity resides predominantly with the R- isomer. The active metabolite, N-desethyloxybutynin, has pharmacological activity on the human detrusor muscle that is similar to that of oxybutynin in *in vitro* studies.

### 12.3 Pharmacokinetics

#### Absorption

Oxybutynin is transported across intact skin and into the systemic circulation by passive diffusion across the stratum corneum. Steady-state concentrations are achieved within 7 days of continuous dosing. Absorption of oxybutynin is similar when GELNIQUE is applied to the abdomen, upper arm/shoulders or thighs. Mean plasma concentrations during a randomized, crossover study of the three recommended application sites in 39 healthy men and women are shown in Figure 1.

**Figure 1: Mean ( $\pm$  SD) plasma oxybutynin concentrations during steady-state application of GELNIQUE to the abdomen, upper arm/shoulder and thigh (N=39).**



Average steady-state plasma oxybutynin concentrations were 4.7, 5.2, and 5.5 ng/mL for the abdomen, upper arm/shoulder and thigh application sites, respectively (Table 2).

**Table 2: Mean (SD) steady-state pharmacokinetic parameters for oxybutynin following GELNIQUE application to the abdomen, upper arm/shoulder and thigh (N = 39).**

Application Site	AUC <sub>0-24</sub> (ng•hr/mL)	C <sub>max</sub> (ng/mL)	C <sub>avg</sub> (ng/mL)
Abdomen	112.7 (58.00)	6.8 (3.93)	4.7 (2.39)
Upper Arm/Shoulder	133.8 (81.58)	8.3 (5.97)	5.5 (3.37)
Thigh	125.1 (84.67)	7.0 (4.95)	5.2 (3.50)

### ***Distribution***

Oxybutynin is widely distributed in body tissues following systemic absorption. The volume of distribution was estimated to be 193 L after intravenous administration of 5 mg oxybutynin chloride.

### ***Metabolism***

Oxybutynin is metabolized primarily by the cytochrome P450 enzyme systems, particularly CYP3A4, found mostly in the liver and gut wall. Metabolites include phenylcyclohexylglycolic acid, which is pharmacologically inactive, and N-desethyloxybutynin (DEO), which is pharmacologically active.

Transdermal administration of oxybutynin bypasses the first-pass gastrointestinal and hepatic metabolism, reducing the formation of the N-desethyloxybutynin metabolite. Only small amounts of CYP3A4 are found in skin, limiting pre-systemic metabolism during transdermal absorption. The AUC ratio of N-desethyloxybutynin metabolite to parent compound following multiple transdermal applications is approximately 1:1 for GELNIQUE.

Following intravenous administration, the elimination half-life of oxybutynin is approximately 2 hours. After the final steady-state dose of GELNIQUE, oxybutynin and N-desethyloxybutynin demonstrated biphasic elimination with plasma concentrations beginning to decrease 24 hours after dosing. Elimination was more rapid between 24 and 48 hours after dosing, during which time plasma concentrations of oxybutynin and N-desethyloxybutynin declined by about one-half. This rapid elimination phase was followed by a more prolonged terminal elimination phase. The apparent elimination half-lives including the terminal elimination phase were 64 hours and 82 hours for oxybutynin and DEO, respectively.

### ***Excretion***

Oxybutynin is extensively metabolized by the liver, with less than 0.1% of the administered dose excreted unchanged in the urine. Less than 0.1% of the administered dose is excreted as the metabolite N-desethyloxybutynin.

### ***Person-to-Person Transference***

The potential for dermal transfer of oxybutynin from a treated person to an untreated person was evaluated in a single-dose study where subjects dosed with GELNIQUE engaged in vigorous contact with an untreated partner for 15 minutes, either with (N = 14 couples) or without (N = 12 couples) clothing covering the application area. The untreated partners not protected by clothing demonstrated detectable plasma concentrations of oxybutynin (mean  $C_{\max}$  = 0.94 ng/mL). Two of the 14 untreated subjects participating in the clothing-to-skin contact regimen had measurable oxybutynin plasma concentrations ( $C_{\max} \leq 0.1$  ng/mL) during the 48 hours following contact with treated subjects; oxybutynin was not detectable with the remaining 12 untreated subjects.

### ***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 shower, 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 overall systemic exposure to oxybutynin.

### ***Race***

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



## Specific Populations:

**Geriatric:** Available data suggest that there are no significant differences in the pharmacokinetics of oxybutynin based on geriatric status in patients following administration of GELNIQUE [see Use in Specific Populations (8.5)].

**Pediatric:** The pharmacokinetics of oxybutynin and N-desethyloxybutynin have not been evaluated in individuals younger than 18 years of age [see Use in Specific Populations (8.4)].

**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.

**Renal Impairment:** The effect of renal impairment on the pharmacokinetics of GELNIQUE has not been studied.

**Hepatic Impairment:** The effect of hepatic impairment on the pharmacokinetics of GELNIQUE has not been studied.

## 13 NONCLINICAL TOXICOLOGY

### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

A 24-month study in rats at dosages of oxybutynin chloride of 20, 80 and 160 mg/kg showed no evidence of carcinogenicity. These doses are approximately 6, 25 and 50 times the maximum exposure in humans taking an oral dose, based on body surface area. Oxybutynin chloride showed no increase of mutagenic activity when tested in *Schizosaccharomyces pompholiciformis*, *Saccharomyces cerevisiae*, and *Salmonella typhimurium* test systems. Reproduction studies with oxybutynin chloride in the mouse, rat, hamster, and rabbit showed no definite evidence of impaired fertility.

## 14 CLINICAL STUDIES

The efficacy and safety of GELNIQUE were evaluated in a single randomized, double-blind, placebo-controlled, parallel group 12-week study for the treatment of overactive bladder with symptoms of urge incontinence, urgency and frequency. Key entry criteria included adults with symptomatic overactive bladder with an average of  $\geq 4$  incontinence episodes in a 3-day period and at least 8 micturitions per day. Patients were randomized to daily applications of GELNIQUE 1 gram or matching placebo gel. A total of 389 patients received GELNIQUE and 400 patients received placebo gel. The majority of patients were Caucasian (86.3%) and female (89.2%), with a mean age of 59.4 years (range: 18 to 88 years). The average duration of urinary incontinence was approximately 8.5 years and approximately 75% of patients had no prior pharmacological treatment for urinary incontinence.

Patients treated with GELNIQUE experienced a statistically significant decrease in the number of urinary incontinence episodes per day from baseline to endpoint compared with placebo ( $p < 0.0001$ ) as well as a decrease in the average daily urinary frequency ( $p = 0.0017$ ) and an increase in the average urine volume per void ( $p = 0.0018$ ).

Mean and median change from baseline in daily incontinence episodes (primary endpoint), urinary frequency, and urinary void volume (secondary endpoints) between placebo and GELNIQUE are summarized in Table 3.

**Table 3: Mean and median change from baseline for incontinence episodes, urinary frequency, and urinary void volume at Week 12 (LOCF\*).**

Parameter	GELNIQUE 1 gram (N = 389)		Placebo (N = 400)	
	Mean (SD)	Median	Mean (SD)	Median
Daily Incontinence Episodes				

Baseline	5.4 (3.26)	4.7	5.4 (3.28)	4.7
Change from baseline	-3.0 (2.73)	-2.7	-2.5 (3.06)	-2.0
Mean difference [GELNIQUE – placebo] (95% CI)	-0.5 (-0.14, -0.87)			
P-value vs. placebo	< 0.0001			
Daily Urinary Frequency				
Baseline	12.4 (3.34)	11.7	12.2 (3.32)	11.3
Change from baseline	-2.7 (3.21)	-2.7	-2.0 (2.82)	-1.7
P-value vs. placebo	0.0017			
Urinary Void Volume (mL)				
Baseline	163.4 (65.85)	160.1	167.9 (68.40)	160.6
Change from Baseline	21.0 (65.33)	11.5	3.8 (53.79)	0.0
P-value vs. placebo	0.0018			

\*Last-Observation-Carried-Forward statistical imputation for missing data

## 16 HOW SUPPLIED/STORAGE AND HANDLING

**Unit Dose:** Heat-sealed sachet containing 1 gram (1.14 mL) of GELNIQUE gel for topical use.

Carton of 30 Sachets (NDC 52544-084-30)

### Storage

Store at 20-25°C (68-77°F). [See USP controlled room temperature.] Protect from moisture and humidity. Apply immediately after the sachets are opened and contents expelled. Discard used sachets in household trash in a manner that prevents accidental application or ingestion by children, pets, or others.

**Keep out of reach of children.**

## 17 PATIENT COUNSELING INFORMATION

[See FDA-Approved Patient Labeling]

### Instructions for Use

GELNIQUE is for topical application only and should not be ingested.

GELNIQUE should not be applied to recently shaved skin surfaces. Patients should wash hands immediately after product application. Application sites should not be subject to showering or water immersion for 1 hour after product application. Application sites should be covered with clothing if close skin-to-skin contact at the application site is anticipated.

Alcohol based gels are flammable. Avoid open fire or smoking until the gel has dried.

### Important Anticholinergic Adverse Reactions

Patients should be informed that anticholinergic (antimuscarinic) agents, such as GELNIQUE, may produce clinically significant adverse reactions related to anticholinergic pharmacological activity including:

- Urinary retention and constipation.
- Heat prostration (due to decreased sweating) when anticholinergics such as GELNIQUE are used in a hot environment.
- Dizziness or blurred vision. Patients should be advised to exercise caution in decisions to engage in potentially dangerous activities until GELNIQUE's effects have been determined.
- Drowsiness that may be worsened by alcohol.

For all medical inquiries contact:

Actavis Pharma, Inc.  
Medical Communications  
Parsippany, NJ 07054  
800-272-5525

Distributed By:

Actavis Pharma, Inc.  
Parsippany, NJ 07054 USA

## **FDA-Approved Patient Labeling**

### **PATIENT INFORMATION**

**GELNIQUE** [*Gel-nēk*]

**(oxybutynin chloride) 10% gel Topical**

**IMPORTANT: For use on the skin only (topical). Do not use GELNIQUE in or near your eyes, nose, or mouth.**

Read the Patient Information that comes with GELNIQUE before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical condition or your treatment. If you do not understand the information, or have any questions about GELNIQUE, talk with your healthcare provider or pharmacist.

### **What is GELNIQUE?**

GELNIQUE is a prescription medicine used to treat the symptoms of overactive bladder:

- Urge urinary incontinence (a strong need to urinate with leaking or wetting accidents).
- Urgency (a strong need to urinate right away).
- Frequency (urinating often).

### **Who should not use GELNIQUE?**

Do not use GELNIQUE if you have:

- **Urinary retention.** Your bladder does not empty or does not empty completely when you urinate.
- **Gastric retention.** Your stomach empties slowly or incompletely after a meal.
- **Uncontrolled narrow-angle glaucoma (high pressure in your eye).**
- **An allergy to oxybutynin or the inactive ingredients in GELNIQUE.** (See the end of this Patient Information leaflet for a complete list of ingredients in GELNIQUE).

### **What should I tell my healthcare provider before using GELNIQUE?**

**Before you use GELNIQUE, tell your healthcare provider if you:**

- have problems emptying your bladder completely
- have stomach problems including:
  - constipation or difficulty emptying your bowels
  - ulcerative colitis (inflamed bowels)
  - gastric reflux disease or esophagitis (inflammation of the tube between your mouth and stomach)
- have Myasthenia Gravis (generalized muscle weakness)
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed
- use medicines called “bisphosphonates” to treat osteoporosis
- use medicines called “anticholinergic”

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

### **How should I use GELNIQUE?**

- **GELNIQUE is for skin use only.**
- Use GELNIQUE exactly as your healthcare provider tells you to use it.
- GELNIQUE should only be applied to dry intact skin on your stomach (abdomen), upper arms, shoulders, or thighs.
- Do not put GELNIQUE on open sores, recently shaved skin, or skin with rashes.
- You should change your application site every day. Do not use the same site 2 days in a row. Changing application sites every day can help reduce your chance of getting skin irritation.
- GELNIQUE contains alcohol and is flammable. Avoid fire, flames or smoking until GELNIQUE has dried.
- After applying GELNIQUE, wash your hands with soap and water right away.
- Cover the application site with clothing if skin-to-skin contact between another person and the application site is expected.
- If someone else is exposed to GELNIQUE by direct contact with the gel or at the application site, that person should wash the area of contact with soap and water as soon as possible.
- If you get GELNIQUE in your eyes, rinse your eyes right away with warm, clean water to flush out any GELNIQUE.
- GELNIQUE may be used with sunscreen.

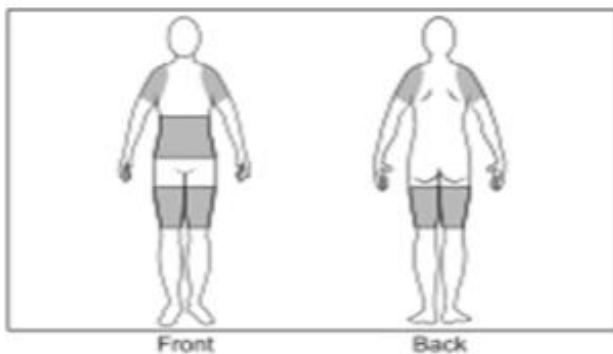
### **Applying GELNIQUE:**

#### **1. Selecting your application site:**

**Apply GELNIQUE only to 1 of the shaded areas shown in the figure below:** (See Figure A)

- stomach (abdomen)
- upper arms
- shoulder
- thigh

**Figure A**

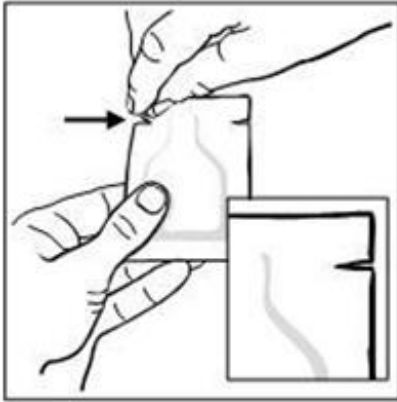


- Wash the area where GELNIQUE will be applied with mild soap and water. Allow the area to dry completely.
- Wash your hands with soap and water.

#### **2. How to use the GELNIQUE packets (sachets):**

- Find the notch at the top of your GELNIQUE packet. Tear off the top of the GELNIQUE packet at the notch (See Figure B).

**Figure B**



- Squeeze all of the GELNIQUE out of the packet onto your hand (palm or fingertips) or you can squeeze all of the GELNIQUE from the packet right onto the application site (See Figure C).
- Squeeze from the bottom of the packet toward the open end. Repeat until the packet is empty. The amount of GELNIQUE in each packet will be about the size of a nickel. Apply GELNIQUE to your skin (shown in Figure C).

**Figure C**



- Wash your hands with soap and water right away.
- Throw away the packet in the trash out of the reach of children to avoid accidental exposure.

**What should I avoid while using GELNIQUE?**

- GELNIQUE can cause tiredness, drowsiness, dizziness or blurred vision. Do not drive, operate machinery, or do other dangerous activities until you know how GELNIQUE affects you.
- Do not take a bath, swim, shower, exercise, or get the application site wet for at least 1 hour after you apply your dose.

**What are the possible side effects of GELNIQUE?**

**GELNIQUE can cause serious side effects including:**

- Allergic reactions, including allergic skin reactions

**The most common side effects of GELNIQUE include:**

- dry mouth
- redness, rash, itching, pain at the application site
- dizziness
- headache
- constipation
- itching

- tiredness
- Other side effects that have been seen with drugs containing oxybutynin, like GELNIQUE, include: dizziness and blurred vision, drowsiness that may be increased with alcohol (beer, wine, or hard liquor), and decreased sweating that may lead to overheating.

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 GELNIQUE. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

#### **How should I store GELNIQUE?**

- Store GELNIQUE at 68°F to 77°F (20°C to 25°C).
- Safely throw away GELNIQUE in household trash. Be careful to prevent accidental exposure to children or pets.
- Keep GELNIQUE sachets in a dry place.

**Keep GELNIQUE and all medicines out of the reach of children.**

#### **General information about GELNIQUE**

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet. Do not use GELNIQUE for a condition for which it was not prescribed. Do not give GELNIQUE 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 GELNIQUE. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about GELNIQUE that is written for health professionals.

For more information about GELNIQUE call 1-800-272-5525 or go to [www.GELNIQUE.com](http://www.GELNIQUE.com)

#### **What are the ingredients of GELNIQUE?**

**Active Ingredient:** oxybutynin chloride

**Inactive Ingredients:** alcohol, USP; glycerin, USP; hydroxypropyl cellulose, NF; sodium hydroxide, NF; and purified water, USP.

For all medical inquiries contact:

Actavis Pharma, Inc.  
Medical Communications  
Parsippany, NJ 07054  
800-272-5525

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Revised: July 2015

#### **PRINCIPAL DISPLAY PANEL**

Gelnique® (oxybutynin chloride) Gel, 10%  
Carton 30 Sachets  
NDC 52544-084-30



## GELNIQUE

oxybutynin chloride gel

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:52544-084
<b>Route of Administration</b>	TRANSDERMAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBUTYNIN CHLORIDE (UNII: L9F3D9RENQ) (OXYBUTYNIN - UNII:K9P6MC7092)	OXYBUTYNIN CHLORIDE	100 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52544-084-30	30 in 1 CARTON		
1		1 g in 1 PACKET; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022204	05/15/2009	

**Labeler** - Actavis Pharma, Inc. (119723554)

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Actavis Pharma, Inc.