

Brief Prescribing Information

ERGODRYL DIN 00156086
(Ergotamine Tartrate - Caffeine Citrate - Diphenhydramine HCl)

Migraine Therapy

For product availability, please contact Erfa Canada Inc.
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INDICATIONS:

ERGODRYL (Ergotamine Tartrate - Caffeine Citrate - Diphenhydramine HCl) is indicated for prevention and relief of migraine and other vascular type headaches.

CONTRAINDICATIONS

ERGODRYL (Ergotamine Tartrate - Caffeine Citrate - Diphenhydramine HCl) is contraindicated in patients with sepsis, occlusive vascular disease (thromboangiitis obliterans, luetic arteritis, severe arteriosclerosis, coronary artery disease, thrombophlebitis, and Raynaud's disease), hepatic disease, renal disease, hypertension, angina pectoris, peptic ulcer, infectious states, malnutrition, severe pruritus, pregnancy. Hypersensitivity to any of the components. Not for use in preadolescent children.

PRECAUTIONS

ERGODRYL (Ergotamine Tartrate - Caffeine Citrate - Diphenhydramine HCl) should not be co-administered with HIV protease inhibitors, such as ritonavir, indinavir, and saquinavir because competition of cytochrome P450 via CYP 3A isoenzyme by these agents could result in inhibition of metabolism of ergotamine. Co-administration of ergotamine or dihydroergotamine and HIV protease inhibitors has been associated with acute ergot toxicity characterized by peripheral vasospasm and ischemia of the extremities.

Occupational hazards: Patients should be cautioned not to operate vehicles or hazardous machinery until their response to the drug has been determined.

Since the depressant effects of antihistamines are additive to those of other drugs affecting the CNS, patients should be cautioned against drinking alcoholic beverages or taking hypnotics, sedatives, psychotherapeutic agents or other drugs with CNS depressant effects during antihistamine therapy.

The atropine like action of diphenhydramine should be considered, e.g. in patients with glaucoma.

Discontinue therapy if patient reports peripheral vascular complications such as cold, numbness, and pain in extremities or muscular cramps.

DOSAGE AND ADMINISTRATION

Adults: Optimal results depend on individual dosage adjustment to the intensity and duration of the attack. For the initial treatment, 1 capsule should be given as early after the onset of symptoms as possible. If the headache is not aborted, an additional capsule may be given at each half hour interval, not to exceed a total dose of 6 capsules per day. In treatment of subsequent attacks after the effective dose has been established, up to as many as 4 capsules may be taken, if necessary, as a single dose with the first indications of an impending attack. This quantity (4 capsules) should not be exceeded as a single dose. Patients should be advised not to take more than 10 capsules during any week.

Adolescents: For the initial attack, dosage is 1 capsule: to be repeated, if necessary, in 30 minutes. Maximum dosage for any one attack should not exceed 2 capsules. Dosage is the same for any subsequent attack.

AVAILABILITY OF DOSAGE FORMS

Each No. 3, hard, pink capsule with green top contains: ergotamine tartrate 1 mg, caffeine citrate 100 mg, and diphenhydramine HCl 25 mg. Nonmedicinal ingredients: citric acid, hydrogenated vegetable oil, lactose and talc. Energy: 3.0 kJ (0.72 kcal). Gluten-, paraben-, sodium-, sulfite- and tartrazine-free. Bottles of 100.