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August 1999

Case Reports

2-deoxy-d-glucose PLO Gel for Treating Warts
Nat Jones, R.Ph.
Suffolk, VA

At a compounding seminar last year, I learned about a new ingredient and several new recipes for the topical treatment of warts. The main ingredient was 2-deoxy-d-glucose, and some of the recipes also included ibuprofen and/or cimetidine.

My eight-year-old son was the first patient treated. He had eight or nine warts on his hands, and acids and freezing by the dermatologist had been unsuccessful; the warts had simply grown back.

Upon my recommendation the dermatologist tried 2% 2-deoxy-d-glucose in pluronic lecithin organogel (PLO), applied three times a day; but after 30 days only minimal results had been achieved. The formulation was changed to include 2% ibuprofen and 10% cimetidine; and this time, after four weeks of application three times a day, all warts were gone, including a persistent 1-cm wart at the nail bed on the index finger that had been present for over four years.

The second case involved a teenage girl who had been diagnosed with lichen sclerosis and genital and perianal warts. Treatment was initiated with topical testosterone with triamcinolone cream, with poor results at 30 days. The physician then focused treatment on the warts, with topical imiquimod 5% cream. After only one application the patient was unable to continue therapy due to pain and extreme irritation.

Upon consultation I recommended topical 2% 2-deoxy-d-glucose in PLO, to be applied three times daily. This was unsuccessful for several weeks, and a laser procedure was performed to remove all lesions. At a postoperative visit 80 days later, it was noted that all symptoms had returned, with greater numbers of lesions than before. At this point the physician ordered interferon injections into each lesion.

While we were awaiting prior approval from the patient’s insurance company, I suggested the combination of 2% 2-deoxy-d-glucose/ibuprofen 2%/cimetidine 10% PLO, to be applied three times daily. After four weeks of therapy (the patient had returned to get the injections), virtually all lesions had healed. Impressed, the physician said that they were “amazed” at the immune response and plans are underway to collect data, hopefully for publication, as more patients are treated.

Obviously, more information needs to be obtained in addition to this small sample, to verify these results. But it is great to see dramatic results for these sometimes difficult and often painful-to-treat conditions, with a fast, side-effect- and surgery-free therapy.

Analgesic Speed Gel for Treating Foot Pain
Tom Marks, R.Ph.
Naperville, IL

A 47-year-old man presented to a podiatrist with severe pain in the bottom of his heel. The pain was associated with getting up in the morning and with running and was described by the patient as feeling like a knife was being stuck into his heel. A weekend athlete, who runs for exercise, the patient had had such severe pain for the past week that he had been unable to run at all.

The podiatrist treated the patient with hydrocortisone shots into the heel for about six months, which relieved the pain. However, the patient was not happy about the
results of the current study are less en-
couraging than those of previous studies
he attributes to more careful selection of
patients than earlier studies, with result-
ant elimination of those with obviously
psychogenic impotence, and possible dif-
f erences in drug preparation and/or dos-
age. Nevertheless, he agrees with the au-
thor's hypothesis that the small number of patients pre-
vent s valid statistical analysis.

References
1. Zorgnuew AO. Experience with buccal pheno-
lamine mesylate for impotence. Int J Impotence
2. Gwinup G. Oral phentolamine in nonspecific
erectile insufficiency. Ann Intern Med

Literature Summaries
Oral Phentolamine for Erectile Dysfunction

Additional (but statistically inconclu-
sive) evidence from a prospective, ran-
domized, double-blind, placebo-controlled
study in Germany last year suggests oral
phentolamine may be helpful in treating
erectile dysfunction.

Patients had a history of erectile dys-
function for less than three years; no sig-
nificant cardiovascular disease, diabetes or
neurological disease; tolerance to the
study medication and a stable relationship.
A comprehensive evaluation included
family history, physical examination,
bloodwork, sexual history (by a psychia-
trist), corpus cavernosum electromyogra-
phy, pharmacological testing using pros-
taglandin E1 and Doppler or color-coded
duplex sonography of the penile arteries.

After a single-blind, placebo phase dur-
ing which four patients were eliminated,
40 patients were randomized to receive ei-
ther placebo or 10, 20, 30, or 60 mg fast-
dissolving phentolamine tablets. Patients
were instructed to make eight attempts at
intercourse.

Blood levels of the study preparations
peaked in about 30 minutes and remained
high for about two hours. Phentolamine was
associated with more full erections than
placebo (three, five and four patients for
success rates of 20%, 30% and 36.7% for
placebo (three, five and four patients for
success rates of 20%, 30% and 36.7% for
placebo respectively, compared to two patients with pla-
cebo, for a 13.4% success rate).

Although the results of this study were
those of a 30-day, double-blind, placebo-
controlled trial in which 100 mg 5-hy-
droxy-4-triptophan given three times daily
was more effective than placebo. The sec-
tory study used the same dosage adminis-
tered over 90 days.

Patients were between 18 and 65 years
of age, had been diagnosed with primary
fibromyalgia on the basis of Yunnus’s cri-
teria, had at least seven typical and consis-
tent tender points and had at least two of
the following symptoms: diffuse muscu-
loskeletal aching, anxiety, poor sleep pat-
tterns, fatigue, irritability, tension, and
morning stiffness. Patients underwent clinical
evaluation at baseline and after 15, 30,
and 90 days of therapy. Assessments in-
cluded total number of tender points, in-
tensity of pain (measured on a ten-point
visual analogue scale), quality of sleep
(five-point analogue score), morning stiff-
ness, anxiety and fatigue (five-point ana-
logue score), and efficacy of treatment
from the perspective of both patients and
investigators.

Toxicity was assessed by means of a com-
plete blood count, urinalysis, chemical
blood survey and erythrocyte sedimenta-
tion rate. Patients were interviewed to as-
sess for adverse effects.

Statistical analysis included the Student’s-
t-test for intragroup differences, the Mann-
Whitney U test for unpaired data and the
Wilcoxon’s test for paired data.

A total of seven patients discontinued the
study due to various side effects (gastric
pain, lack of efficacy or reasons unrelated
to treatment. Increased myalgias were re-
ported by one patient, but they were mild and
transient. Treatment resulted in a sig-
nificant decrease from baseline in all clini-
ical variables studied (p<0.001). No fur-
ther improvement was seen after 60 days’
treatment. Both patients and investigators
rated overall patients’ condition as indi-
cating good clinical improvement in nearly
half the patients during 15 to 90 days of
treatment. In all, 15 (30%) patients re-
ported side effects, but no occurrence of
eosinophilia was noted.

Moldofsky and Caruso suggested that pri-
mary fibromyalgia syndrome may be caused
by insufficient circulating trypt-
ophan, which then results in inadequate
serotonin to maintain slow-wave sleep.
They cited the following: 5-hydroxy-
bound tryptophan in the plasma of primary
fibromyalgia patients was inversely pro-
tional to the severity of their symp-
toms.

The association of eosinophilia-myalgia
syndrome with consumption of 1-
tryptophan products has mediated the im-
pact of the positive results of two studies by
Puttini and Caruso; however, it remains
unclear whether the syndrome is caused
by tryptophan or by chemical constituents
involved in the manufacturing process.
The main source of l-tryptophan was identified as a single Japanese manufacturer.

References
1. Caruso I, Puttini PS, Cazzola M et al. Double-
blind study of 5-hydroxy-tryptophan versus pla-
cebo in the treatment of primary fibromyalgia
and musculoskeletal pain in non-articular rheu-
3. Belongia EA, Hedberg CW, Gleich GI et al. An
investigation of the cause of the eosinophilia-
myalgia syndrome associated with tryptophan use.

Prescriber Q & A

Jeffrey Gibbs & Anne Marie Murphy
Q: Some of my patients have been de-
ined reimbursement because com-
pounded medications don’t have NDC
numbers. What is an NDC number and
do compounded drugs need them?
A: The National Drug Code (NDC) sys-
tem was established in 1969 as a univer-
sal system for identifying prescription
drugs. But submission of information was
voluntary, and fell short of FDA’s needs.
So, in 1977, the National Prescription
and Cosmetic Act was amended to make NDC report-
ing mandatory for all commercial drugs.

The first step in obtaining the NDC num-
ber, which typically appears on all drug
labels, is to register at a commercial dis-
courting establishment. FDA requires that
the labeler code to identify the estab-
lishment. In addition, drug products
must be “listed” with FDA. When pro-
cucts are listed, FDA assigns the 10-
character NDC number. The first five
characters consist of two parts that
identify the drug and the package size,
respectively.

Retail pharmacies, including those that
compound drugs, are specifically exempt
from FDA registration and listing, pro-
vided that all products are sold “in the
regular course of [their] business . . . at retail,”
and meet other requirements. The phar-
macy then retransmit the NDC number,
a labeler code, the basis for the NDC num-
ber. Thus, compounded products typically
do not receive NDC numbers, and do not need to bear them.

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