

DERM PRACTICE

Incorporating Levulan[®]-PDT Into Practice

Tips on introducing this treatment to your patients and a review of its benefits for them and for your practice.



Also:

- Expert Advice
- Why Dermatologists Should Care about Compounding

The Newsletter For Dermatology Practices

Summer 2007

This newsletter is sponsored by DUSA Pharmaceuticals.

LETTER

DEAR FELLOW DERMATOLOGIST:

We are pleased to bring you this latest issue of *Derm Practice*, a quarterly newsletter for practicing dermatologists.

DUSA Pharmaceuticals brings you this newsletter to help you address some of the challenges you face in daily practice with articles that are timely and relevant to the clinical and practice management sides of your practice. As a fellow dermatologist, I know the challenges you face running the business end of a practice while continuing to treat patients with the best available treatments.

In this issue, don't miss the "Expert Advice" column. First, we answer a reader's question about how to build a research unit onto a clinical practice. Incorporating a research unit is not easy, but is possible. Read on for tips on making it work for your practice. Then, we look into the topic of fractional resurfacing and whether it really works. With many devices to choose from, it's important to know the advantages and disadvantages of the devices. This column answers questions of possible treatments, efficacy and downtime for various devices.

In this issue's cover story, I offer advice on incorporating Levulan® Kerastick™ (aminolevulinic acid HCl) and photodynamic therapy (Levulan-PDT) into your practice and its benefits to you and your patients. I review treatment strategies for acne and actinic keratoses and tips on introducing the treatment to patients. I also offer advice on what equipment you'll need and the best ways to schedule patients for treatment.

Also in this issue, I take another look at the topic of compounding and why we, as dermatologists, should care about this issue. While some companies promise monetary savings through the use of compounded products, sometimes the products aren't as efficacious and sometimes there are legal ramifications for using compounded products. It's important to do your homework and know when compounding is not a good idea.

I hope you find this issue of *Derm Practice* useful. Please e-mail stuleya@hmpcommunications.com with any comments or suggestions for the newsletter. We look forward to hearing from you.

Sincerely,
Michael H. Gold, M.D.

Q: How Can I Build A Research Unit Onto My Clinical Practice?

A: Other physicians often ask me how to incorporate a clinical research unit into a clinical practice. It is not an easy task but one that can be done if appropriately thought out.

I was introduced into dermatologic clinical research while I was in my residency. My chairman insisted that all of his residents get involved with faculty and be involved with research from the early days of our residency. I guess that is where and when I got hooked, and my involvement has expanded over the years to what we have now — the Tennessee Clinical Research Center with seven full-time nurse coordinators, a medical assistant, and an administrator who is in charge of the unit and the regulatory work that goes along with it.

At the Tennessee Clinical Research Center, we perform clinical research for the pharmaceutical industry, the device industry and for the cosmeceutical industry. All of our work is done under strict FDA guidelines so that if an audit is ever performed, we are all confident that all of our ducks are in a row.

When initiating a clinical research unit, start slow. Assigning a nurse to the role of nurse coordinator is usually a good first step. The next step is to find a clinical trial in which to participate. This can be accomplished through referrals from colleagues who already have relationships with companies or from your pharmaceutical representatives who can recommend your site for a clinical trial. You and your nurse coordinator must learn the trial-related lingo, especially where it relates to FDA forms and requirements from institutional review boards (IRBs). This will help you when dealing with the intermediaries of the clinical trials, the clinical research organizations (CROs) or the companies themselves if they do their own research trials. You will need to become familiar with good clinical practice (GCP), case report forms (CRFs), consent forms and other forms necessary for proper documentation of everything you do.

In terms of physical space, you will also need a secure area (locked) to store your binders and drugs utilized during the trials as well as a place to store the documents you accumulate,

EXPERT ADVICE

THIS ESTABLISHED PRACTITIONER AND CLINICAL AND PRACTICE MANAGEMENT EXPERT ANSWERS YOUR MOST PRESSING QUESTIONS.

EDITED BY MICHAEL H. GOLD, M.D., MEDICAL EDITOR



Before



After 1 treatment with the Sciton ProFractional.

because most trials require you to store documents for up to 15 years.

It sounds daunting, but it really isn't. It is getting the first trial under your belt, following the rules, documenting everything you do and signing everything you receive that will allow you to enter the trial market. If you do well on your first trial, others should follow. If you like to speak or publish, those opportunities will also be available, based on the trial and your relationships with the sponsors.

You and your coordinators will have the opportunity to become certified in clinical research by one of the two clinical research societies that exist in the United States, ACRP (American College of Research Professionals) or SoCRA (Society of Clinical Research Associates). All of my staff, including myself, are certified by one of these groups, reinforcing our commitment to clinical research.

Performing clinical research has opened up exciting new doors for my office and for me. We enjoy being part of the new research endeavors and look forward to the new frontiers of dermatology.

Q: Does Fractional Resurfacing Work?

A: Fractional resurfacing has become the latest buzzword in laser circles and at laser meetings. Having just returned from the European Academy of Dermatology, I am amazed to see how much this field has progressed over the past several years. There are near-infrared fractional devices, erbium laser fractionated systems, YSGG fractionated lasers (slightly shorter wavelengths than erbium), and CO₂ fractionated systems. They all seem to work and all have advantages/disadvantages you should be aware of when contemplating incorporating one of them into your clinical practice. All of these devices are being promoted for skin rejuvenation, the treatment of acne and other traumatic scars, for pigmentary concerns such as melasma, and for the treatment of scars themselves.

Near infrared fractionated devices go by names of Fraxel (1550 nm,

Reliant), Affirm (1440 nm, Cynosure) and Lux 1540 (1540 nm, Palomar). These devices work by creating areas of damage next to normal skin, all sparing epidermal injury. They work by promoting new collagen following the denaturation of the collagen destroyed by the laser treatment. All have shown good efficacy, usually requiring a series of four to six treatments, with downtime from 1 to 3 days.

The YSGG (Cutera Pearl, Palomar YSGG) and erbium laser fractionated devices (Alma Pixel, Sciton ProFractional) actually create holes in the skin, next to normal skin. The surrounding coagulation acts as a wound promoter to make the fractionated process work to its fullest. Most of these procedures work in one to two sessions, but sometime results in downtimes of anywhere from 3 to 5 days.

The CO₂ fractionated systems (Active FX, Lumenis), which are becoming more popular with many devices under investigation, usually require only one treatment but may have downtime from 5 to 7 days.

Clinicians will have to determine which one of these devices will work best in their clinical office settings to provide the maximum benefits for their patients. Remember, that as we are getting more aggressive with these kinds of lasers, the potential for adverse events exist, although reports suggest they are rare and not of any major significance at this time. ■

Dr. Gold is Medical Director of Gold Skin Care Center and Tennessee Clinical Research Center in Nashville, TN. He is also Clinical Assistant Professor in the Department of Medicine, Division of Dermatology at Vanderbilt University School of Medicine and School of Nursing in Nashville, TN.



INCORPORATING LEVULAN®-PDT INTO PRACTICE

TIPS ON INTRODUCING THIS TREATMENT TO YOUR PATIENTS AND A REVIEW OF ITS BENEFITS FOR THEM AND FOR YOUR PRACTICE.

BY MICHAEL H. GOLD, M.D.

I am often confronted with dermatologists who, for some reason or other, are hesitant to utilize aminolevulinic acid HCl (Levulan® Kerastick™) and photodynamic therapy (ALA-PDT) in their medical or surgical practices.

They ask questions about how to incorporate PDT into their practices and how to decide which patients are appropriate candidates for PDT treatment. These are not very difficult questions, but beyond the scope of this *Derm Practice* article to fully

answer. However, I will give some brief overviews of how we were able to incorporate PDT into our busy dermatology practice.

The FDA-approved indication for the use of ALA-PDT is for the treatment of non-hyperkeratotic actinic keratoses (AKs) of the face and scalp utilizing a drug incubation time of 14 to 18 hours and a blue light source for 16 minutes and 40 seconds. All other uses for ALA in the United State are considered off-label

at this time. Clinical research endeavors, all available from peer-reviewed medical journals, have shown that ALA-PDT utilizing a full-face, short-contact approach, of about an hour, and utilizing either blue light sources or other lasers/light sources that fall in the appropriate absorption spectrum will be useful in the utilization of ALA. In this country, clinical studies have demonstrated the usefulness of this approach in treating AKs, in treating

photorejuvenation, and in treating moderate to severe inflammatory acne vulgaris. These newer indications have become the standard of care in the United States for the uses of ALA-PDT, but are still considered off-label.

TREATING ACNE VULGARIS

I had been introduced to blue light for treating inflammatory acne vulgaris some 10 years ago. I have always found this to be a useful adjuvant to my medical therapy for my patients suffering from acne.

My patients routinely would come into the office one to two times per week for 4 or more weeks, and I found a high success rate with this approach to acne management, again when used with appropriate prescription oral and topical medicines.

By the time PDT came along, I had two blue light sources in my office. Patients would be taking acne medications and after a few weeks, if they were not responding quickly, blue light was offered and added to the treatment. If patients wanted to get better at the fastest rate I knew to be possible, blue light was started immediately.

The price per treatment was kept reasonable (there is no cure for acne), and our blue light acne machines were being utilized almost on a continuous basis. Also, it was simple for us to use — turn the timer on, monitor the time under the light and wait for the next patient to arrive — there is very little staff utilization and this allows me to keep seeing other patients while one is undergoing treatment.

AK TREATMENT

We purchased our third blue light source when PDT came along — this one was a different model — the one from the ALA company, which was even simpler to use than our other machines. Now we had to figure out how we were going to incorporate this into our practice to treat AKs, the approved FDA indication. Would this be hard and would our patients accept this form of treatment? Well, the answer was simple enough. Acne is the most common entity dermatologists see in practices, and this is no different in my practice. But after acne, AKs are the second most common thing I see, and with the aging population, the incidence of AKs appearing in our exam rooms should and will only increase.

I started utilizing PDT using the FDA-approved protocol — two office visits and a long time in the blue light source. Pain and photosensitivity were major problems with some of our early patients and required some intense nursing training and hand holding with

our patients. The PDT effect, downtime with healing of up to 1 week, was common, and some of our patients were not happy. However, when patients were healed, results were remarkable — 90% of the treated AKs responded and more than 90% of the patients noted an improvement in the cosmetic appearance of their skin, which is something we had not seen with any of the other AK treatments available for our patients.

The American Society for Photodynamic Therapy published treatment guidelines in January, 2006, which showed similar effica-

Patients would be taking acne medications and after a few weeks, if they were not responding quickly, blue light was offered and added to the treatment.

cies in treating AKs and photorejuvenation with short-contact, full-face treatments, and this has become the standard use in the United States at this time, though, again, this is off-label. The results, verified in numerous clinical trials, have become the way PDT is utilized in my practice. Acne therapies have yielded similar results in clinical trials and are being regularly used in my practice as well.

INTRODUCING ALA-PDT TREATMENT TO PATIENTS

When I see a patient present with numerous AKs I always inform him/her about PDT as a viable option for therapy. I explain how it works, what we do, and that we use the treatment in an off-label approach, but within the standards of clinical practice. I tell my patients what the clinical trials have demonstrated and that newer studies indicate that the time to formation of new AKs may be prolonged by the use of PDT. Many of my AK patients have opted for PDT treatments when we have explained how it works and what can be expected from the treatments.

The same works for my acne patients with moderate to severe inflammatory acne who want to experience what I consider the fastest acting of all the acne treatments available. With acne, I believe that PDT is best utilized as

an adjunct to medical therapy. INCORPORATING ALA-PDT INTO PRACTICE

Currently, we have three blue lights in our office, some for treating AKs and for performing photorejuvenation and others for treating acne. Our patients are scheduled to accommodate their busy lives as best as we can. We also have “walk-in appointments” for those patients I see in the clinic who opt for treatment on the same day. We decide on an appropriate drug incubation time and light source time and make sure that all of the patients are cared for in the best manner possible.

Incorporating PDT into my practice has been easy. We have many blue lights and other lasers/light sources that activate ALA. Most offices won't have the same luxury I have, but should not be deterred from utilizing and incorporating ALA-PDT into practice.

Clinical trials have documented PDT's efficacy, reimbursement rates for AKs are higher than ever (photorejuvenation and acne treatments are fee-for-service procedures), and patient satisfaction is extremely high.

The use of the blue light source is relatively simple — turning it on and making sure it turns off after the desired time in the light. It allows you, the clinician, to do other things while staff can monitor the patient and the blue light source. Of course, it is crucial to make sure the patient has specific written instructions on post-treatment care, especially sun avoidance for 24 to 48 hours, which will then prevent much of the potential for a photosensitivity reaction.

Pain during treatment is minimized by the use of short-contact ALA, and by the use of fans or other cooling devices during the treatments. This therapy is well tolerated and efficacious for your patients.

Medical practices should learn how easy PDT treatments can be incorporated — with very little effort. Cosmetic practices, too, can benefit. Our patients learn much about our cosmetic procedures during the ALA incubation time and throughout the entire process; and with the positive results they ultimately receive, many are converted into cosmetic patients.

Incorporate ALA-PDT into your practices — you and your patients will be glad you did.

Dr. Gold is Medical Director of Gold Skin Care Center and Tennessee Clinical Research Center in Nashville, TN. He is also Clinical Assistant Professor in the Department of Medicine, Division of Dermatology at Vanderbilt University School of Medicine and School of

WHY SHOULD A DERMATOLOGIST CARE ABOUT COMPOUNDING DRUGS?

KNOW THE LAW AND WHEN IT'S BEST TO USE BRANDED DRUGS.

BY MICHAEL H. GOLD, M.D.

As a specialty, dermatologists have been pioneers in the dispensing of generic equivalents to some of the most common medications of our times. It was not uncommon for a dermatologist to work in concert with his/her local pharmacy and adopt a referral-type of system where only the doctor's prescribed medication was available from that particular pharmacist.

When I first moved to Nashville, I often heard from patients who previously had been prescribed what came to be known as the "magic pink medicine". It didn't matter what kind of condition a patient had — there were pink medicines for facial dermatoses, pink medicines for trunk rashes and pink medicines for acne and other skin infections. After a while I came to assume that most of my early patients would always come to me for a pink medicine — some generic drug mixed with a red food dye additive to give it its characteristic pink color and unique doctor advantage.

A RESPONSIBLE DOCTOR

Don't get me wrong — I had many patients who were very happy with their pink medicines and some who were beyond dismay that their new dermatologist, laser trained and surgically inclined, did not routinely prescribe a pink medicine for all of their ills. I had to explain, on more than one occasion, that I believed some of our newer medicines were better, stronger and perhaps more useful than their old pink medicines.

I also believed, and still believe, that most of our branded medications were more efficacious than their older counterparts and that by writing a prescription for a branded drug, we would be supporting pharmaceutical companies and helping to support the specialty as a whole, including the many research endeavors that led to many of these new medications being available to our patients. These same pharmaceutical companies provide a strong educational basis for all dermatologists, and it was my responsibility to prescribe appropriate medicines.

Then came Levulan® Kerastick™ (aminolevulinic acid HCl) and photo-

dynamic therapy (Levulan-PDT) from DUSA Pharmaceuticals. I became a devoted user of Levulan-PDT. I was able to see first-hand the incredible results my patients experienced when utilizing the medicine for the treatment of actinic keratoses or for acne vulgaris. My patients were thrilled with their outcomes, and I had many patients who would come into the office requesting Levulan-PDT as a treatment option. My PDT practice took off quickly.

DO YOUR HOMEWORK: WHEN NOT TO COMPOUND

I was then confronted by a company who asked me if I wanted to save some money by using their compounded ALA instead of DUSA's Levulan when I was treating patients with PDT. I considered this option and thought it might be a good idea. It was a way to save some money and accomplish the task at hand — provide my patients with the finest dermatologic care available anywhere, a creed that we have had at our office since its inception some 18 years ago. So I began to look at the compounded ALA to see if there were any reasons not to use it.

I found a very good reason not to use compounded ALA. DUSA has a "use patent" on ALA. That is, they own the right to use ALA in PDT to treat acne, actinic keratoses and several other disorders. Any physician who uses ALA-PDT to treat patients for acne or actinic keratoses is violating DUSA's patent rights unless the physician gets a patent license from DUSA.

I thought that no pharmaceutical company had a right to tell me what to do — if I wanted to mix an ALA product and use it on my patients, I had that opportunity and right.

Then I began to do some more homework and found out a few more of the details regarding ALA. DUSA Pharmaceuticals purchased the license for ALA-PDT from the group of physicians/scientists at Queens University in Ontario, Canada, who had discovered how ALA could be used in PDT. DUSA and the Queens University researchers spent years developing this technology and eventually obtained FDA approval to sell

ALA made in DUSA's inspected and regulated manufacturing facility. They also obtained use patents, which give DUSA the exclusive right to use ALA-PDT to treat acne, actinic keratoses and other conditions. That means that although anyone legally has the right to make ALA, only DUSA has the right to use ALA-PDT on a patient with a disease process. That is the law. Most of us would not knowingly break the law.

FOLLOWING THE LAW

DUSA and Queens University have their use patents and we are obliged to use only the DUSA product in treating patients with ALA-PDT.

Does it really mean that we will be sued if we do not follow the law and treat patients using compounded ALA? That is a question I am unable to answer. Needless to say, it is an area from which I intend to stay far away. DUSA has sent warning letters to several dermatologists who have used compounded ALA and has filed several lawsuits against non-dermatologists who have continued to use compounded products, despite receiving letters from DUSA encouraging them not to do so. In each case, the use patent held by DUSA and Queens University has been upheld.

I also believe that the compounded products available really do not save me a great deal of money.

I am a true believer in supporting pharmaceutical companies that support the specialty of dermatology. DUSA has been there at every turn for us, from meetings to educational grants for grand rounds for our residents, to other CME programs, and by supporting the American Society for Photodynamic Therapy. DUSA has been a good partner for dermatology, and we should show our support by using only branded Levulan Kerastick. ■

Dr. Gold is Medical Director of Gold Skin Care Center and Tennessee Clinical Research Center in Nashville, TN. He is also Clinical Assistant Professor in the Department of Medicine, Division of Dermatology at Vanderbilt University School of Medicine and School of Nursing in Nashville, TN.

ClindaReach™

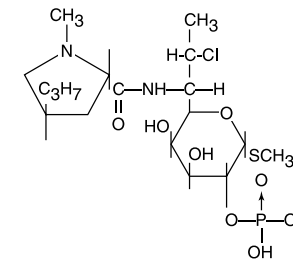
(Clindamycin Phosphate Topical Solution USP, 1%) Pledgets
For External Use Only

DESCRIPTION

ClindaReach™ (Clindamycin Phosphate Topical Solution USP, 1%), Pledgets (ClindaReach™) contain clindamycin phosphate, USP at a concentration equivalent to 10 mg clindamycin per milliliter. Each ClindaReach™ pledget applicator contains approximately 1 mL of topical solution.

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 solution contains isopropyl alcohol 50% v/v, propylene glycol, sodium hydroxide (to adjust the pH to between 4.0-7.0) and purified water. The structural formula is represented below:



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). It has a molecular weight of 504.96, and the molecular formula is C₁₈H₃₄ClN₂O₈PS. Flash point 75°F.

CLINICAL PHARMACOLOGY

Although clindamycin phosphate is inactive *in vitro*, rapid *in vivo* hydrolysis converts this compound to the antibacterially active clindamycin.

Cross resistance has been demonstrated between clindamycin and lincomycin.

Antagonism has been demonstrated between clindamycin and erythromycin.

Following multiple topical applications of clindamycin phosphate at a concentration equivalent to 10 mg clindamycin per mL in an isopropyl alcohol and water solution, very low levels of clindamycin are present in the serum (0-3 ng/mL) and less than 0.2% of the dose is recovered in urine as clindamycin.

Clindamycin activity has been demonstrated in comedones from acne patients. The mean concentration of antibiotic activity in extracted comedones after application of Clindamycin Phosphate Topical Solution for 4 weeks was 597 mcg/g of comedonal material (range 0-1490). Clindamycin *in vitro* inhibits all *Propionibacterium acnes* cultures tested (MICs 0.4 mcg/mL). Free fatty acids on the skin surface have been decreased from approximately 14% to 2% following application of clindamycin.

INDICATIONS AND USAGE

ClindaReach™ is indicated in the treatment of acne vulgaris. In view of the potential for diarrhea, bloody diarrhea and pseudomembranous colitis, the physician should consider whether other agents are more appropriate. (See CONTRAINDICATIONS, WARNINGS and ADVERSE REACTIONS.)

CONTRAINDICATIONS

ClindaReach™ is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin, a history of regional enteritis or ulcerative colitis, or a history of antibiotic-associated colitis.

WARNINGS

Orally and parenterally administered clindamycin has been associated with severe colitis which may result in patient death. Use of the topical formulation of clindamycin results in absorption of the antibiotic from the skin surface. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin.

Studies indicate a 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. Endoscopic examination may reveal pseudomembranous colitis. Stool culture for *Clostridium difficile* and stool assay for *C. difficile* toxin may be helpful diagnostically.

When significant diarrhea occurs, the drug should be discontinued. Large bowel endoscopy should be considered to establish a definitive diagnosis in cases of severe diarrhea.

Antiperistaltic agents such as opiates and diphenoxylate with atropine may prolong and/or worsen the condition. Vancomycin has been found to be effective in the treatment of antibiotic-associated pseudomembranous colitis produced by *Clostridium difficile*. The usual adult dosage is 500 milligrams to 2 grams of vancomycin orally per day in three to four divided doses administered for 7 to 10 days. Cholestyramine or colestipol resins bind vancomycin *in vitro*. If both a resin and vancomycin are to be administered concurrently, it may be advisable to separate the time of administration of each drug.

Diarrhea, colitis, and pseudomembranous colitis have been observed to begin up to several weeks following cessation of oral and parenteral therapy with clindamycin.

PRECAUTIONS

General

ClindaReach™ contains an alcohol base that will cause burning and irritation of the eye. In the event of accidental contact with sensitive surfaces (eye, abraded skin, mucous membranes), bathe with copious amounts of cool tap water. The solution has an unpleasant taste and caution should be exercised when applying medication around the mouth.

ClindaReach™ should be prescribed with caution in atopic individuals.

Drug Interactions

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

Pregnancy: Teratogenic Effects—Pregnancy Category B

Reproduction studies have been performed in rats and mice using subcutaneous and oral doses of clindamycin ranging from 100 to 600 mg/kg/day and have revealed no evidence of impaired fertility or harm to the fetus due to clindamycin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers

It is not known whether clindamycin is excreted in human milk following use of ClindaReach™. 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 discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in pediatric patients under the age of 12 have not been established.

ADVERSE REACTIONS

In 18 clinical studies of various formulations of topical Clindamycin Phosphate using placebo vehicle and/or active comparator drugs as controls, patients experienced a number of treatment emergent adverse dermatologic events [see table below].

Treatment Emergent Adverse Event	Number of Patients Reporting Events		
	Solution n=553 (%)	Gel n=148 (%)	Lotion n=160 (%)
Burning	62 (11)	15 (10)	17 (11)
Itching	36 (7)	15 (10)	17 (11)
Burning/Itching	60 (11)	# (—)	# (—)
Dryness	105 (19)	34 (23)	29 (18)
Erythema	86 (16)	10 (7)	22 (14)
Oiliness/Oily Skin	8 (1)	26 (18)	12* (10)
Peeling	61 (11)	# (—)	11 (7)

not recorded

* of 126 subjects

Orally and parenterally administered clindamycin has been associated with severe colitis which may end fatally.

Cases of diarrhea, bloody diarrhea and colitis (including pseudomembranous colitis) have been reported as adverse reactions in patients treated with oral and parenteral formulations of clindamycin and rarely with topical clindamycin (see WARNINGS).

Abdominal pain and gastrointestinal disturbances as well as gram-negative folliculitis have also been reported in association with the use of topical formulations of clindamycin.

OVERDOSAGE

Topically applied ClindaReach™ can be absorbed in sufficient amounts to produce systemic effects. (See WARNINGS.)

DOSAGE AND ADMINISTRATION

Apply a thin film of ClindaReach™ twice daily to affected area. More than one pledget may be used. Each pledget should be used only once and then be discarded.

Pledget: Remove pledget from jar just before use. Do not use if the seal under the cap is broken. Discard after single use.

Keep all liquid dosage forms in containers tightly closed.

HOW SUPPLIED

ClindaReach™ Pledgets contain Clindamycin Phosphate Topical Solution. The solution contains Clindamycin Phosphate equivalent to 10 mg clindamycin per milliliter.

ClindaReach™ is supplied as 120 single use pledgets, packaged as two jars of 60 single use pledgets each.

Store at controlled room temperature 15° to 30°C (59° to 86°F) [See USP]. Protect from freezing. Flash Point 75°F.

R only

Manufactured for: Sirius Laboratories,
a wholly owned subsidiary of DUSA Pharmaceuticals, Inc., 25 Upton Dr, Wilmington, MA 01887

DUSA®

Manufactured by:
PERRIGO, Bronx, NY 10457
Patent pending

MKT-1402 Rev A



Arm your patients with the integrated, easy-to-use ClindaReach™ system.

64 EasyCling™ Disposable Appliqués



64 EasyCleanse™ Unmedicated Pads



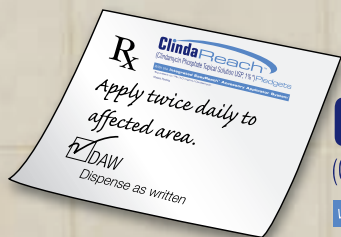
120 Clindamycin Medicated Pledgets



1 EasyReach™ Applicator Arm

A generous supply in one kit

- 120 medicated pledgets
- Month(s) of treatment for patient*



ClindaReach™
 (Clindamycin Phosphate Topical Solution USP, 1%*) Pledgets
 With the Integrated EasyReach™ Accessory Applicator System
*Equivalent to 1% (10 mg/mL) Clindamycin
 †Patent Pending

Results within reach.

Please see Full Prescribing Information on adjacent page.

*Dependent on the surface area treated, the number of daily applications, and prescribed regimen.

ClindaReach is indicated in the treatment of acne vulgaris. In view of the potential for diarrhea, bloody diarrhea, and pseudo-membranous colitis, the physician should consider whether other agents are more appropriate. ClindaReach is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin, or a history of regional enteritis.

ClindaReach™ is manufactured for Sirius Laboratories, Inc., a wholly owned subsidiary of DUSA Pharmaceuticals, Inc.®

DUSA
MKT-1452 REV A

FOUNTS, HANAUER, EUROSTAL, LTD. SUI.

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