

A. INGREDIENT NAME:

PHENINDAMINE TARTRATE

B. Chemical Name:

1,2,3,4-Tetrahydro-2-methyl-9-phenyl-2-azafluorene hydrogen tartrate; 2,3,4,9-Tetrahydro-2-methyl-9-phenyl-1*H*-indeno-[2,1*c*]pyridine hydrogen tartrate.

C. Common Name:

Thephorin, Dalca, Nolamine, Melodan, Cerose, Carrhist

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

	<i>(Limits)</i>	<i>(Results)</i>
Dry Basis:	98.0% - 101.5%	99.7%

E. Information about how the ingredient is supplied:

A white to cream white crystalline powder. Odorless or almost odorless.

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

Arg., Br., Ind., Int., and Turk.
British Pharmacopeia 1993

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

Witek, T. J., Canastrari, D. A., and Miller, R. D. The effects of phenindamine tartrate on sleepiness and psychomotor performance. *J. Allergy Clin Immunol*, 1992;90(6 Pt 1): 953-961.

Sigidinenko, L. V. Various principles of therapeutic tactics in epilepsy patients during pregnancy. *Zh Nevropatol Psikhiatr*, 1984; 84(6): 897-899.

1998-3454B1-02-34-BDL21

H. Information about dosage forms used:

Tablets
Liquid
Elixir
Capsules

I. Information about strength:

25-50mg

J. Information about route of administration:

Orally

K. Stability data:

Melts at about 162-167° with decomposition.

Solutions were unstable above pH 7 and were most stable at pH 3.5-5. Heating could cause phenindamine to isomerise to an inactive form.

L. Formulations:

M. Miscellaneous Information:

National Library of Medicine: IGM Full Record Screen



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	Order Documents	92/71 Other Years	Log off IGM	



TITLE: [Various principles of therapeutic tactics in epilepsy patients during pregnancy]

AUTHOR: Sigidinenko LV

SOURCE: Zh Nevropatol Psikhiatr 1984;84(6):897-9

NLM CIT. ID: 84276611

ABSTRACT: Forty-two epileptics were examined during pregnancy. According to the severity of the paroxysmal symptomatology, the authors identified three clinical groups: the first included patients with a therapeutic remission; the second, those with non-convulsive paroxysms; and the third group comprised patients with convulsive paroxysms. With due regard for impairments identified in the blood content of neurotransmitters, the patients received the multiple modality treatment, which included vitamins of group "B", potassium orotate, antihistamine drugs, the substitution of chloracon for phenobarbital and benzonal for diphenylhydantoin sodium; at the later stage of pregnancy the patients were given phenindamine tartrate. The use of the multiple modality treatment facilitated the cessation of attacks and served as the prevention of epileptic exacerbation in patients during the gestational and post-partal periods.

MAIN MESH SUBJECTS: Anticonvulsants/*ADMINISTRATION & DOSAGE
Epilepsy/BLOOD/*DRUG THERAPY
Neurotransmitters/*BLOOD
Pregnancy Complications/BLOOD/*DRUG THERAPY

ADDITIONAL MESH SUBJECTS: Adult
Drug Therapy, Combination
English Abstract
Epinephrine/BLOOD
Female
Histamine/BLOOD
Human
Norepinephrine/BLOOD
Pregnancy
Serotonin/BLOOD

PUBLICATION TYPES: JOURNAL ARTICLE

LANGUAGE: Rus

REGISTRY NUMBERS: 0 (Anticonvulsants)
0 (Neurotransmitters)
50-67-9 (Serotonin)
51-41-2 (Norepinephrine)
51-43-4 (Epinephrine)

National Library of Medicine: IGM Full Record Screen



Order Documents	92 67 71 Other Years	Log off IGM
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TITLE: The effects of phenindamine tartrate on sleepiness and psychomotor performance.

AUTHOR: Witek TJ Jr; Canestrari DA; Miller RD; Yang JY; Riker DK

AUTHOR AFFILIATION: Regulatory and Clinical Development, Richardson-Vicks USA (A Procter & Gamble Company), Shelton, Conn.

SOURCE: J Allergy Clin Immunol 1992 Dec;90(6 Pt 1):953-61

NLM CIT. ID: 93094481

ABSTRACT: Phenindamine, an H1-receptor antagonist that was developed almost 50 years ago, has been associated with both drowsiness and insomnia. Since its central nervous system profile has not been well characterized, we used a series of psychomotor tests to conduct two studies. In the first, 12 subjects received single oral doses of phenindamine (25 mg), diphenhydramine (50 mg), terfenadine (60 mg), or placebo in a four-way crossover study. Psychomotor tests included choice reaction time (CRT), tracking, and hand steadiness (HS). In the second trial, 15 subjects received single oral doses of phenindamine (25 mg), pseudoephedrine (60 mg), phenindamine and pseudoephedrine, diphenhydramine (50 mg), or placebo in a five-way crossover study. Psychomotor tests included CRT, HS, and a task that divided attention between tracking and reaction time. Introspective drowsiness was measured in both trials with use of a visual analog scale (VAS) and the Stanford Sleepiness Scale (SSS). All assessments were made before and 1, 3, and 5 hours after drug administration. In the first trial, diphenhydramine produced significant impairment relative to placebo ($p < 0.05$) in CRT, tracking, and HS tasks and higher SSS and VAS scores, with peak effect noted at 3 hours. Phenindamine did not significantly differ from placebo or terfenadine. In the second trial, diphenhydramine produced significant impairment relative to placebo ($p < 0.05$) in CRT, divided attention, HS, and VAS, and SSS, also peaking at 3 hours. Stanford Sleepiness Scale scores after phenindamine were greater than placebo at 3 hours ($p < 0.05$) but significantly less than diphenhydramine ($p < 0.05$). (ABSTRACT TRUNCATED AT 250 WORDS)

MAIN MESH SUBJECTS: Histamine H1 Antagonists/*PHARMACOLOGY
Psychomotor Performance/*DRUG EFFECTS
Pyridines/*PHARMACOLOGY
Sleep/*DRUG EFFECTS

ADDITIONAL MESH SUBJECTS: Adolescence
Adult
Diphenhydramine/PHARMACOLOGY
Ephedrine/PHARMACOLOGY
Human

Middle Age
Time Factors
PUBLICATION TYPES: CLINICAL TRIAL
JOURNAL ARTICLE
RANDOMIZED CONTROLLED TRIAL
LANGUAGE: Eng
REGISTRY 0 (Histamine H1 Antagonists)
NUMBERS: 0 (Pyridines)
299-42-3 (Ephedrine)
58-73-1 (Diphenhydramine)
82-88-2 (phenindamine)

National Library of Medicine: IGM Full Record Screen



Order Documents	92,71 67 Other Years	Log off IGM
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TITLE: Pharmacological investigation on the neurohumoral transmission of the vasomotor regulation.

AUTHOR: Porszasz J; Gibiszer KP; Porszasz J Jr

SOURCE: Acta Physiol Acad Sci Hung 1977;49(2):139-65

NLM CIT. ID: 79252230

ABSTRACT: Renal efferent sympathetic activity and its changes due to stimulation of the central stump of the vagal, sciatic and ulnar nerves were investigated. In addition, the effect on basal activity and sympathetic reflexes of drugs with well defined site of action was studied (diazepam, tofizopam, phentolamine, dihydroergotamine, chlorpromazine, reserpine, clonidine, atropine, methysergide and phenindamine). The sympathetic efferent activity and the changes in sympathetic reflexes allowed conclusions to be drawn as to the functional state of the vasomotor centre. Neither methysergide nor phenindamine inhibited efferent sympathetic activity or influenced sympathetic reflexes. These findings exclude the possibility of serotonin or histamine being the transmitter substance in the vasomotor neurone. Experiments with atropine revealed that the muscarinic action of acetylcholine does not figure in the sympathetic inhibitory or excitatory reflex processes. Of the drugs investigated only diazepam and clonidine inhibited efferent sympathetic activity. Clonidine was more selective and acted in much lower doses (20 micrograms/kg) than diazepam (0.5--1 mg/kg). The alpha blocking agents inhibited the viscerosympathetic inhibitory reflex arch more intensely than the somatosympathetic inhibitory one. The transmitter is presumably noradrenaline. The sympathetic excitatory reflexes were decreased by diazepam and tofizopam and increased by clonidine and phentolamine. The other substances were ineffective. As to the transmitter substance figuring in the sympathetic excitatory reflexes no unequivocal answer could be obtained in the present experiments.

MAIN MESH SUBJECTS: Kidney/*BLOOD SUPPLY/INNERVATION
Neurotransmitters/*PHYSIOLOGY
Reflex/*PHYSIOLOGY
Vasomotor System/*PHYSIOLOGY

ADDITIONAL MESH SUBJECTS: Animal
Autonomic Fibers, Postganglionic/PHYSIOLOGY
Carotid Arteries/PHYSIOLOGY
Cats
Comparative Study
Splanchnic Nerves/PHYSIOLOGY
Tibial Nerve/PHYSIOLOGY
Vagus Nerve/PHYSIOLOGY

PUBLICATION JOURNAL ARTICLE

TYPES:

LANGUAGE: Eng

No. Records Request
* 1 5 phenindamine

Record 1 of 1 - IPA 1970-3/98

TI: Oral facial dyskinesia associated with prolonged use of antihistaminic decongestants

AU: Thach-BT; Chase-TN; Bosma-JF

SO: N-Engl-J-Med (New-England-Journal-of-Medicine); 1975; 293(Sep 4); 486-487

PY: 1975

AB: Persistent involuntary movements of the face and mouth were reported in 2 patients who took antihistaminic-sympathomimetic drug combinations which were used for symptomatic treatment of upper respiratory tract congestion. The first patient took 2 medications. One was a timed-release capsule containing brompheniramine maleate 12 mg, phenylephrine HCl, 15 mg, and phenylpropanolamine HCl, 15 mg. The second medication was a tablet which contained phenindamine tartrate, 10 mg, and phenylephrine HCl, 5 mg. The second patient took a capsule containing chlorpheniramine maleate, 8 mg, phenylpropanolamine, 50 mg, and isopropamide, 2.5 mg.

AN: 13-2772

PHENINDAMINE

Oral LD50 in rodent is 280 mg/kg. Allergic reactions and skin sensitization may occur. Nausea and emesis, diarrhea, anorexia, G.I. pain, CNS stimulation with convulsions and coma have occurred.

Toxicological information is lacking.

Used as an antihistamine.

REFERENCES

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2. ter-Laak AM, Venhorst J, Donne Op den Kelder GM, et al. The histamine H1-receptor antagonist binding site. A stereoselective pharmacophoric model based upon (semi-) rigid H1-antagonists and including a known interaction site on the receptor. *J Med Chem* 1995; 38(17):3351-60.
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4. Branch SK, Casy AF, Hussain R, et al. The structure of phenindamine base and salts in the solute state. *J Pharm Pharmacol* 1988; 40(1):83-4.
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6. Sigidinenko LV. [Various principles of therapeutic tactics in epilepsy patients during pregnancy]. *Zh Nevropatol Psikhiatr* 1984; 84(6):897-9.
7. Tscherne RJ, Umagat H. Determination of isophenindamine in phenindamine tartrate using an argentated high performance liquid chromatographic mobile phase. *J Pharm Sci* 1980; 69(Mar):342-4.
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9. Thach BT, Chase TN, Bosma JF. Oral facial dyskinesia associated with prolonged use of antihistaminic decongestants. *N Engl J Med* 1975; 293(Sep 4):486-7.
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