

Warnings

Tolerance usually develops within a few weeks. When this occurs the recommended dose should not be exceeded in an attempt to increase the anorectic effect.

Because of the effect on the central nervous system, anorectic agents may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; the patient should therefore be cautioned accordingly.

DRUG DEPENDENCE: Tolerance and extreme psychological dependence have occurred with drugs of this class. Patients have been known to increase the dosage of drugs of this type to many times that recommended. Abrupt cessation following prolonged high dosage administration results in extreme fatigue and mental depression as well as prolonged changes noted on the sleep EEG. Authorities differ as to whether such withdrawal manifestations indicate true physical dependence. Manifestations of chronic intoxication with agents of this class include severe dermatoses, marked insomnia, irritability, hyperactivity and personality changes. The most severe manifestation of chronic intoxication is psychosis, often clinically indistinguishable from schizophrenia.

USAGE IN PREGNANCY: Safe use in pregnancy has not been established. Reproduction studies in mammals at high multiples of the human dose on some anorectic drugs have suggested both an embryotoxic and a teratogenic potential for this type of drug. Therefore, use of anorectic agents by women who are or who may become pregnant, and especially those in the first trimester of pregnancy, requires that the potential benefit be weighed against the possible hazard to mother and infant.

USAGE IN CHILDREN: Not recommended for use in children under 12 years of age.

Precautions

Caution is to be exercised in patients in whom there is even mild hypertension.

Insulin requirements in diabetes mellitus may be altered in association with use of these drugs and the concomitant dietary restrictions.

Psychological disturbances have been reported in patients who concomitantly receive an anorectic agent and a restrictive dietary regime.