

To provide you with the necessary information, we enclose a revised monograph for insertion at page 527 in your 1967 *PDR*. The nature and extent of the additions of previously omitted information are indicated by the use of italics.

Sincerely yours,

J. A. HUBATA, M.D.,
Medical Director.

(NOTE.—Prescribing information for H.P.* ACTHAR® GEL which appears on Pages 527 and 528 of the 1967 *PDR* has been revised and is completely replaced by the following. The nature and extent of the additions of previously omitted information are indicated by the use of italics.)

ARMOUR PHARMACEUTICAL COMPANY

CHICAGO, ILL.

H. P.* ACTHAR® GEL

(Repository Corticotropin injection)

Highly Purified

AND

ACTHAR®

(Corticotropin injection)

Description: H.P.* ACTHAR GEL (Repository Corticotropin Injection) is a Highly Purified preparation of CORTICOTROPIN in gelatin which has both rapid onset and prolonged action. One injection may have 24- to 72-hour effectiveness. The high degree of purity also allows its administration by intravenous infusion. Each milliliter contains the labeled activity of Corticotropin U.S.P., 16% Gelatin, 0.5% Phenol, not more than 0.1% Cysteine (added) and Water for Injection, q.s. ACTHAR (Corticotripin Injection) is sterile powered lyophilized ACTH which in the dry form is stable at room temperature. Each vial contains the labeled activity of Corticotropin U.S.P. and approximately 9 milligrams of hydrolyzed Gelatin.

Actions: ACTHAR (Corticotropin Injection) is the Armour Pharmaceutical Company brand of ACTH (Corticotropin). ACTH is the anterior pituitary hormone which stimulates the functioning adrenal cortex to produce and secrete all of its steroids, which number over 30. In contrast, corticosteroids may depress adrenal cortical function and produce adrenal atrophy. The fact that ACTH acts directly on the adrenal cortex provides a rationale for use of ACTH in treatment of the adrenal insufficiency produced by cortisone, hydrocortisone, prednisone and prednisolone.

Indications: *Allergic Diseases*—Angioneurotic Edema, Asthma, Drug Reactions, Hay Fever, Serum Sickness. *Note:* Epinephrine is the drug of choice for acute allergic reactions, corticotropin or steroid therapy being adjunctive. *Collagen Diseases*—Acute Rheumatic Fever; Arthritis, Rheumatoid; Bursitis; Lupus Erythematosus; Periarthritis Nodosa; Psoriatic Arthritis; Scleroderma; Spondylitis, Rheumatoid; Still's Disease; Tenosynovitis. *Dermatologic Diseases*—Anogenital Pruritus, Atopic Dermatitis, Dermatitis Venenata, Dermatitis Medicamentosa, Exfoliative Dermatitis, Dermatomyositis, Pemphigus, Psoriasis, Urticaria. *Endocrine Diseases*—Panhypopituitarism. *Eye Diseases*—Choroiditis; Conjunctivitis; Glaucoma, Acute Secondary; Iritis; Keratitis; Optic Neuritis; Sympathetic Ophthalmia; Uveitis. *Hemolytic Diseases*—Acquired Hemolytic Jaundice. *Other Uses*—ACTHAR (Corticotropin) preparations have also been used in numerous other disease states such as: Agranulocytosis; Aplastic Anemia; Bell's Palsy; Beryllium Poisoning; Burns; Erythema Nodosum; Erythroblastosis Fetalis; Fibrositis; Gout; Guillain-Barre Syndrome; Heat Sickness; Hepatic Coma; Hodgkin's Disease; Hypoglycemia, Idiopathic; Infections, Acute Overwhelming (e.g., Peritonitis, Meningitis); Insect Bites; Leukemias, Acute and Chronic Lymphatic; Loeffler's Syndrome; Myositis; Nephrotic Syndrome; Neuritis; Orchitis; Rhinitis; Sarcoidosis; Shoulder-Hand Syndrome; Snake Bite; Sprue Syndrome; Stevens-Johnson Syndrome; Thyroiditis; Ulcerative Colitis.