



## YOU HAVE QUESTIONS? **WE HAVE ANSWERS!**

Your physician has prescribed ONEXTON to help you fight acne so be sure to use it exactly as advised.

### **Q** WHAT IS ONEXTON?

**A** ONEXTON (clindamycin phosphate and benzoyl peroxide) Gel, 1.2%/3.75% is a prescription medicine used on the skin (topical) to treat acne in people 12 years and older. It is not known if ONEXTON is safe and effective for use longer than 12 weeks. It is not known if ONEXTON is safe and effective in children under 12 years of age.

### **Q** HOW LONG DO I NEED TO USE ONEXTON?

**A** In a clinical study, ONEXTON was used for a period of 12 weeks. Make sure you follow your dermatologist's instructions and use as long as directed. Acne treatment takes time to work, so it's important to keep applying as instructed.

### **Q** WHO SHOULD NOT USE ONEXTON?

**A** Do not use ONEXTON if you have

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

Talk to your doctor if you are not sure if you have one of these conditions.

### **Q** WHAT SHOULD I TELL MY DOCTOR BEFORE USING ONEXTON?

**A** Before using ONEXTON, 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 will harm your unborn baby
- are breastfeeding or plan to breastfeed. It is not known if ONEXTON passes into your breast milk. ONEXTON 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 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.

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

## **Q WHAT SHOULD I AVOID WHILE USING ONEXTON?**

**A** 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 an SPF 15 rating or higher. Avoid getting ONEXTON in your hair or on colored fabric. ONEXTON may bleach hair or colored fabric. Avoid getting ONEXTON in your mouth, eyes, vagina, on your lips, or on cuts or open wounds. ONEXTON should not be used with erythromycin-containing products because of its clindamycin component.

## **Q DOES ONEXTON CAUSE SIDE EFFECTS?**

**A** ONEXTON may cause serious side effects, including

- Inflammation of the colon (colitis). Stop using ONEXTON and call your doctor right away if you have severe watery diarrhea or bloody diarrhea.
- Allergic reactions. Stop using ONEXTON, 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 is skin irritation. Stop using ONEXTON 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.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088, or by visiting [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

You may also report side effects to Ortho Dermatologics at 1-800-321-4576.

## **Q WHY AM I STILL GETTING ACNE?**

**A** Some reasons may include a family history of acne, hormonal changes, stress, and certain makeup and hair care products.

## **Q WHAT ELSE CAN I DO TO HELP IMPROVE MY ACNE?**

**A** Remember to be kind to your skin and don't pop or squeeze your pimples. Try not to scrub your skin or use cleansing puffs, washcloths, or abrasive cleaners. Even though you may feel like this is "cleaning up" the issue, this may actually be irritating your skin and can lead to more breakouts.

## **Q HOW DOES ONEXTON WORK?**

**A** This FDA-approved prescription treatment fights acne. It is proven to treat acne breakouts, such as whiteheads, blackheads, and pimples.

## **Q HOW IS ONEXTON DIFFERENT?**

**A** ONEXTON is the first and only formulation of clindamycin 1.2% and benzoyl peroxide 3.75%.

## Q CAN I USE ONEXTON WITH MAKEUP?

A Yes. Before you apply ONEXTON, wash your face gently with a mild soap, rinse with warm water, and pat your skin dry. After ONEXTON is applied, you are free to use makeup. Non-pore-clogging (noncomedogenic) makeup is recommended.

## INDICATION

ONEXTON (clindamycin phosphate and benzoyl peroxide) Gel, 1.2%/3.75% is a prescription medicine used on the skin (topical) to treat acne vulgaris in people 12 years and older.

Do not get ONEXTON Gel in your mouth, eyes, or vagina, or on your lips. It is not known whether ONEXTON Gel is safe and effective for use longer than 12 weeks, or in children under 12 years of age.

## IMPORTANT SAFETY INFORMATION

**Do not use ONEXTON Gel if you have:** Crohn's disease, ulcerative colitis, had inflammation of the colon (colitis) or severe diarrhea with past antibiotic use. Talk with your doctor if you are not sure if you have one of these conditions.

### ONEXTON Gel can 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 have any of the following symptoms: severe itching; swelling of your face, eyes, lips, tongue or throat; or trouble breathing.

**Common side effects with ONEXTON Gel include skin irritation.** Stop using ONEXTON Gel and call your doctor if you have a skin rash 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.

**Tell your doctor about all the medicines and skin products you use.** Especially tell your doctor if you will have surgery with general anesthesia. One of the medicines in ONEXTON Gel (clindamycin) can affect how certain medicines work when used in general anesthesia.

- ONEXTON Gel should not be used with products that contain erythromycin.
- Other skin and topical acne products may increase the irritation of your skin when used with ONEXTON Gel.

**Pregnancy and Nursing Mothers:** It is not known whether ONEXTON Gel will harm your unborn baby or nursing infant, so talk to your doctor if you are pregnant. If you are nursing, you and your doctor should decide if you will use ONEXTON Gel while breastfeeding.

**Sun Protection:** When 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.

You are encouraged to report negative side effects of prescription drugs. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

Please [click here](#) for full Prescribing Information, including Patient Information.

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**ONEXTON**<sup>®</sup>  
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Gel, 1.2%/3.75%