

A. INGREDIENT NAME:

HYDRAZINE SULFATE

B. Chemical Name:

Hydrazinium Sulfate, Hydrazonium Sulfate

C. Common Name:

D. Chemical grade or description of the strength, quality, and purity of the ingredient:

	<i>(Specifications)</i>	<i>(Results)</i>
Assay:	99.0% min.	99.3%

E. Information about how the ingredient is supplied:

White Crystalline Powder

F. Information about recognition of the substance in foreign pharmacopeias:

USP 23, Indian Pharmacopeia 3rd Ed.

G. Bibliography of available safety and efficacy data including peer reviewed medical literature:

Gold, J. Use of Hydrazine Sulfate in terminal and Preterminal Cancer patients: results of investigational new drug (IND) study in 84 valuable patients. *Oncology*. 1975; 32(1): 1-10

Chlebowski, R. T., Bulcavage, L., and Grosvenor, M. Hydrazine Sulfate in Cancer patients with weight loss. A placebo-controlled clinical experience. *Cancer*. 1987; 59(3): 406-410.

Bairam, A. Theophylline versus caffeine: comparative effects in treatment of idiopathic apnea in the preterm infant. *J. Pediatr*. 1987; 110:636.

1998-3454B1_02_29-BDL16

Eisenberg, M. G. and Kang, N. Stability of citrated caffeine solutions for injectable and external use. *Am. J. Hosp. Pharm.* 1984;41:2405.

H. Information about dosage forms used:

I. Information about strength:

60mg, 3 times/d

J. Information about route of administration:

Orally

K. Stability data:

Melts at about 254°

Oxidizing Agents

Bases

L. Formulations:

M. Miscellaneous Information:

National Library of Medicine: IGM Full Record Screen



Order Documents	Other Years	Log off IGM
Next Record	Details of Search	Return to Results
	Return to Search Screen	Previous Record



TITLE: Use of hydrazine sulfate in terminal and preterminal cancer patients: results of investigational new drug (IND) study in 84 evaluable patients.

AUTHOR: Gold J

SOURCE: Oncology 1975;32(1):1-10

NLM CIT. ID: 76101548

ABSTRACT: In a series of 84 various evaluable disseminated cancer patients treated with hydrazine sulfate as a result of a pharmaceutical-sponsored investigational new drug (IND) study, it was found that 59/84 or 70% of the cases improved subjectively and 14/84 or 17% improved objectively. Subjective responses included increased appetite with either weight gain or cessation of weight loss, increase in strength and improved performance status and decrease in pain. Objective responses included measurable tumor regression, disappearance of or decrease in neoplastic-associated disorders and long-term (over 1 year) 'stabilized condition'. Of the overall 59 subjective improvements 25 (42%) had no concurrent or prior (within 3 months) anticancer therapy of any type. Of the 14 objective improvements 7 (50%) had no concurrent or prior anticancer therapy. Of the remaining cases in which there was either concurrent or prior anticancer therapy, improvements occurred only after the addition of hydrazine sulfate to the treatment regimen. Duration of improvement was variable, from temporary to long-term and continuing. Side effects were mild, comprising for the most part low incidences of extremity paresthesias, nausea, pruritis and drowsiness; there was no indication of bone marrow depression.

MAIN MESH SUBJECTS: Hydrazines/ADVERSE EFFECTS/PHARMACOLOGY/*THERAPEUTIC USE
Neoplasms/*DRUG THERAPY/METABOLISM

ADDITIONAL MESH SUBJECTS: Drug Evaluation
Gluconeogenesis/DRUG EFFECTS
Human

**Paresthesia/CHEMICALLY INDUCED
Remission, Spontaneous
PUBLICATION JOURNAL ARTICLE
TYPES:
LANGUAGE: Eng**

	 Order Documents	 Other Years	 Log off IGM	
 Next Record	 Details of Search	 Return to Results	 Return to Search Screen	 Previous Record

National Library of Medicine: IGM Full Record Screen



TITLE: Hydrazine sulfate in cancer patients with weight loss. A placebo-controlled clinical experience.

AUTHOR: Chlebowski RT; Bulcavage L; Grosvenor M; Tsunokai R; Block JB; Heber D; Scrooc M; Chlebowski JS; Chi J; Oktay E; et al

SOURCE: Cancer 1987 Feb 1;59(3):406-10

NLM CIT. ID: 87077829

ABSTRACT: Hydrazine sulfate was evaluated using 24-hour dietary recalls and body weight determinations before and after 30 days of either placebo or hydrazine (60 mg, 3 times/d) oral administration in 101 heavily pretreated cancer patients with weight loss. After 1 month, 83% of hydrazine and only 53% of placebo patients completing repeat evaluation maintained or increased their weight (P less than 0.05). In addition, appetite improvement was more frequent in the hydrazine group (63% versus 25%, P less than 0.05). Although caloric intake was only slightly greater in hydrazine-treated patients, an increased caloric intake was more commonly associated with weight gain in patients receiving hydrazine compared with those receiving placebo (81% versus 53%, respectively). Hydrazine toxicity was mild, with 71% of patients reporting no toxic effects. Hydrazine sulfate circulatory levels were obtained from a subset of 14 patients who completed 30 days of treatment, with a single sample obtained in the morning at least 9 hours after the last dose. Mean maintenance hydrazine sulfate levels, determined using a spectrofluorometric assay, ranged from 0 to 89 ng/ml (mean 45 +/- 16 ng/ml). These data, which demonstrate an association between 1 month of hydrazine sulfate administration and body weight maintenance in patients with cancer, suggest future clinical trials of hydrazine sulfate are indicated to definitively assess its long-term impact on important clinical outcome parameters in defined cancer populations.

MAIN MESH SUBJECTS: Cachexia/*DRUG THERAPY/ETIOLOGY
Hydrazines/*THERAPEUTIC USE
Neoplasms/*COMPLICATIONS/DRUG THERAPY

HYDRAZINE

Human Toxicities:

Acute effects:

A safe level of hydrazine has been calculated as 0.2 mcg/kg . Cases of oral ingestion of 1 mouthful to a cupful resulted in vomiting, loss of consciousness, ataxia, inability to write if conscious, sporadic violence, elevated liver function tests, paresthesias and limb weakness.

Topical contact has produced eye, skin, and lung irritation, rhinitis, sensitization, facial edema and hydrazine is potentially corrosive.

Multiple systemic exposures have caused anorexia, emesis, thrombocytopenia, liver and kidney damage, hemolysis, methemoglobinemia, G.I. damage, CNS stimulation, convulsions and coma. It is well absorbed by all routes of exposure.

IARC considers hydrazine to be a Group 2B carcinogen thus as a **potential carcinogen to humans.**

Animal Toxicities:

When given orally to rats, mice and hamsters, it is carcinogenic and produces tumors in the lung and liver primarily and benign and malignant nasal tumors by inhalation (rat). It also produces myocarditis and hypotension (direct and indirect effect). It is a mutagen in the Ames' test, Drosophila, sister chromatid exchange and produces malignant transformation on Syrian hamster embryo (SHE) cells. No data appears available for reproductive toxicities. An IND was rescinded in 1991. The chemical was being tested for treating cachexia in cancer patients.

REFERENCES

1. Gold J. Use of hydrazine sulfate in terminal and preterminal cancer patients: results of investigational new drug (IND) study in 84 evaluable patients. *Oncology* 1975; 32(1):1-10.
2. Chlebowski RT, Bulcavage L, Grosvenor M, et al. Hydrazine sulfate in cancer patients with weight loss. A placebo-controlled clinical experience. *Cancer* 1987; 59(3):406-10.
3. Kaegi E. Unconventional therapies for cancer: 4. Hydrazine sulfate. Task Force on Alternative Therapies of the Canadian Breast Cancer Research Initiative. *CMAJ* 1998; 158(10):1327-30.
4. Gagnon B, Bruera E. A review of the drug treatment of cachexia associated with cancer. *Drugs* 1998; 55(5):675-88.
5. Kaegi E. Unconventional therapies for cancer: 1. Essiac. The Task Force on Alternative Therapies of the Canadian Breast Cancer Research Initiative. *CMAJ* 1998; 158(7):897-902.
6. Wheeler BM. Re: Biology of cachexia [letter; comment]. *J Natl Cancer Inst* 1998; 90(8):628.
7. Filov VA, Gershanovich ML, Danova, et al. Experience of the treatment with Sehydrin (Hydrazine Sulfate, HS) in the advanced cancer patients. *Invest New Drugs* 1995; 13(1):89-97.
8. Herndon JE 2nd, Fleishman S, Kosty MP, et al. A longitudinal study of quality of life in advanced non-small cell lung cancer: Cancer and Leukemia Group B (CALGB) 8931 [see comments]. *Control Clin Trials* 1997; 18(4):286-300.
9. Holzman D. Green tea, mistletoe, and more: Canadians test alternative cancer therapies [news]. *J Natl Cancer Inst* 1997; 89(10):683-4.
10. Chlebowski RT, Palomares MR, Lillington L, et al. Recent implications of weight loss in lung cancer management. *Nutrition* 1996; 12(1 Suppl):S43-7.
11. Loprinzi CL. Management of cancer anorexia/cachexia. *Support Care Cancer* 1995; 3(2):120-2.
12. Tayek JA, Sutter L, Manglik S, et al. Altered metabolism and mortality in patients with colon cancer receiving chemotherapy. *Am J Med Sci* 1995; 310(2):48-55.
13. Bergman B, Aaronson NK. Quality-of-Life and cost-effectiveness assessment in lung cancer [see comments]. *Curr Opin Oncol* 1995; 7(2):138-43.
14. Kosty MP, Herndon JE 2nd, Green MR, et al. Placebo-controlled randomized study of hydrazine sulfate in lung cancer [letter; comment]. *J Clin Oncol* 1995; 13(6):1529-30.
15. Vigano A, Watanabe S, Bruera E. Anorexia and cachexia in advanced cancer patients. *Cancer Surv* 1994; 21:99-115.
16. Jia F, Morrison DC, Silverstein R. hydrazine sulfate selectively modulates the TNF response to endotoxin in mouse macrophages. *Circ Shock* 1994; 42(2):111-4.
17. Loprinzi CL, Goldberg RM, Su JQ, et al. Placebo-controlled trial of hydrazine sulfate in patients with newly diagnosed non-small-cell lung cancer [see comments]. *J Clin Oncol* 1994; 12(6):1126-9.
18. Loprinzi CL, Kuross SA, O'Fallon JR, et al. Randomized placebo-controlled evaluation of hydrazine sulfate in patients with advanced colorectal cancer [see comments]. *J Clin Oncol* 1994; 12(6):1121-5.

19. Kosty MP, Fleishman SB, Herndon JE 2nd, et al. Cisplatin, vinblastine, and hydrazine sulfate in advanced, non-small-cell lung cancer: a randomized placebo-controlled, double-blind phase III study of the Cancer and Leukemia Group B [see comments]. *J Clin Oncol* 1994; 12(6):1113-20.
20. Herbert V. Three stakes in hydrazine sulfate's heart, but questionable cancer remedies, like vampires, always rise again [editorial; comment]. *J Clin Oncol* 1994; 12(6):1107-8.
21. Shilatifard A, Merkle RK, Helland DE, et al. Complex-type N-linked oligosaccharides of gp120 from human immunodeficiency virus type 1 contain sulfated N-acetylglucosamine. *J Virol* 1993; 67(2):943-52.
22. Bruera E. Is the pharmacological treatment of cancer cachexia possible? [see comments]. *Support Care Cancer* 1993; 1(6):298-304.
23. Pisters PW, Pearlstone DB. Protein and amino acid metabolism in cancer cachexia: investigative techniques and therapeutic interventions. *Crit Rev Clin Lab Sci* 1993; 30(3):223-72.
24. Tchekmedyian NS. Clinical approaches to nutritional support in cancer. *Curr Opin Oncol* 1993; 5(4):633-8.
25. Jenks S. Hydrazine sulfate ad is "offensive" [news]. *J Natl Cancer Inst* 1993; 85(7):528-9.
26. Tchekmedyian NS, Halpert C, Ashley J, et al. Nutrition in advanced cancer: anorexia as an outcome variable and target of therapy. *JPEN J Parenter Enteral Nutr* 1992; 16(6 Suppl):88S-92S.
27. Bruera E. Clinical management of anorexia and cachexia in patients with advanced cancer. *Oncology* 1992; 49 Suppl 2:35-42.
28. Gorter R. Management of anorexia-cachexia associated with cancer and HIV infection. *Oncology (Huntingt)* 1991;5(9 Suppl):13-7.
29. Loprinzi CL, Goldberg RM, Burnham NL. Cancer-associated anorexia and cachexia. Implications for drug therapy. *Drugs* 1992; 43(4):499-506.
30. Loprinzi CL, Goldberg RM, Burnham NL. Cancer-associated anorexia and cachexia. Implications for drug therapy. *New Ethics* 1992; 29(Sep):125-31.
31. Supportive care drug studies: some promising, some not [news]. *Oncology (Huntingt)* 1992; 6(9):93-4.
32. Heber D, Tchekmeydian NS. Pathophysiology of cancer: hormonal and metabolic abnormalities. *Oncology* 1992; 49 Suppl 2:28-31.
33. Hawkins MJ, Friedman MA. National Cancer Institute's evaluation of unconventional cancer treatments. *J Natl Cancer Inst* 1992; 84(22):1699-702.
34. Parnes HL, Aisner J. Protein calorie malnutrition and cancer therapy. *Drug Saf* 1992; 7(60):404-16.
35. Bruera E. Current pharmacological management of anorexia in cancer patients. *Oncology (Huntingt)* 1992; 6(1):125-30; discussion 132, 137.
36. Bode J, Kohwi Y, Dickinson L, et al. Biological significance of unwinding capability of nuclear matrix-associating DNAs. *Science* 1992; 255(5041):195-7.
37. Chlebowski RT, Bulcavage L, Grosvenor M, et al. Hydrazine Sulfate influence on nutritional status and survival in non-small-cell lung cancer. *J Clin Oncol* 1990; 8(1):9-15.

38. Mortensen AM, Novak RF. Enhanced proteolysis and changes in membrane-associated calpain following phenylhydrazine insult to human red cells. *Toxicol Appl Pharmacol* 1991; 110(3):435-49.
39. Gold J. Hydrazine sulfate in nonsmall-cell lung cancer [letter, comment]. *J Clin Oncol* 1990; 8(6):1117-8.
40. Loprinzi CL, Ellison NM, Goldberg RM, et al. Alleviation of cancer anorexia and cachexia: studies of the Mayo Clinic and the North Central Cancer Treatment Group. *Semin Oncol* 1990; 17(6 Suppl 9):8-12.
41. Smigel K. Hydrazine sulfate used in cancer patients [news]. *J Natl Cancer Inst* 1990; 82(4):254.
42. Piantadosi S. Hazards of small clinical trials [see comments]. *J Clin Oncol* 1990; 8(1):1-3.
43. Tayek JA, Heber D, Chlebowski. Effect of hydrazine sulfate on whole body protein breakdown measured by ¹⁴C-lysine metabolism in lung cancer patients. *Lancet* 1987; 2(Aug 1):241-4.
44. Renault H, Cals MJ. Preparation of S35 labeled thiosemicarbazone. *Ann Pharm Fr* 1982; 40(4):377-80.
45. Dusic Z. Determination of hexitol by potentiometric titration. *Arh Farm* 1981; 31(4):191-5.
46. Holak W. Collaborative study of the differential pulse polarographic analysis of cacodylate injections. *J Assoc Off Anal Chem* 1977; 60(Sep):1015-7.
47. Dusic Z. Determination of arabinose, xylose and ribose by periodate oxidation. *Acta Pharm Jugosl* 1975; 25(Jan-Mar):35-41.
48. Dusic Z, Berka A. Determination of glucose (dextrose) by periodate oxidation. *Acta Pharm Jugosl* 1975; 25(Jan-Mar):43-9.
49. Barakat MZ, El-Makarem MA, El-Raouf MA. Microdetermination of hydrazine salts and certain derivatives with N-chlorosuccinimide. *Anal Chem* 1974; 46(May):777-9.