

nullo

Internal Deodorant Tablets



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*Clinical Studies Report
Consistent Results in
Control of Odors Due to:*

- Incontinence
- Colostomy
- Ileostomy

A Product Review for Healthcare Professionals
from DeWitt USA Professional Services



INTRODUCTION

DeWitt USA Professional Services has prepared these resource materials on the control of odor by chlorophyllin copper complex for healthcare professionals.

Chlorophyllin copper complex, the main ingredient in Nullo® internal deodorant tablets, has been used effectively for over forty years. In May, 1990, the Food and Drug Administration issued final regulations recognizing that chlorophyllin copper complex is both safe and effective in reducing fecal odors related to incontinence and for odor associated with colostomies and ileostomies. This is especially good news for the growing elderly segment of our population for whom body odors from these causes are a source of serious complaint.

For those taking a variety of medications, it is encouraging that no instances of toxicity or drug interaction have been reported when Nullo® internal deodorant tablets are used.

It is our hope that this pamphlet will provide useful information to healthcare professionals and promote more dialogue among healthcare providers and those patients suffering from body odors due to incontinence and ostomies.

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OVERVIEW

Since 1947, the odor reducing capabilities of water-soluble chlorophyll preparations have been under scientific study. It was discovered early that such preparations reduce odors during wound healing. Later, it was shown that a daily dosage of 100 to 200 mg. of chlorophyllin copper complex helps control fecal odors related to incontinence.

This ingredient was among over-the-counter (OTC) items included in a comprehensive drug products evaluation program launched by The Food and Drug Administration (FDA) in 1972. The purpose was to assure the public that OTC drugs are safe and effective for their intended purposes and that they are accurately and clearly labeled.

In May of 1990, following consideration of a report from an advisory review panel, the FDA issued a final regulation recognizing the safety and efficacy of chlorophyllin copper complex taken orally for the reduction of odors relating to fecal incontinence, colostomy and ileostomy.



KEY FACTS

ABOUT NULLO INTERNAL DEODORANT TABLETS

(A Product of DeWitt USA Consumer Products)

DOSAGE FORM

Each Nullo deodorant tablet contains 100 mg. of chlorophyllin copper complex. Nullo tablets are formulated to offer users the unique advantage of flexibility in controlling dosage amounts according to individual requirements.

INDICATIONS

For use in controlling body odor due to:

- Incontinence
- Colostomy
- Ileostomy

RECOMMENDED DOSAGE

Adults twelve years of age and older: swallow one or two tablets three times a day, depending upon severity of odor, until odor is eliminated (from two to ten days). Then take one tablet three times a day as needed to control odor. For children under twelve years of age, consult a physician.

POUCH CARE

Ostomates should place one or two tablets in empty pouch each time it is changed or reused for freshness and odor elimination.

DRUG INTERACTION

No drug interaction has ever been reported. The ingredient has been ruled safe and effective when taken for established uses.

TOXICITY

Chlorophyllin copper complex has not demonstrated toxicity in more than four decades of marketing experience. The FDA specifically exempts OTC oral deodorant drug products containing chlorophyllin copper complex from a toxicity warning on the label.

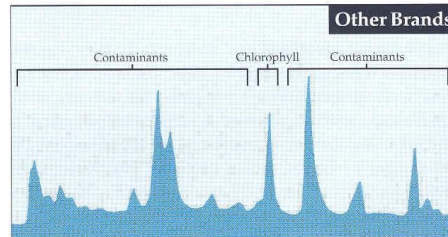
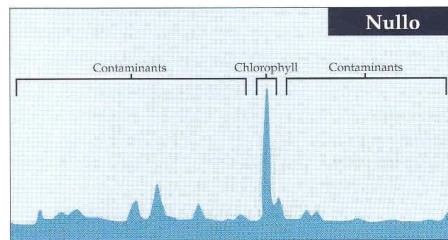
SIDE EFFECTS

Few side effects have been reported even with divided oral doses up to 300mg. daily for varying durations, each exceeding one week. Temporary mild diarrhea has occurred with some humans. There also is the expected green coloration of the stool. One case of abdominal cramps and one of excessive gas were reported.

PURITY

Only Nullo can deliver the purest dosage of chlorophyllin copper complex to the user. Nullo's process of obtaining the purest form of chlorophyll with fewer contaminants than the competition distinguishes Nullo as the best product available.

See below:



HPLC profile of Chlorophyllin Copper Complex obtained from various industrial sources. 1, 4 and 7- unidentified prophyrin-like compounds; 2- chlorine6; 3-Cu chlorine6; 5-isochlorin e4; 6-Cu isochlorin e4; 8- pheophorbide a; 9-Cu pheophorbide a. The monitoring was done with A 405 (from our studies).

CLINICAL STUDIES SUMMARIZED

The FDA Advisory Review Panel reviewed a number of studies during deliberations regarding effectiveness of chlorophyllin copper complex in the control of body odors due to incontinence and ostomy.

INCONTINENCE

Three major studies dealing with the control of body odors resulting from incontinence concluded that chlorophyllin copper complex produced significant reductions in such odors in a relatively brief period of time.

1. For six months, Young and Beregi⁽¹⁾ studied the effectiveness of chlorophyllin copper complex among 62 female patients, aged 65 or older, in a large geriatric hospital. One subgroup of 32 incontinent patients had foul fecal odor. A second subgroup of 30 patients had problems with constipation, hypochondriac symptoms, and excessive flatus. Dosage was 100 mg. three times daily for the first seven days, and 100 mg. twice daily thereafter.

Results: Based on observers' daily evaluation, successful results were estimated to be at least 85% for control of body and fecal odor. No side effects were noted. Bacteriologic studies showed no antibacterial effect for chlorophyllin copper complex against culture of *Proteus vulgaris*, *Escherichia coli*, or *Staphylococcus aureus*. As with other mechanism studies, these findings indicate activity is at least partially due to interference with bacterial metabolism, without demonstrable antibacterial effect.

2. In a three-month trial with 170 incontinent, Morrison⁽²⁾ tested chlorophyllin copper complex among patients with varying degrees of odor problems. Patients took 100 mg. of the ingredient after breakfast daily with no other change in their care.

Results: In one week, attending personnel noted a marked reduction in odor. Soon, odors associated with incontinence disappeared and incontinent wards were nearly indistinguishable from others in terms of odor.

3. In a mental institution, Laitner⁽³⁾ used chlorophyllin copper complex with 60 patients in incontinent wards where previous odor control measures had failed. In one ward, 40 patients were given 100 mg. daily, and in a second ward, 20 patients were given 200 mg. daily.

Results: In both wards, pronounced reduction of odor occurred in a week. By the second week, customary odors had disappeared. Several patients with persistent halitosis of different origins also showed marked improvement. No side effects were noted. Equal improvement was noted in both wards, showing that the 100 mg. daily dosage was as effective as 200 mg.



Four significant studies demonstrated the effectiveness of chlorophyllin copper complex in controlling odors due to ostomy surgery.

1. Weingarten and Payson⁽⁴⁾ reported striking reduction in objectionable odor within 48 hours among eight hospitalized colostomy patients. They were given daily oral doses of 60-120 mg. in tablet form.

Results: The lower dosage gradually reduced and eliminated odor of colostomy discharge, while 120 mg. produced the most rapid and total effect.

2. Siegel⁽⁵⁾ evaluated a daily dosage of the ingredient with 15 ostomy patients (seven colostomies; eight ileostomies). Recommended initial dosage was 100 mg. twice daily, and patients were advised to adjust dosage at their discretion up to 400 mg. daily. Use was interrupted at intervals so that each patient could act as his own control in evaluating the degree of effectiveness in odor reduction.

Results: 14 of the 15 subjects rated odor control as "very good" or "excellent," noting return of odor when treatment was discontinued. Most reported complete control at 200 mg. daily. This study also indicated colostomy patients gained more complete control of odor than ileostomies. The author suggested that the more odorous colostomy served as a more critical contrast control than the ileostomy.

AVAILABILITY

Bottles containing 60 and 135 tablets of Nullo are available without a prescription at drugstores, pharmacies, medical supply houses through incontinence and ostomy mail order houses, or through DeWitt USA by calling 1-800-735-0666.

3. Over a two-year period, Golden and Burke⁽⁶⁾ used the ingredient with 50 patients, including those with chronic malodorous wounds and ulcerations and 25 with colostomy, ileostomy, and fecal fistula. Dosage varied from 100 mg. to 600 mg. daily in divided doses, continuing with observation from three month to one year. With ostomy patients, tablets were administered orally or placed in the ostomy bag.

Results: Consistently favorable results were shown across the treatment groups. Ostomy patients overall showed best results. While not a placebo controlled study, the authors did substitute placebo substances from time to time during which distressing odors reappeared with patient protests. No undesirable side effects were observed in this study.

4. Joseph⁽⁷⁾ reported a thirty-patient study to evaluate the effectiveness of chlorophyllin copper complex in reducing bedpan odors in hospitalized patients. Ten colostomy and 20 bedridden patients were included in the study. The starting dosage was 120 mg. daily in divided doses. It was gradually reduced to 60 mg. daily.

Results: Excellent results were reported for all patients. Offensive odors disappeared in approximately 48 hours.

PROBABLE MECHANISMS OF NULLO® ACTIVITY

Two important studies reviewed by the FDA panel addressed the mechanism of chlorophyllin copper complex activity in the G.I. tract. While the exact mechanism is still not fully understood, it seems that the ingredient causes a change in metabolism in hydrogen sulfide-producing bacteria, and a neutralization (complexing or adsorption) of hydrogen sulfide in bacterial cultures. This works to reduce or eliminate odors in bodily wastes.

1. Coren and Barnard® report the two likely complementary mechanisms noted above. They report that fecal odor is basically due to production of hydrogen sulfide and other sulfhydryl compounds by enteric organisms. In-vitro studies with four hydrogen sulfide producing gastrointestinal organisms demonstrated decrease or elimination of hydrogen sulfide production with chlorophyllin concentrations in the same order of magnitude present in the bowel after ingestion of normal doses of chlorophyllin. No apparent effects on bacterial growth or parameters other than hydrogen sulfide production were noted.

These studies also indicated adsorption or binding of hydrogen sulfide with chlorophyllin copper complex. This action eliminated noticeable odor in bacterial cultures where hydrogen sulfide production was detected by an indicator added to the culture medium. The intestinal tract offers a large surface area for such adsorptive activity.

Finally, it was noted that each affected organism resumed production of hydrogen sulfide after transfer to a chlorophyllin-free medium. This reversible action supports the belief that chlorophyllin causes a reversible change in bacterial metabolism, rather than an antibiotic or toxic effect.

2. In a study of the deodorant capacity of a large series of chlorophyll derivatives, Langley⁽⁹⁾ reported deodorization of hydrogen sulfide and mercaptans. In studies with dogs, he evaluated the effect on skatole, a strong smelling crystalline amine in feces. When the dogs were given chlorophyll derivatives orally, skatole concentration decreased significantly, which the author felt supported the dramatic clinical findings in colostomy patients.

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