

THE S. E. MASSENGILL CO.,
Bristol, Tenn., November 1, 1967.

DEAR DOCTOR: The Food and Drug Administration has requested that we call your attention to the monographs for our products, Predsem, Salcort and Salcort-Delta, in the current (1967) *Physicians' Desk Reference*. The FDA considers these monographs to be incomplete in presenting the necessary information for the safe and effective use of these drugs and therefore potentially misleading.

To provide you with the necessary information, we enclose revised monographs for insertion at page 812 of your current (1967) PDR. The nature and extent of the additions and other revisions in the enclosed monographs are emphasized by use of italics.

Sincerely,

ROBERT P. EWING,
Vice President, Marketing.

PROFESSIONAL PRODUCTS INFORMATION (P. 812)

PREDSEM

Composition: Each multiple-compressed white tablet contains:

Prednisone	5.0 mg.
Calcium pantothenate	10 mg.
Aluminum hydroxide gel, dried	0.2 Gm.
Magnesium trisilicate	0.1 Gm.

Prescribing information for Predsem which appears on page 812 of the 1967 PHYSICIAN'S DESK REFERENCE has been revised and is completely replaced by the following. The nature and extent of the additions and other revisions in the monograph are emphasized by use of italics.

Action and uses: For the treatment of the acute phase of rheumatoid arthritis and related diseases. Also of value in other conditions in which corticosteroid therapy is indicated. Antacids are incorporated to reduce gastric distress caused by hyperacidity in relation to steroid therapy.

Contraindications: Tuberculosis (active or latent), chronic nephritis, acute psychosis, Cushing's syndrome, peptic ulcer and in patients prone to thrombophlebitis. *Herpes simplex of the eye is usually an absolute contraindication. The appearance of ocular herpes simplex in patients receiving adrenocortical steroids systemically, or locally in the eye for other conditions, has been reported. If this occurs, Predsem Tablet should be discontinued unless the need for them is greater than the risk to the function of the eye.*

Relative Contraindications: As in the case of other powerful therapeutic agents, the physician must weigh the advantages of treatment with prednisone against the possible harmful effects. In congestive heart failure, hypertension, diabetes, frank osteoporosis associated with senility or with rheumatoid arthritis, renal insufficiency, history of peptic ulcer and mental disease. Predsem must be administered with caution.

In patients with diabetes mellitus being treated for a concurrent disease amenable to therapy with Predsem Tablets, the hyperglycemia may be aggravated; therefore, the diabetic status must be followed and regulated with great care. Usually it is possible to control the diabetes by increasing the insulin dosage.

While euphoria is the usual psychic reaction to large doses of prednisone, occasionally pronounced psychic derangements may appear. Early symptoms include insomnia, swings in mood and increased psychomotor activity.

Precautions: Corticosteroids should be used with caution in congestive heart failure, diabetes, renal insufficiency, history of peptic ulcer and mental disease. Predsem can mask infections by interfering with elevation of temperature, etc. If there is any question, drug should be temporarily discontinued until accurate diagnosis is made. May be reinstituted as soon as adequate measures have been taken to treat the infection.

Special Precautions: Furthermore, because edema and weight gain from prednisone are extremely infrequent, the physician must be especially on his guard to detect less conspicuous side effects.