(NOTE.—Prescribing information for Medrol (methylprednisolone) Tablets which appears on pages 1143–1144 of your 1967 *PDR* has been revised and is completely replaced by the following.)

MEDROL TABLETS

(Methylprednisolone)

Composition: Each tablet contains methylprednisolone 16 mg., 4 mg. or 2 mg.

Action and Uses: Medrol is indicated in conditions known to be responsive to corticoid therapy, including: (1) collagen diseases, (2) allergic diseases, (3) certain dermatological conditions, (4) acute ocular inflammatory disease, (5) certain leukemias and lymphatic neoplastic diseases, (6) ulcerative colitis, nephrosis and as adjunctive therapy in pulmonary and meningeal tuberculosis.

Administration and Dosage: The average total daily doses recommended should be given in four equally divided dosages and should be individualized according to the severity, duration and patient's response. The average daily dosage of Medrol is approximately two-thirds (0.7) the required daily dosage of prednisolone. Initial suppressive dosages should be continued for 3 to 7 days during which time satisfactory clinical response is usually obtained. Should there be no satisfactory response within 7 days, re-evaluation of the case to confirm the original diagnosis is indicated.

Reduction of dosage to maintenance levels should be accomplished slowly in decrements of not more than 2 mg. at intervals of 7 days when the initial daily dosage is 15 mg. or more. (See table below)

Adjustment of the dose level is indicated from time to time in concert with fluctuations in the disease activity and patient response. Experience has indicated that long-term benefits are greater when steroid maintenance is accomplished at the lowest possible dose level. Dose levels for protracted use of methylprednisolone should be in the range of 1.5 to 2.0 mg. daily for children and adolescents, 4 to 5 mg. daily for young women, 3 to 4 mg. daily for postmenopausal women, and 5 to 7 mg. daily for men. IMPORTANT—In the management of patients with chronic disease such as rheumatoid arthritis, methylprednisolone should be regarded as a valuable adjunct to be used in conjunction with but not as replacement for standard therapeutic measures.

Diuresis and increased excretion of sodium have occurred following administration of Medrol to adrenalectomized animals, normal human subjects and patients with cardiac edema or cirrhosis of the liver with ascites. These findings have suggested the value of this agent as adjunct to therapy of these and other forms of edema. Medrol has been reported to potentiate the actions of mercurial and carbonic anhydrase inhibiting diuretic agents and the restore response to diuretics in patients with resistant cardiac edema.

The use of corticoids in tuberculosis, while usually contraindicated, may be life saving when given with adequate and effective dosage of antituberculosis agents to patients with fulminating pulmonary tuberculosis or meningeal tuberculosis. Rapid improvement with defervescence, weight gain and clearing of pulmonary lesions have been reported.

Adverse Reactions: Adverse reactions associated with use of corticosteroids, including Medrol (methylprednisolone), include electrolyte imbalance, osteoporsis which is reversible only with difficulty, spontaneous fractures, aseptic necrosis of the hip, activation and complication of peptic ulcer including perforation and hemorrhage, hyperglycemia, glycosuria, hypertension, neverousness, acne, hirsutism, rounded facies, cutaneous striac, amenorrhea, cervicothoracic hump, acute pancreatitis, necrotizing angiitis, thinning of scalp hair, petechiae and purpura, posterior subcapsular cataracts occasionally requiring extraction, myopathy, growth retadiation in children, relative adrenocortical insufficiency (particularly in times of stress due to trauma, surgery or severe illness), protein catabolism with negative nitrogen balance, weakness, aggravation or masking of infection, increased intracranial or intraocular pressure., thromboembolism ulcerative esophagitis, psychic disturbances, abnormal euphoria, insomnia, headache, vertigo, facial flushing, sweating, and abnormal fat deposits.

When adverse reactions occur, they are usually reversible and disappear when the hormone is discontinued.

Precautions: Medrol (methylprednisolone) should be given only with full knowledge of the characteristic activity of, and the varied responses to, adrenocortial hormones.