

elevation of temperature, etc. If there is any question, the drug should be temporarily discontinued until an accurate diagnosis is made. It may be reinstated as soon as adequate measures have been taken to treat the infection.

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, Salcort-Delta Tablets 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, Salcort-Delta must be administered with caution.

In a patient with diabetes mellitus being treated for a concurrent disease amenable to therapy with Salcort-Delta 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: Since edema and weight gain due to prednisone are infrequent, the physician must be especially watchful for the development of less conspicuous side effects. The use of prednisone tends to depress the normal pituitary-adrenocortical mechanism and the patient should be carefully supervised, not only during, but following therapy. The dosage should be reduced very gradually, but even then a potentially critical degree of adrenocortical insufficiency may persist asymptotically for some time. Therefore, if the patient is subjected to stress, such as surgery or trauma within at least six months after therapy has been terminated, steroid therapy should be reinstituted. Furthermore, if a patient is subjected to unusual stress while receiving Salcort-Delta Tablets, steroid therapy should be continued for the duration of the stress and immediately following it. In both instances, proportionately much larger dosages of prednisone, cortisone, or hydrocortisone than that of the previously used Salcort-Delta should be used during the stress. As the prednisone, cortisone, or hydrocortisone is being discontinued, Salcort-Delta may be resumed in the former dosage.

After discontinuation of Salcort-Delta Tablets, continued supervision of the patient is essential, because there may be sudden reappearance of the disease for which the patient was treated.

In administering Salcort-Delta Tablets the possibility of the occurrence of the side effects of salicylates should be borne in mind. Any form of salicylates should be administered with caution to patients with hypoprothrombinemia and bleeding or with asthma and other allergic conditions.

Administration and Dosage: Can be started at 12 tablets daily in divided doses and dose diminished as symptoms subside.

How Supplied: In bottles of 100 multiple compressed, monogrammed yellow tablets.

THE UPJOHN CO.,
Kalamazoo, Mich., November 15, 1967.

DEAR DOCTOR: The Food and Drug Administration has asked us to call your attention to certain promotional messages for Medrol Tablets which the FDA regards as misleading.

Some journal advertisements have recommended use of Medrol 16 mg. Tablets by an alternate day dose regimen. Although reports of this usage have appeared in the literature, the FDA points out that information currently available and submitted by us to them is not adequate to justify this regimen as advertised. Consequently, we are ceasing all reference to alternate day therapy in our promotion of the product.

The monograph for Medrol Tablets in the 1967 *Physicians' Desk Reference* is considered by the FDA to be inadequate in presenting information for the safe and effective use of the product. To provide you with the necessary information, we enclose a revised monograph for insertion at page 1143 of your current (1967) *PDR*.

Sincerely yours,

FENIMORE T. JOHNSON, M.D.