

Bulk Drug Substance to be Used in Pharmacy Compounding

Docket No. 98N-0182

Bulk Drug Substance

Ingredient Name: Chlorodinitrobenzene; CDNB; Dinitrochlorobenzene; DNCB
Chemical Name: 1-Chloro-2,4-Dinitrobenzene CAS: 97-00-7
Chemical Grade or Strength: Minimum 98%
How Supplied: Loose powder and/or chunks
International Pharmacopeial Recognition: Martindale The Extra Pharmacopoeia p.1698
Bibliography: 1) MSDS attached
2) Medline search identified 856 articles since 1966. A bibliography of 175 articles appearing since 1990 is attached.

Compounded Product

Formulations: Topical liquid. DNCB dissolved in acetone.
Strength(s): Bulk stock solution compounded at 2 mg/0.1 mL.
Dilutions in acetone prepared at concentrations of:
100 µg/0.1 mL
50 µg/0.1 mL
25 µg/0.1 mL
12.5 µg/0.1 mL
6.25 µg/0.1 mL
Route of Administration: Topically on skin.
Past/Proposed Use: DNCB is used as a skin sensitizer to estimate immune system competency. See attached articles. No commercial product of DNCB exists.
Stability Data: None available
Additional Information: None
Nominated by: University of Texas M. D. Anderson Cancer Center
Division of Pharmacy (Box 90)
1515 Holcombe Blvd.
Houston, Texas 77030

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1998-3454B1-02-24-BDL11

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TITLE: UVA II exposure of human skin results in decreased immunization capacity, increased induction of tolerance and a unique pattern of epidermal antigen-presenting cell alteration.

AUTHOR: LeVee GJ; Oberhelman L; Anderson T; Koren H; Cooper KD
AUTHOR AFFILIATION: Department of Dermatology, University of Michigan, Ann Arbor, USA.

SOURCE: Photochem Photobiol 1997 Apr;65(4):622-9
NLM CIT. ID: 97269823

ABSTRACT: The risks incurred from increased exposure to UVA II (320-340 nm) (i.e. during sunscreen use and extended outdoor exposure, tanning parlors) are not well understood. Therefore, we explored the effects of UVA II on skin immune responses in humans. After a single local exposure (4 minimum erythemal dose [MED]) using a xenon arc lamp filtered with a narrow bandpass filter (335 +/- 5 nm full width at half maximum), individuals were contact-sensitized with dinitrochlorobenzene (DNCB) through a UVA II exposure site or through normal skin. UVA II induced a marked decrease in the magnitude of skin immune responses ($P < 0.0001$). The UVA II group had only 29% successful sensitizations, as compared to 83% in the control group. The percentage of individuals who remained tolerant to DNCB after two sensitizations was 23.6% for the UVA II-exposed group, as compared to 3.8% in the controls ($P = 0.006$). UVA II also uniquely altered the type of antigen-presenting cells present in the epidermis. Human leukocyte antigen (HLA)-DR+ cells in control epidermal cell suspensions (C-EC) comprised a single, homogeneous population of Langerhans cells (LC) with the phenotype: CD1ahi DRmid CD11b CD36 (1.5 +/- 0.3% of EC). UVA II irradiation reduced the number of such LC to 0.6 +/- 0.2% of EC. Although cells expressing the macrophage phenotype: CD1a- DRhi CD11b+ CD36+ were increased in UVA II skin, relative to C-EC, these comprised only 10.1 +/- 6.1% of the DR+ cells, which is less than that after UVB exposure. Also distinct from UVB, a third population was found in UVA II-EC, which exhibited a novel phenotype: CD1a+ DR+ CD36+ CD11b+; these comprised 11.1 +/- 6.9% of the DR+ UVA II-EC. In conclusion, despite the above differences in infiltrating DR+ cells, both UVB and UVA II reduce the skin's ability to support contact sensitization, induce active suppression (tolerance) and induce a reduction in LC.

MAIN MESH SUBJECTS: Adaptation, Physiological/*RADIATION EFFECTS
 Antigen-Presenting Cells/*RADIATION EFFECTS
 Epidermis/IMMUNOLOGY/PHYSIOLOGY/*RADIATION EFFECTS
 Skin/IMMUNOLOGY/PHYSIOLOGY/*RADIATION EFFECTS
 *Ultraviolet Rays

ADDITIONAL MESH SUBJECTS: Dinitrochlorobenzene/ADMINISTRATION & DOSAGE/PHARMACOLOGY
 Human
 HLA-DR Antigens/IMMUNOLOGY
 Immunization
 Skin Physiology

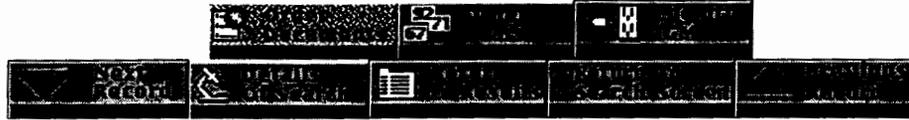
PUBLICATION MEETING REPORT

TYPES:

LANGUAGE: Eng

REGISTRY 0 (HLA-DR Antigens)

NUMBERS: 97-00-7 (Dinitrochlorobenzene)



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TITLE: The prognostic significance of delayed hypersensitivity to dinitrochlorobenzene and mechlorethamine hydrochloride in cutaneous T cell lymphoma.

AUTHOR: Vonderheid EC; Ekbote SK; Kerrigan K; Kalmanson JD; Van Scott EJ; Rook AH; Abrams JT

AUTHOR AFFILIATION: Department of Dermatology, Allegheny University of the Health Sciences, Philadelphia, Pennsylvania, USA.

SOURCE: J Invest Dermatol 1998 Jun;110(6):946-50

NLM CIT. ID: 98281613

ABSTRACT: Recent studies suggest that cells elaborating type 1 cytokines are important mediators of anti-tumor cell-mediated immunity in cutaneous T cell lymphoma. Type 1 cell-mediated immune responsiveness was assessed in 276 patients with cutaneous T cell lymphoma (mycosis fungoides and Sezary syndrome) using 2,4-dinitrochlorobenzene (DNCB) skin testing as part of the initial evaluation. The overall rate of sensitization after one and two DNCB challenges was 32% and 67%, respectively, which is much decreased compared with the expected rate of more than 95% for normal individuals. Moreover, the frequency of DNCB sensitization and allergic contact dermatitis to topically applied mechlorethamine decreased with advancing stage of disease. In addition to the expected strong correlation with stage, we observed that patients who were DNCB test positive were significantly less likely to experience disease progression and had a better overall prognosis compared with DNCB-negative patients. These results support the concept that cell-mediated responses are important in cutaneous T cell lymphoma, and that augmentation of these responses would be therapeutically beneficial.

MAIN MESH SUBJECTS: Dinitrochlorobenzene/ADMINISTRATION & DOSAGE/IMMUNOLOGY/*PHARMACOLOGY
 Drug Hypersensitivity/*DIAGNOSIS/ETIOLOGY/IMMUNOLOGY
 Hypersensitivity, Delayed/*CHEMICALLY INDUCED/IMMUNOLOGY
 Irritants/ADMINISTRATION & DOSAGE/*PHARMACOLOGY
 Lymphoma, T-Cell, Cutaneous/*DRUG THERAPY/IMMUNOLOGY
 Mechlorethamine/ADMINISTRATION & DOSAGE/IMMUNOLOGY/*THERAPEUTIC USE
 Skin Neoplasms/*DRUG THERAPY/IMMUNOLOGY

ADDITIONAL MESH SUBJECTS: Administration, Topical
 Adolescence
 Adult
 Aged
 Aged, 80 and over
 Disease Progression

Predictive Value of Tests
Prognosis
Severity of Illness Index
Skin/DRUG EFFECTS/IMMUNOLOGY
Skin Tests
Support, Non-U.S. Gov't
Survival Analysis

PUBLICATION JOURNAL ARTICLE

TYPES:

LANGUAGE: Eng

REGISTRY 0 (Irritants)

NUMBERS: 51-75-2 (Mechlorethamine)
97-00-7 (Dinitrochlorobenzene)



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TITLE: Topical immune modulation with dinitrochlorobenzene in HIV disease: a controlled trial from Brazil.

AUTHOR: Traub A; Margulis SB; Stricker RB

AUTHOR AFFILIATION: Sexually Transmitted Disease Unit, Irmandade da Santa Casa de Misericordia, Porto Alegre, Brazil.

SOURCE: Dermatology 1997;195(4):369-73

NLM CIT. ID: 98190377

ABSTRACT: **OBJECTIVE:** Despite the rapid spread of human immunodeficiency virus (HIV) in the developing countries of Africa, Asia and Latin America, accessible and affordable antiretroviral therapies have not been developed. Dinitrochlorobenzene (DNCB) is an inexpensive contact sensitizing agent that stimulates cell-mediated immunity when applied to the skin. We have examined the clinical and immunologic effects of topical DNCB therapy in a cohort of indigent patients with HIV disease from Brazil. **DESIGN AND METHODS:** Thirty-five HIV-infected subjects were divided into a control group that refused DNCB therapy (6 patients) and a treatment group that applied topical DNCB on a weekly basis throughout the study (29 patients). Subjects were monitored for adverse clinical events, progression to AIDS and changes in body weight. CD4 and CD8 T-cell counts were also monitored in both groups. **RESULTS:** Control and treated patients were evenly matched in terms of age, initial clinical status and prior adverse clinical events. The mean follow-up was 19.7 months for the control group and 17.8 months for the DNCB group. Control patients had significantly more adverse clinical events and progression to AIDS during the study than the treatment group ($p = 0.002$ and $p = 0.013$, respectively). There were no deaths in either group. Control patient weights decreased over the study period while DNCB patient weights increased ($p < 0.001$). CD4 and CD8 T-cell counts decreased significantly in the control group and increased in the DNCB group ($p < 0.001$ and $p = 0.031$, respectively). DNCB therapy was well tolerated. **CONCLUSIONS:** Topical DNCB therapy affords a rational, effective and inexpensive treatment approach for HIV disease. DNCB should benefit patients in developing nations with limited access to health care.

MAIN MESH SUBJECTS: Adjuvants, Immunologic/ADMINISTRATION & DOSAGE/ECONOMICS/*THERAPEUTIC USE
Dinitrochlorobenzene/ADMINISTRATION & DOSAGE/ECONOMICS/*THERAPEUTIC USE
HIV Infections/PHYSIOPATHOLOGY/*THERAPY
*Immunotherapy/ECONOMICS
Irritants/ADMINISTRATION & DOSAGE/ECONOMICS/*THERAPEUTIC USE

ADDITIONAL MESH SUBJECTS: Acquired Immunodeficiency Syndrome/PHYSIOPATHOLOGY
Administration, Cutaneous
Adult
Anti-HIV Agents/THERAPEUTIC USE
Body Weight

Brazil
Case-Control Studies
Cohort Studies
Costs and Cost Analysis
CD4 Lymphocyte Count
CD8-Positive T-Lymphocytes/PATHOLOGY
Developing Countries
Disease Progression
Drug Monitoring
Female
Follow-Up Studies
Health Services Accessibility
Human
Immunity, Cellular/DRUG EFFECTS
Lymphocyte Count
Male
Medical Indigency

PUBLICATION TYPES: **CLINICAL TRIAL**
CONTROLLED CLINICAL TRIAL
JOURNAL ARTICLE

LANGUAGE: **Eng**
REGISTRY **0 (Adjuvants, Immunologic)**
NUMBERS: **0 (Anti-HIV Agents)**
0 (Irritants)
97-00-7 (Dinitrochlorobenzene)



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TITLE: T-cell evaluation in patients with colon cancer: dinitrochlorobenzene skin testing versus plasma levels of sIL-2r and sCD8.

AUTHOR: Bleeker WA; de Ley L; Oeseburg HB; Martens A; Mulder NH; Hermans J; Plukker JT

AUTHOR AFFILIATION: Department of Surgery, University Hospital, Groningen, The Netherlands.

SOURCE: Ann Surg Oncol 1998 Apr-May;5(3):209-12

NLM CIT. ID: 98268635

ABSTRACT: **BACKGROUND:** Developing reliable methods to test the T-cell system may be important in the treatment of colon cancer patients with 5-fluorouracil/levamisole. In a pilot study we explored whether DNCB (dinitrochlorobenzene) skin testing correlated with plasma levels of soluble interleukin-2 receptor (sIL-2r) and soluble CD8 (sCD8) and, secondly, whether the application of DNCB had any influence on the production of sIL-2r and sCD8. **METHODS:** In 10 patients with advanced colon cancer and in 10 healthy volunteers, plasma levels of sIL-2r and sCD8 were measured before and 10 days after the application of 2 mg DNCB on the inner side of the forearm. **RESULTS:** As expected, colon cancer patients showed a depressed immune system compared to healthy volunteers (DNCB skin test: P = .005, sIL2r [medians 700 vs 295, P = .002], sCD8 [medians 158 vs 90, P = .03], M-W test). The plasma levels for sIL-2r and sCD8 were significantly lower in the skin-positive cases (P = .01 and P = .03, M-W test). However, a large overlap in plasma levels could be observed between the two skin categories. DNCB had no influence on the production of sIL-2r and sCD8; median change skin-negative and skin-positive -10 vs +25, P = .14, respectively; 48 vs 0, P = .32 (M-W test). **CONCLUSIONS:** DNCB skin testing and plasma levels of sIL-2r and sCD8 seem to be equally useful in evaluating the T-cell system and can be used simultaneously.

MAIN MESH SUBJECTS: Antigenes, CD8/*BLOOD
Colonic Neoplasms/*BLOOD/DRUG THERAPY/*IMMUNOLOGY/PATHOLOGY
Dinitrochlorobenzene/*DIAGNOSTIC USE
*Indicators and Reagents
Receptors, Interleukin-2/*BLOOD
Skin Tests/*METHODS
T-Lymphocytes/*IMMUNOLOGY

ADDITIONAL MESH SUBJECTS: Adjuvants, Immunologic/ADMINISTRATION & DOSAGE
Aged
Aged, 80 and over
Antineoplastic Agents, Combined/THERAPEUTIC USE

**Pilot Projects
Reproducibility of Results**

PUBLICATION JOURNAL ARTICLE

TYPES:

LANGUAGE: Eng

REGISTRY 0 (Adjuvants, Immunologic)

NUMBERS: 0 (Antigens, CD8)
0 (Antineoplastic Agents, Combined)
0 (Indicators and Reagents)
0 (Receptors, Interleukin-2)
14769-73-4 (Levamisole)
51-21-8 (Fluorouracil)
97-00-7 (Dinitrochlorobenzene)



DNCB

Human Toxicities:

Highly toxic in doses as little as 5 to 50 mg/kg.

It is a primary irritant and causes severe allergic dermatitis in almost everyone after repeated skin contact. Following systemic exposure, methemoglobinemia has been produced. In chronic poisoning, there is a gradual onset of symptoms of retrobulbar neuritis with blurring of vision, central scotoma and constriction of visual fields. Optic neuritis may gradually become evident that could lead to optic atrophy. Pupillary reactions are impaired. Peripheral neuritis manifest as paresthesias, and pain in the legs and burning of the feet may occur.

It is toxic by ingestion, inhalation and dermal absorption. It may cause dermatitis of both primary and allergic types. It is almost a universal sensitizer, causing contact dermatitis in from 60-80% of individuals having even minute contact with it. It is a severe eye and skin irritant.

Non-Human Toxicities:

-mutagenic in Salmonella (Ames' test) with and without metabolic activation. Positive for DNA damage in rat liver and morphologically transformed hamster kidney cells. In human skin fibroblasts, it has caused sister chromatid exchanges.

-it is flammable and can produce hydrogen gas if in contact with metal in an aqueous environment. Label has many cautionary statements.

Uses:

DNCB is used diagnostically in certain diseases. Used as an immunostimulant in leprosy, in HIV patients and some forms of cancer, and in the treatment of alopecia and warts.

REFERENCES

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