ONEXTON Gel is a combination of clindamycin phosphate (a lincosamide antibiotic) and benzoyl peroxide, indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

6.1 Clinical Trials Experience

ONEXTON Gel was evaluated for safety and efficacy in 406 patients aged 12 years and older. These patients used ONEXTON Gel once daily for 12 weeks.

7.1 Erythromycin

Avoid using ONEXTON Gel in combination with erythromycin-containing products because of the possibility of clindamycin and erythromycin interacting.

8.1 Pregnancy

Clindamycin and benzoyl peroxide are considered to be Category C agents by the US Food and Drug Administration.

9.2 Information for Patients

In vitro studies have shown antagonism between erythromycin and clindamycin. The clinical significance of this antagonism is not known.

12.1 Mechanism of Action

12.2 Pharmacokinetics

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

ADVERSE REACTIONS

This highlights the information needed to use ONEXTON Gel safety and effectively. See full prescribing information for ONEXTON Gel.

7.3 Neuromuscular Blocking Agents

ONEXTON Gel should not be used in combination with erythromycin-containing products because of the possibility of clindamycin and erythromycin interacting.

5.1 Colitis

Clindamycin can cause severe colitis, which may result in death. Severe colitis has occurred following oral and parenteral administration of clindamycin. Severe colitis may result in death.

14.1 CLINICAL STUDIES

The skin reactions associated with ONEXTON Gel can be minimized by using ONEXTON Gel exactly as your doctor tells you to use it.

14.2 Other Nonclinical Toxicology

ONEXTON Gel is contraindicated in:

17.1 PEDIATRIC CONSELING INFORMATION

Each gram of ONEXTON Gel contains equal to 10 mg (1%) clindamycin phosphate, and 37.5 mg (3.75%) benzoyl peroxide. (3) A single pea-sized amount of ONEXTON Gel contains:

18.3 Animal Testing

ONEXTON Gel should not be used in combination with erythromycin-containing products because of the possibility of clindamycin and erythromycin interacting.

18.4 Human Testing

ONEXTON Gel is a combination of clindamycin phosphate (a lincosamide antibiotic) and benzoyl peroxide, indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

1. INDICATIONS AND USAGE

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

8.1 Pregnancy

ONEXTON Gel contains clindamycin phosphate (a lincosamide antibiotic) and benzoyl peroxide, any components of the formulation, or lincomycin. Anaphylaxis, as defined as anaphylactic or anaphylactoid reactions leading to hospitalization, has been reported in postmarketing use with ONEXTON Gel. See Alimentary Tract and Other infections (1.2).

8.5 Geriatric Use

ONEXTON Gel should be used with caution in patients over the age of 65 years. In clinical trials, patients 65 years of age and older showed a lower rate (1%) of severe colitis compared to younger age groups (2-20%).

13.2 Developmental and Reproductive Toxicology

Animal reproduction studies have not been conducted with ONEXTON Gel or benzoyl peroxide. Developmental toxicity studies of clindamycin performed in rats and mice using doses of up to 600 mg/kg/day (240 and 120 times the amount of clindamycin in the highest recommended adult human dose based on mg/m², respectively) or subcutaneous doses of up to 200 mg/kg/day (0.45 times the amount of clindamycin in the highest recommended adult human dose based on mg/m², respectively) revealed no evidence of teratogenicity.

18.5 Embryotoxicity

During Pregnancy (13.1) and Lactation (13.2), clindamycin is excreted in human milk. It is not known whether clindamycin is excreted in breast milk.

7.5 Interactions with Other Drugs

16.2 STOPPED STORAGE AND HANDLING

7.4 Drug Interactions

If irritancy or dermatitis occurs, reduce frequency of application. (5.2)

ONEXTON Gel should be discontinued if the irritation persists.

10.4 Other Nonclinical Toxicology

ONEXTON Gel is contraindicated in:

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

ONEXTON Gel is contraindicated in:

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application of ONEXTON Gel. However, orally administered clindamycin has been associated with severe diarrhea and pseudomembranous colitis because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the medication, taking into account the importance of the drug to the mother.

6.4 Pediatric Use

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

6.5 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. In general, dose selection in geriatric patients should be guided by the same principles that apply to younger subjects, but the lower renal function of the elderly, as reflected in the creatinine clearance, may require lower doses to avoid overexposure. 

The most common side effect of ONEXTON Gel is skin irritation. Stop using ONEXTON Gel and contact your doctor if 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 of ONEXTON Gel.

What should I avoid while using ONEXTON Gel?

Do not use ONEXTON Gel near your eyes or on other areas of your body that are irritated. Avoid getting ONEXTON Gel in your hair or on colored fabric.

What is the recommended dose of ONEXTON Gel for treatment of acne?

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 diarrhea, blood in your stool, or a change in your bowel habits.

Inflamed and non-inflammatory lesions:

- **Non-Inflammatory Lesions:**
  - 50% reduction from baseline
  - Less than or equal to 40% concentration

- **Inflammatory Lesions:**
  - 2-Grade reduction from baseline
  - More than 40% concentration

ONEXTON Gel contains the following inactive ingredients: carbomer 980, potassium hydroxide, propylene glycol, and purified water.

Molecular Formula: \( C_{40}H_{80}ClN \)

Molecular Weight: 504.97

Benzoyl peroxide is an anti-inflammatory and keratolytic agent. The structure/formula for benzoyl peroxide is represented below.

Benzoyl peroxide:

| Molecular Formula: \( C_{14}H_{20}O \)
| Molecular Weight: 242.23
| Benzoyl Peroxide: Benzoyl peroxide is an oxidizing agent with antioxidant and keratolytic effects, but the precise mechanism of action is unknown.

The safety and efficacy of once daily use of ONEXTON Gel was assessed in a 12-week multicenter randomized, blinded study in subjects 12 years and older with moderate to severe inflammatory acne vulgaris. ONEXTON Gel is for topical application.

The co-primary efficacy variables for this trial were:

1. Mean absolute reduction from baseline (described below) on Global Severity (EGS) score.
2. Percent of subjects who had a 2-grade reduction from baseline on an Evaluator's Global Severity (EGS) score.

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

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Clear</td>
<td>Normal, clear skin with no evidence of acne</td>
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<tr>
<td>Almost Clear</td>
<td>Rare non-inflammatory lesions present, with rare non-inflamed papules/pustules only, not more than 5 papules/pustules per lesion</td>
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The results of the Trial at Week 12 are presented in Table 3:

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The recommended dose for ONEXTON Gel is 1.25% in 1% benzoyl peroxide gel applied to affected areas 1-2 times per day.

What are the possible side effects of 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 diarrhea, blood in your stool, or a change in your bowel habits.

- 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.

- Non-Infammatory Lesions:
  - 50% reduction from baseline
  - Less than or equal to 40% concentration

- Inflammatory Lesions:
  - 2-Grade reduction from baseline
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