**BRIEF SUMMARY OF PRESCRIBING INFORMATION**

**Claripel® Cream**
With Sunscreens
**(Hydroquinone USP, 4%)**

**FOR EXTERNAL USE ONLY** **Rx only**

**INDICATIONS AND USAGE:** Claripel Cream is indicated for the gradual treatment of ultraviolet induced dyschromia and discoloration resulting from the use of oral contraceptives, pregnancy, hormone replacement therapy, or skin trauma.

**CONTRAINDICATIONS:** Claripel Cream is contraindicated in any patient that has a prior history of hypersensitivity or allergic reaction to hydroquinone or any of the other ingredients. The safety of topical hydroquinone use during pregnancy or on children (12 years and under) has not been established.

**WARNINGS:**

A. CAUTION: Hydroquinone is a depigmenting agent which may produce unwanted cosmetic effects if not used as directed. The physician should be familiar with the contents of this insert before prescribing or dispensing this medication.

B. Test for skin sensitivity before using Claripel Cream by applying a small amount to an unbroken patch of skin and check within 24 hours. Minor redness is not a contraindication, but where there is itching, vesicle formation, or excessive inflammatory response further treatment is not advised. Close patient supervision is recommended. Contact with the eyes should be avoided. If no lightening effect is noted after two months of treatment,
use of Claripel Cream should be discontinued. Claripel Cream is formulated for use as a treatment for dyschromia and should not be used for the prevention of sunburn.

C. Sunscreen use is an essential aspect of hydroquinone therapy, because even minimal sunlight sustains melanocytic activity. The sunscreens in Claripel Cream provide the necessary sun protection during therapy. During and after the use of Claripel Cream, sun exposure should be limited or sun-protective clothing should be used to cover the treated areas to prevent repigmentation.

D. Keep this and all medications out of the reach of children. In case of accidental ingestion, contact a physician or a poison control center immediately.

E. WARNING: Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

F. On rare occasions, a gradual blue-black darkening of the skin may occur. In which case, use of Claripel Cream should be discontinued and a physician contacted immediately.

**PRECAUTIONS:** SEE WARNINGS

A. Pregnancy Category C: Animal reproduction studies have not been conducted with topical hydroquinone. It is also not known whether hydroquinone can cause fetal harm when used topically on a pregnant woman or can affect reproductive capacity. It is not known to what degree, if any, topical hydroquinone is absorbed systemically. Topical hydroquinone should be used in pregnant women only where clearly indicated.

B. Nursing mothers: It is not known whether topical hydroquinone is absorbed or excreted in human milk. Caution is advised when hydroquinone is used by a nursing mother.

C. Pediatric usage: Safety and effectiveness in pediatric patients below the age of 12 years have not been established.

**ADVERSE REACTIONS:** No systemic reactions have been reported. Occasional cutaneous hypersensitivity (localized contact dermatitis) may occur, in which case the medication should be discontinued and the physician notified immediately.

**OVERDOSAGE:** There have been no systemic reactions reported from the use of topical hydroquinone. However, treatment should be limited to relatively small areas of the body at one time, since some patients experience a transient skin reddening and a mild burning sensation which does not preclude treatment.

**HOW SUPPLIED:**

| Claripel Cream is available as follows: | Tube Size | NDC Number |
|---|---|---|
| | 28 gram | |
| 0145-2516-03 | | |
| | 45 gram | |
| 0145-2516-05 | | |

Claripel Cream should be stored at controlled room temperature: 15°-30° C (59°-86° F).

U.S. Patent No. 6,699,464
Patent Pending

Stiefel Laboratories, Inc.
Coral Gables, FL 33134

861380 Rev. 0904
CLP-09-2004-USA.

Claripel is a registered trademark.
Tyrostat is a trademark of Fytokem Products Inc.
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References:
[1]Data on file, Stiefel Laboratories, Inc.
[2,3]Data on file, August C. Stiefel Research Institute, Inc.

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## Under My Skin

# Mistakes Don't Correct Themselves

People like to quote George Santayana, who said that those who forget history are doomed to repeat it. Few realize he was referring to the treatment of cutaneous fungal infections.

OK, he wasn't *exactly* referring to ringworm, but he could have been.

In complex matters like politics and human relations, history is hard to learn from because no two situations are exactly the same.

BY ALAN ROCKOFF, M.D.

Scaly skin rashes, however, are not complicated at all. There are only a few possibilities, the most common of which are fungus and eczema. Two simple tests can distinguish them: a potassium hydroxide (KOH) prep and a culture. Even without testing, simple observation of clinical response should do the trick. A steroid cream makes a fungus worse and eczema better; an antifungal cream makes fungus better and does little or nothing for eczema.

Yet generations of nondermatologists continue to treat inflammatory rashes—nummular eczema, balanitis, submammary intertrigo, and so forth—with antifungal creams. My question is not how they can make that mistake; anyone can make a mistake. My question is why they keep making it. Why do so many experienced clinicians, decade after decade, never seem to get any better at making this straightforward, clear-cut distinction?

A close analysis is needed. The mechanism for perpetuating this simple mistake may shed light on the persistence of errors of greater consequence. I will map the intellectual progress of a doctor I'll call XY, to avoid gender bias. There are four steps:

**1. Childhood training.** Along with everyone else, XY learns early that skin diseases are connected with dirt. The germs presumed to cause rashes are dirty too, especially fungi. Tell Jane she has eczema and she protests, "But I shower every day!" Joey can't fathom why he breaks out—he washes so often. And of course everybody wears flip-flops in the locker room, since we all know what you catch there.

**2. (Non)education.** In medical school, XY learns nothing about managing ordinary skin problems. The occasional slide presentation may provide passing mastery of discoid lupus or acanthosis nigricans, conditions of interest to the presenter. XY departs medical school with the same assumptions about the rash-dirt nexus with which he or she entered.

**3. Pavlovian reinforcement.** When XY encounters skin problems during residency, the rash is always incidental to the patient's true problem: heart disease, cancer, and other illnesses of real importance. If the skin issue is noted at all, senior staff will instruct XY that it is probably fungal and treat accordingly. Should XY have the temerity to suggest otherwise and propose treatment with a topical steroid, faculty will exclaim, "Steroids weaken the immune system—you can't put them on an infection!" XY won't make *that* mistake again.

**4. Indifference.** Clinical practice will provide XY with few stimuli to unlearn default fungal assumption. When the disease at hand is actually fungal, antifungal creams make the patients better. More often, such creams are irrelevant except as emollients, but the patients don't call to complain. Perhaps the rash never bothered them that much, or the eczema remitted on its own. XY therefore never discovers the error. More severe rashes may generate a dermatologic consultation. The dermatologist's referral letter is read with little interest, if any. XY expects no collegial pats on the back for getting rashes right, fears no lawsuit or public ridicule at grand rounds for getting them wrong.

The mistake therefore does not correct itself, and life goes on.

Santayana notwithstanding, history lessons are hard to learn. When matters are complex, its lessons may be nuanced and ambiguous. What history teaches may be hard to understand or painful to accept.

Then again we may not learn because of simple indifference; we just aren't motivated to bother. Glory and shame are good motivators. Professional integrity and intellectual curiosity should work too, but the evidence suggests they often don't. XY is not interested in learning the distinction between fungus and eczema, XY's educators are not interested in teaching it, and XY's patients aren't bothered enough by the problem to bring the issue to a head.

We all make mistakes. Scaly skin rashes are just an example of the process by which we can go on making the same ones. It might be useful now and then to stop and investigate how many errors we make every day because we can't be bothered to find out that we made them. ■

Dr. Rockoff *practices dermatology in Brookline, Mass. To respond to this column, write Dr. Rockoff at our editorial offices or e-mail him at sknews@elsevier.com.*

## Letters

### Feds Shouldn't Have Health Care Role

Predictably, neither of the commentators in the health savings accounts debate made an effort to correctly diagnose the problem; they just want to treat symptoms, an approach that we physicians should know is not optimal ("Will health savings accounts leave people vulnerable to bankruptcy?" Pro & Con, July, 2005, p. 11).

Diagnose first, if possible; then prescribe.

The "symptom," obviously, is the high cost of medical care. Neither Dr. Steffie Woolhandler nor Greg Scandlen diagnosed the reason why medical costs are high. They just argued about how to help people pay them. One is left to assume that they think that high costs are inevitable, perhaps because of the technology involved, the length of time and costs incurred in medical training, etc.

In fact, medical costs are high for a completely different reason: government regulation and restriction of the supply of medical resources for the consumer. The combination of the Food and Drug Administration and state licensing provisions increases the cost of making medical resources available, and naturally the costs are passed on. They also act to restrict the supply of medical resources available, which increases costs through the law of supply and demand.

These government regulations tend to be self-perpetuating in a subtle, but pernicious manner. Once granted a partial monopoly on the legal ability to supply medical resources to consumers, both physicians and drug companies have an interest in maintaining that monopoly. We, therefore, will object when proponents of limited government propose to do away with the FDA or medical practice acts.

The government should have no role in the provision, licensing, regulation, restriction, or any other aspect of medical care, save quarantine in the case of communicable diseases that threaten public safety.

One citizen should be free to pay another citizen for any medical advice or procedure that the latter agrees to perform for the former. Any citizen should be free to purchase any medication from any citizen who wants to sell it. It is inappropriate, and immoral, for the government to involve itself in these matters. What makes anyone think that the government is competent to tell citizens who is a good physician and which medicines are safe and effective to use? It certainly wasn't what the founders of this nation thought that government was designed to do.

Many people would view the abolition of such regulations with horror, but it is by no means clear what would happen if such regulations were abolished. For more than half of this country's history, there was no federal involvement in medical care and little state involvement.

It is likely that, were all these regulations abolished, medical care would be so plentiful and cheap that there would be far fewer underserved people than there are now.

*Jeremy Klein, M.D.*
*Louisa, Ky.*

### Letters

Letters in response to articles in Skin & Allergy News and its supplements should include your name and address, affiliation, and conflicts of interest in regard to the topic discussed. Letters may be edited for space and clarity.

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