HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ONEXTON Gel safely and effectively. See full prescribing information for ONEXTON Gel.

ONEXTON™ (clindamycin phosphate and benzoyl peroxide) Gel, 1.2%/3.75% for topical use
Initial U.S. Approval: 2000

----------INDICATIONS AND USAGE----------
ONEXTON Gel is a combination of clindamycin phosphate (a lincosamide antibacterial) and benzoyl peroxide indicated for the topical treatment of acne vulgaris in patients 12 years of age and older. (1)

----------DOSAGE AND ADMINISTRATION----------
- Apply a pea-sized amount of ONEXTON Gel to the face once daily. (2)
- Not for oral, ophthalmic, or intravaginal use. (2)

----------DOSAGE FORMS AND STRENGTHS----------
Gel, 1.2%/3.75%

Each gram of ONEXTON Gel contains 12 mg (1.2%) clindamycin phosphate, equivalent to 10 mg (1%) clindamycin, and 37.5 mg (3.75%) benzoyl peroxide. (3)

----------CONTRAINDICATIONS----------
ONEXTON Gel is contraindicated in:
- Patients who have demonstrated hypersensitivity (e.g., anaphylaxis) to clindamycin, benzoyl peroxide, any components of the formulation, or lincomycin. (4.1)
- Patients with a history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis. (4.2)

----------WARNINGS AND PRECAUTIONS----------
- Colitis: Clindamycin can cause severe colitis, which may result in death. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of clindamycin. ONEXTON Gel should be discontinued if significant diarrhea occurs. (5.1)
- Ultraviolet Light and Environmental Exposure: Minimize sun exposure following drug application. (5.2)

----------ADVERSE REACTIONS----------
- The most common adverse reactions are: burning sensation (0.4%); contact dermatitis (0.4%); pruritus (0.4%); and rash (0.4%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Valeant Pharmaceuticals North America LLC at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------
- ONEXTON Gel should not be used in combination with erythromycin-containing products because of its clindamycin component. (7.1)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 11/2014

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

ONEXTON™ (clindamycin phosphate and benzoyl peroxide) Gel, 1.2%/3.75% is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

2 DOSAGE AND ADMINISTRATION

Before applying ONEXTON Gel, wash the face gently with a mild soap, rinse with warm water, and pat the skin dry. Apply a pea-sized amount of ONEXTON Gel to the face once daily. Avoid the eyes, mouth, lips, mucous membranes, or areas of broken skin.

Use of ONEXTON Gel beyond 12 weeks has not been evaluated.

ONEXTON Gel is not for oral, ophthalmic, or intravaginal use.

3 DOSAGE FORMS AND STRENGTHS

Gel, 1.2%/3.75%

Each gram of ONEXTON Gel contains 12 mg (1.2%) clindamycin phosphate, equivalent to 10 mg (1%) clindamycin, and 37.5 mg (3.75%) benzoyl peroxide in a white to off-white, opaque, smooth gel.

4 CONTRAINDICATIONS

4.1 Hypersensitivity

ONEXTON Gel is contraindicated in those individuals who have shown hypersensitivity to clindamycin, benzoyl peroxide, any components of the formulation, or lincomycin. Anaphylaxis, as well as allergic reactions leading to hospitalization, has been reported in postmarketing use with ONEXTON Gel [see *Adverse Reactions (6.2)*].

4.2 Colitis/Enteritis

ONEXTON Gel is contraindicated in patients with a history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis [see *Warnings and Precautions (5.1)*].

5 WARNINGS AND PRECAUTIONS

5.1 Colitis

Systemic absorption of clindamycin has been demonstrated following topical use of clindamycin. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin. If significant diarrhea occurs, ONEXTON Gel should be discontinued.

Severe colitis has occurred following oral and parenteral administration of clindamycin with an onset of up to several weeks following cessation of therapy. Antiperistaltic agents such as opiates and diphenoxylate with atropine may prolong and/or worsen severe colitis. Severe colitis may result in death.

Studies indicate toxin(s) produced by Clostridia is one primary cause of antibiotic-associated colitis. The colitis is usually characterized by severe persistent diarrhea and severe abdominal cramps and may be associated with the passage of blood and mucus. Stool cultures for *Clostridium difficile* and stool assay for *C. difficile* toxin may be helpful diagnostically.

5.2 Ultraviolet Light and Environmental Exposure

Minimize sun exposure (including use of tanning beds or sun lamps) following drug application [see *Nonclinical Toxicology (13.1)*].

6 ADVERSE REACTIONS

The following adverse reaction is described in more detail in the *Warnings and Precautions* section of the label:

- Colitis [*See Warnings and Precautions (5.1)*].

6.1 Clinical Trials Experience

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

These adverse reactions occurred in less than 0.5% of subjects treated with ONEXTON Gel: burning sensation (0.4%); contact dermatitis (0.4%); pruritus (0.4%); and rash (0.4%).

During the clinical trial, subjects were assessed for local cutaneous signs and symptoms of erythema, scaling, itching, burning and stinging. Most local skin reactions either were the same as baseline or increased and peaked around week 4 and were near or improved

from baseline levels by week 12. The percentage of subjects that had symptoms present before treatment (at baseline), during treatment, and the percent with symptoms present at week 12 are shown in Table 1.

Table 1: Local Skin Reactions - Percent of Subjects with Symptoms Present. Results from the Phase 3 Trial of ONEXTON Gel 1.2%/3.75% (N = 243)

	Before Treatment (Baseline)			During Treatment			End of Treatment (Week 12)		
	Mild	**Mod.***	**Severe**	**Mild**	**Mod.***	**Severe**	**Mild**	**Mod.***	**Severe**
Erythema	20	6	0	28	5	<1	15	2	0
Scaling	10	1	0	19	3	0	10	<1	0
Itching	14	3	<1	15	3	0	7	2	0
Burning	5	<1	<1	7	1	<1	3	<1	0
Stinging	5	<1	0	7	0	<1	3	0	<1

*Mod. = Moderate

6.2 Postmarketing Experience

Because postmarketing adverse 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.

Anaphylaxis, as well as allergic reactions leading to hospitalizations, has been reported in postmarketing use of products containing clindamycin phosphate/benzoyl peroxide.

7 DRUG INTERACTIONS

7.1 Erythromycin

Avoid using ONEXTON Gel in combination with topical or oral erythromycin-containing products due to its clindamycin component. *In vitro* studies have shown antagonism between erythromycin and clindamycin. The clinical significance of this *in vitro* antagonism is not known.

7.2 Concomitant Topical Medications

Concomitant topical acne therapy should be used with caution since a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating, or abrasive agents. If irritancy or dermatitis occurs, reduce frequency of application or temporarily interrupt treatment and resume once the irritation subsides. Treatment should be discontinued if the irritation persists.

7.3 Neuromuscular Blocking Agents

Clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. ONEXTON Gel should be used with caution in patients receiving such agents.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C.

There are no adequate and well-controlled studies in pregnant women treated with ONEXTON Gel. ONEXTON Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Animal reproductive/developmental toxicity studies have not been conducted with ONEXTON Gel or benzoyl peroxide. Developmental toxicity studies of clindamycin performed in rats and mice using oral doses of up to 600 mg/kg/day (240 and 120 times amount of clindamycin in the highest recommended adult human dose based on mg/m^2, respectively) or subcutaneous doses of up to 200 mg/kg/day (80 and 40 times the amount of clindamycin in the highest recommended adult human dose based on mg/m^2, respectively) revealed no evidence of teratogenicity.

8.3 Nursing Mothers

It is not known whether clindamycin is excreted in human milk after topical application of ONEXTON Gel. However, orally and parenterally administered clindamycin has been reported to appear in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to use ONEXTON Gel while nursing, taking into account the importance of the drug to the mother.

8.4 Pediatric Use

Safety and effectiveness of ONEXTON Gel in pediatric patients under the age of 12 years have not been evaluated.

8.5 Geriatric Use

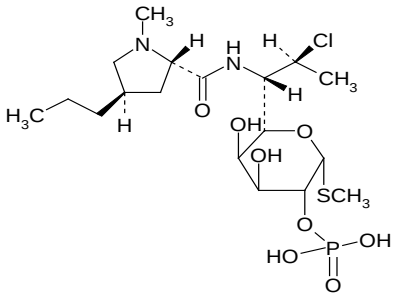
Clinical trials of ONEXTON Gel did not include sufficient numbers of subjects age 65 years and older to determine whether they respond differently from younger subjects.

11 DESCRIPTION

ONEXTON Gel is a combination product with two active ingredients in a white to off-white, opaque, smooth, aqueous gel formulation intended for topical use. Clindamycin phosphate is a water-soluble ester of the semi-synthetic antibiotic produced by a 7(S)-chloro-substitution of the 7(R)-hydroxyl group of the parent antibiotic lincomycin.

The chemical name for clindamycin phosphate is *Methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-trans-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-threo-α-D-galacto-octopyranoside 2*-(dihydrogen phosphate). The structural formula for clindamycin phosphate is represented below:

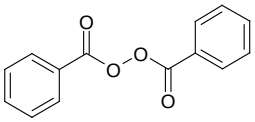
Clindamycin phosphate:



Molecular Formula: $C_{18}H_{34}ClN_2O_8PS$ Molecular Weight: 504.97

Benzoyl peroxide is an antibacterial and keratolytic agent. The structural formula for benzoyl peroxide is represented below:

Benzoyl peroxide:



Molecular Formula: $C_{14}H_{10}O_4$ Molecular Weight: 242.23

ONEXTON Gel contains the following inactive ingredients: carbomer 980, potassium hydroxide, propylene glycol, and purified water. Each gram of ONEXTON Gel contains 12 mg (1.2%) clindamycin phosphate, equivalent to 10 mg (1%) clindamycin, and 37.5 mg (3.75%) benzoyl peroxide.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Clindamycin: Clindamycin is a lincosamide antibacterial [see *Clinical Pharmacology (12.4)*].

Benzoyl Peroxide: Benzoyl peroxide is an oxidizing agent with bactericidal and keratolytic effects, but the precise mechanism of action is unknown.

12.3 Pharmacokinetics

The systemic absorption of ONEXTON Gel has not been evaluated. The systemic absorption of clindamycin was investigated in an open-label, multiple-dose trial in 16 adult subjects with moderate to severe acne vulgaris treated with 1 gram of a marketed gel containing clindamycin 1%/benzoyl peroxide 2.5% applied to the face once daily for 30 days. This product has the same formulation as ONEXTON Gel but with a lower concentration of benzoyl peroxide. Twelve subjects (75%) had at least one quantifiable clindamycin plasma concentration above the lower limit of quantification (LOQ = 0.5 ng/mL) on Day 1 or Day 30. On Day 1, the mean (± standard deviation) peak plasma concentrations (C_{max}) was 0.78 ± 0.22 ng/mL (n=9 with measurable concentrations), and the

mean AUC_{0-t} was 5.29 ± 0.81 h.ng/mL (n=4). On Day 30, the mean C_{max} was 1.22 ± 0.88 ng/mL (n=10), and the mean AUC_{0-t} was 8.42 ± 6.01 h.ng/mL (n=6). Clindamycin plasma concentrations were below LOQ in all subjects at 24 hours post-dose on the three tested days (Day 1, 15, and 30).

Benzoyl peroxide has been shown to be absorbed by the skin where it is converted to benzoic acid.

12.4 Microbiology

Clindamycin binds to the 50S ribosomal subunits of susceptible bacteria and prevents elongation of peptide chains by interfering with peptidyl transfer, thereby suppressing bacterial protein synthesis.

Clindamycin and benzoyl peroxide individually have been shown to have *in vitro* activity against *Propionibacterium acnes*, an organism which has been associated with acne vulgaris. In an *in vitro* study, the MIC for benzoyl peroxide against *Propionibacterium acnes* is 128 mg/L. The clinical significance of this activity against *P. acnes* is not known.

P. acnes resistance to clindamycin has been documented. Resistance to clindamycin is often associated with resistance to erythromycin.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity, mutagenicity and impairment of fertility testing of ONEXTON Gel have not been performed.

Benzoyl peroxide has been shown to be a tumor promoter and progression agent in a number of animal studies. Benzoyl peroxide in acetone at doses of 5 and 10 mg administered topically twice per week for 20 weeks induced skin tumors in transgenic Tg.AC mice. The clinical significance of this is unknown.

Carcinogenicity studies have been conducted with a gel formulation containing 1% clindamycin and 5% benzoyl peroxide. In a 2-year dermal carcinogenicity study in mice, treatment with the gel formulation at doses of 900, 2700, and 15000 mg/kg/day (1.8, 5.4, and 30 times amount of clindamycin and 2.4, 7.2, and 40 times amount of benzoyl peroxide in the highest recommended adult human dose of 2.5 g ONEXTON Gel based on mg/m^2, respectively) did not cause any increase in tumors. However, topical treatment with a different gel formulation containing 1% clindamycin and 5% benzoyl peroxide at doses of 100, 500, and 2000 mg/kg/day caused a dose-dependent increase in the incidence of keratoacanthoma at the treated skin site of male rats in a 2-year dermal carcinogenicity study in rats. In an oral (gavage) carcinogenicity study in rats, treatment with the gel formulation at doses of 300, 900 and 3000 mg/kg/day (1.2, 3.6, and 12 times amount of clindamycin and 1.6, 4.8, and 16 times amount of benzoyl peroxide in the highest recommended adult human dose of 2.5 g ONEXTON Gel based on mg/m^2, respectively) for up to 97 weeks did not cause any increase in tumors. In a 52-week dermal photocarcinogenicity study in hairless mice, (40 weeks of treatment followed by 12 weeks of observation), the median time to onset of skin tumor formation decreased and the number of tumors per mouse increased relative to controls following chronic concurrent topical administration of the higher concentration benzoyl peroxide formulation (5000 and 10000 mg/kg/day, 5 days/week) and exposure to ultraviolet radiation.

Clindamycin phosphate was not genotoxic in the human lymphocyte chromosome aberration assay. Benzoyl peroxide has been found to cause DNA strand breaks in a variety of mammalian cell types, to be mutagenic in *S. typhimurium* tests by some but not all investigators, and to cause sister chromatid exchanges in Chinese hamster ovary cells.

Fertility studies have not been performed with ONEXTON Gel or benzoyl peroxide, but fertility and mating ability have been studied with clindamycin. Fertility studies in rats treated orally with up to 300 mg/kg/day of clindamycin (approximately 120 times the amount of clindamycin in the highest recommended adult human dose of 2.5 g ONEXTON Gel, based on mg/m^2) revealed no effects on fertility or mating ability.

14 CLINICAL STUDIES

The safety and efficacy of once daily use of ONEXTON Gel was assessed in a 12-week multi-center, randomized, blinded trial in subjects 12 years and older with moderate to severe acne vulgaris. This trial evaluated ONEXTON Gel compared to vehicle gel.

The co-primary efficacy variables for this trial were:

(1) Mean absolute change from baseline at week 12 in

- Inflammatory lesion counts
- Non-inflammatory lesion counts

(2) Percent of subjects who had a two grade reduction from baseline on an Evaluator's Global Severity (EGS) score.

The EGS scoring scale used in the clinical trial for ONEXTON Gel is as follows:

Table 2: EGS Scoring Scale

Grade	Description
Clear	Normal, clear skin with no evidence of acne
Almost Clear	Rare non-inflammatory lesions present, with rare non-inflamed papules (papules must be resolving and may be hyperpigmented, though not pink-red)
Mild	Some non-inflammatory lesions are present, with few inflammatory lesions (papules/pustules only; no nodulocystic lesions)
Moderate	Non-inflammatory lesions predominate, with multiple inflammatory lesions evident: several to many comedones and papules/pustules, and there may or may not be one small nodulocystic lesion
Severe	Inflammatory lesions are more apparent, many comedones and papules/pustules, there may or may not be up to 2 nodulocystic lesions
Very Severe	Highly inflammatory lesions predominate, variable number of comedones, many papules/pustules and more than 2 nodulocystic lesions

The results of the trial at Week 12 are presented in Table 3:

Table 3: Results of Phase 3 Trial with ONEXTON Gel 1.2%/3.75% at Week 12

	ONEXTON Gel N = 253	**Vehicle Gel N = 245**
EGSS:		
Clear or Almost Clear	29%	15%
2-grade reduction from baseline	35%	17%
Inflammatory Lesions:		
Mean absolute reduction	16.3	8.2
Mean percent (%) reduction	60.4%	31.3%
Non-Inflammatory Lesions:		
Mean absolute reduction	19.2	9.6
Mean percent (%) reduction	51.8%	27.6%

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

ONEXTON Gel 1.2%/3.75% is a white to off-white smooth gel supplied as a 50 g pump (NDC 0187-3050-50)

16.2 Dispensing Instructions for the Pharmacist

- Dispense ONEXTON Gel with a 10 week expiration date.
- Specify “Store at room temperature up to 25°C (77°F). Do not freeze.”

16.3 Storage and Handling

- PHARMACIST: Prior to Dispensing: Store in a refrigerator, 2°C to 8°C (36°F to 46°F).
- PATIENT: Store at room temperature at or below 25°C (77°F).
- Protect from freezing.
- Store pump upright.

17 PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling (Patient Information).

- Patients who develop allergic reactions such as severe swelling or shortness of breath should discontinue use and contact their physician immediately.
- ONEXTON Gel may cause irritation such as erythema, scaling, itching, or burning, especially when used in combination with other topical acne therapies.
- Patients should limit excessive or prolonged exposure to sunlight. To minimize exposure to sunlight, a hat or other clothing should be worn. Sunscreen may also be used.
- ONEXTON Gel may bleach hair or colored fabric.

PATIENT INFORMATION
ONEXTON™ (ON-EX-TUN)
(clindamycin phosphate and benzoyl peroxide) Gel, 1.2% / 3.75%

Important information: For use on skin only (topical use). Do not get ONEXTON Gel in your mouth, eyes, vagina, on your lips, or on cuts or open wounds.

What is ONEXTON Gel?

ONEXTON Gel is a prescription medicine used on the skin (topical) to treat acne vulgaris in people 12 years of age and older. ONEXTON Gel contains clindamycin phosphate and benzoyl peroxide.

It is not known if ONEXTON Gel is safe and effective for use longer than 12 weeks.
It is not known if ONEXTON Gel is safe and effective in children under 12 years of age.

Who should not use ONEXTON Gel?

Do not use ONEXTON Gel if you have:

- had an allergic reaction to clindamycin, benzoyl peroxide, lincomycin or any of the ingredients in ONEXTON Gel. See the end of this leaflet for a complete list of ingredients in ONEXTON Gel.
- Crohn's disease or ulcerative colitis
- had inflammation of the colon (colitis), or severe diarrhea with past antibiotic use

What should I tell my doctor before using ONEXTON Gel?

Before using ONEXTON Gel, tell your doctor about all of your medical conditions, including if you:

- plan to have surgery with general anesthesia
- are pregnant or plan to become pregnant. It is not known if ONEXTON Gel will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ONEXTON Gel passes into your breast milk. ONEXTON Gel contains the medicine clindamycin. Clindamycin when taken by mouth or by injection has been reported to appear in breast milk. You and your doctor should decide if you will use ONEXTON Gel while breastfeeding.

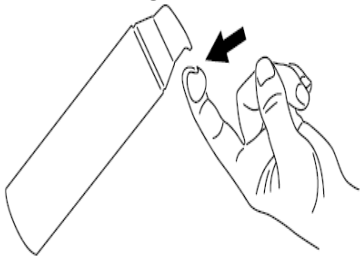
Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, herbal supplements, and skin products you use. Using other topical acne products may increase the irritation of your skin when used with ONEXTON Gel.

- Especially tell your doctor if you take a medicine that contains erythromycin. ONEXTON Gel should not be used with products that contain erythromycin.

How should I use ONEXTON Gel?

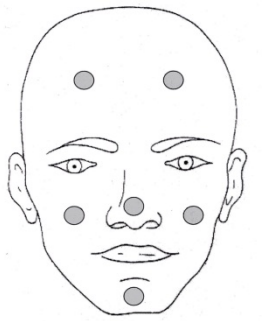
- Use ONEXTON Gel exactly as your doctor tells you to use it.
- Apply ONEXTON Gel to your face 1 time each day.
- Before you apply ONEXTON Gel, wash your face gently with a mild soap, rinse with warm water, and pat your skin dry.
- To apply ONEXTON Gel to your face, use the pump to dispense 1 pea-sized amount of ONEXTON Gel onto your fingertip (See Figure 1). One pea-sized amount of ONEXTON Gel should be enough to cover your entire face.

Figure 1



- Dot the 1 pea-sized amount of ONEXTON Gel onto six areas of your face (chin, left cheek, right cheek, nose, left forehead, right forehead). See Figure 2.

Figure 2



- After applying the ONEXTON Gel this way, spread the gel over your face and gently rub it in. It is important to spread the gel over your whole face.
- Wash your hands with soap and water after applying ONEXTON Gel.
- If your doctor tells you to put ONEXTON Gel on other areas of your skin with acne, be sure to ask how much you should use.
- Do not use more ONEXTON Gel than prescribed.

What should I avoid while using ONEXTON Gel?

- Limit your time in sunlight. Avoid using tanning beds or sun lamps. If you have to be in sunlight, wear a wide-brimmed hat or other protective clothing, and a sunscreen with SPF 15 rating or higher.
- Avoid getting ONEXTON Gel in your hair or on colored fabric. ONEXTON Gel may bleach hair or colored fabric.

What are possible side effects with ONEXTON Gel?

ONEXTON Gel may cause serious side effects, including:

- **Inflammation of the colon (colitis).** Stop using ONEXTON Gel and call your doctor right away if you have severe watery diarrhea, or bloody diarrhea.
- **Allergic reactions.** Stop using ONEXTON Gel, call your doctor and get help right away if you get severe itching, swelling of your face, eyes, lips tongue or throat, or trouble breathing.

The most common side effect with ONEXTON Gel is skin irritation. Stop using ONEXTON Gel and call your doctor if you have a skin rash or burning, or your skin becomes very red, itchy or swollen.

Talk to your doctor about any side effect that bothers you or that does not go away. These are not all the possible side effects with ONEXTON Gel.

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

You may also report side effects to Valeant Pharmaceuticals North America LLC at 1-800-321-4576.

How should I store ONEXTON Gel?

- Store ONEXTON Gel at room temperature at or below 77°F (25°C). Do not freeze.
- Store pump upright.
- Keep the container tightly closed.
- The expiration date of ONEXTON Gel is 10 weeks from the date you fill your prescription. Safely throw away expired ONEXTON Gel.

Keep ONEXTON Gel and all medicines out of the reach of children.

General information about the safe and effective use of ONEXTON Gel

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

What are the ingredients in ONEXTON Gel?

Active ingredients: clindamycin phosphate 1.2% and benzoyl peroxide 3.75%

Inactive ingredients: carbomer 980, potassium hydroxide, propylene glycol, and purified water

Manufactured for: Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA
By: Contract Pharmaceuticals Limited, Mississauga, Ontario, Canada L5N 6L6
U.S. Patents 5,733,886 and 8,288,434 For more information about ONEXTON Gel, call 1-800-321-4576.

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

9389300 Rev. 11/2014