

for moderate to severe anxiety with coexisting depression

TRIAVIL®

containing perphenazine and amitriptyline HCl
TRANQUILIZER-ANTIDEPRESSANT

TRIAVIL®2-10: Each tablet contains 2 mg. of perphenazine and 10 mg. of amitriptyline hydrochloride.

TRIAVIL®2-25: Each tablet contains 2 mg. of perphenazine and 25 mg. of amitriptyline hydrochloride.

TRIAVIL®4-10: Each tablet contains 4 mg. of perphenazine and 10 mg. of amitriptyline hydrochloride.

TRIAVIL®4-25: Each tablet contains 4 mg. of perphenazine and 25 mg. of amitriptyline hydrochloride.

INDICATIONS: Patients with moderate to severe anxiety and/or agitation and depressed mood; patients with depression in whom anxiety and/or agitation are severe; patients with depression and anxiety in association with chronic physical disease; schizophrenics with associated depressive symptoms.

CONTRAINDICATIONS: Central nervous system depression from drugs (barbiturates, alcohol, narcotics, analgesics, antihistamines); bone marrow depression; urinary retention; pregnancy; glaucoma. Do not give in combination with MAOI drugs because of possible potentiation that may even cause death. Allow at least 2 weeks between therapies. In such patients therapy with TRIAVIL should be initiated cautiously, with gradual increase in the dosage required to obtain a satisfactory response.

WARNINGS: Patients should be warned against driving a car or operating machinery or apparatus requiring alert attention, and that response to alcohol may be potentiated.

PRECAUTIONS: Suicide is always a possibility in mental depression and may remain until significant remission occurs. Supervise patients closely in case they may require hospitalization or concomitant electroshock therapy. Unwanted reactions have been reported after the combined use of antidepressant agents having various modes of activity. Accordingly, consider possibility of potentiation in combined use of antidepressants. Not recommended for use in children. Mania or hypomania may be precipitated in manic-depressives (perphenazine in TRIAVIL seems to reduce likelihood of this effect). If hypotension develops, epinephrine should not be employed, as its action is blocked and partially reversed by perphenazine. Caution patients about errors of judgment due to change in mood.

SIDE EFFECTS: Similar to those reported with either constituent alone. **Perphenazine:** Should not be used indiscriminately. Use caution in patients with history of convulsive disorders or severe reactions to other phenothiazines. Likelihood of untoward actions greater with high doses. Closely supervise with any dosage. Side effects may be any of those reported with phenothiazine drugs: blood dyscrasias (pancytopenia, thrombocytopenic purpura, leukopenia, agranulocytosis, eosinophilia); liver damage (jaundice, biliary stasis); extrapyramidal symptoms (opisthotonos, oculogyric crisis, hyperreflexia, dystonia, akathisia, dyskinesia, parkinsonism) usually controlled by the concomitant use of effective antiparkinsonian drugs and/or by reduction in dosage, but sometimes persist after discontinuation of the phenothiazine; severe acute hypo-

tension (of particular concern in patients with mitral insufficiency or pheochromocytoma); skin disorders (photosensitivity, itching, erythema, urticaria, eczema, up to exfoliative dermatitis); other allergic reactions (asthma, laryngeal edema, angioneurotic edema, anaphylactoid reactions); peripheral edema; reversed epinephrine effect; endocrine disturbances (lactation, galactorrhea, disturbances of menstrual cycle); grand mal convulsions; cerebral edema; altered cerebrospinal fluid proteins, polyphagia; paradoxical excitement; photophobia; skin pigmentation; failure of ejaculation; EKG abnormalities (quinidine-like effect); reactivation of psychotic processes; catatonic-like states; autonomic reactions such as dryness of the mouth, headache, nausea, vomiting, constipation, obstipation, urinary frequency, blurred vision, nasal congestion, and a change in the pulse rate; hypnotic effects; pigmentary retinopathy; corneal and lenticular pigmentation; occasional lassitude; muscle weakness; mild insomnia; significant unexplained rise in body temperature may suggest intolerance to perphenazine, in which case discontinue. Antiemetic effect may obscure signs of toxicity due to overdosage of other drugs or make diagnosis of other disorders such as brain tumors or intestinal obstruction difficult. May potentiate central nervous system depressants (opiates, analgesics, antihistamines, barbiturates, alcohol), atropine, heat, and phosphorous insecticides. **Amitriptyline:** Careful observation of all patients recommended. Side effects include drowsiness (may occur within the first few days of therapy); dizziness; nausea; excitement; hypotension; fainting; fine tremor; jitteriness; weakness; headache; heartburn; anorexia; increased perspiration; incontinence; allergic-type reactions manifested by skin rash, swelling of face and tongue, itching; numbness and tingling of limbs, including peripheral neuropathy; activation of latent schizophrenia (however, the perphenazine content may prevent this reaction in some cases); epileptiform seizures in chronic schizophrenics; temporary confusion, disturbed concentration, or transient visual hallucinations on high doses; evidence of anticholinergic activity, such as tachycardia, dryness of mouth, blurring of vision, urinary retention, constipation, paralytic ileus; agranulocytosis; jaundice. The antidepressant activity may be evident within 3 or 4 days or may take as long as 30 days to develop adequately, and lack of response sometimes occurs. Response to medication will vary according to severity as well as type of depression present. Elderly patients and adolescents can often be managed on lower dosage levels.



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For more detailed information consult your Merck Sharp and Dohme representative or see the package circular.