

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 83-009

PRINTED LABELING

Expires:
USUAL DOSAGE: See package insert.
See accompanying literature for more information.
3E01273

NDC 0032-2808-10

**ORASONE 1TM
PREDNISONE
USP**

1 mg.



**ORASONE 1TM
PREDNISONE
USP**
1 mg.
1000 Tablets

CM
JAN 29 1974
APPROVED

CAUTION: Federal law prohibits dispensing without prescription.
Licensed under Pat. No. 3,134,718.

ROWELL
LABORATORIES, INC.
BAUDETTE, MN 56623

Expires:
USUAL DOSAGE: See package insert.
See accompanying literature for more information.
3E01273

NDC 0032-2808-01

**ORASONE 1TM
PREDNISONE
USP**

1 mg.



**ORASONE 1TM
PREDNISONE
USP**
1 mg.
100 Tablets

CAUTION: Federal law prohibits dispensing without prescription.
Licensed under Pat. No. 3,134,718.

CM
JAN 29 1974
APPROVED

ROWELL
LABORATORIES, INC.
BAUDETTE, MN 56623

NDC 32-2812-10

1000 TABLETS

**ORASONE 10TM
PREDNISONE
USP**

10 mg.



**ORASONE 10TM
PREDNISONE**

10 mg.

USUAL DOSAGE: See package insert
CAUTION: Federal law prohibits dispensing without prescription.
See accompanying literature for more information.
Licensed under Pat. No. 3,134,718.

3E0773

Expires:

ROWELL
LABORATORIES, INC.
BAUDETTE, MN 56623

CM
JAN 29 1974
APPROVED

Expires:
USUAL DOSAGE: See package insert.
See accompanying literature for more information.
4E0673

NDC 32-2812-01

**ORASONE 10TM
PREDNISONE
USP**

10 mg.



**ORASONE 10TM
PREDNISONE
USP**

10 mg.
100 Tablets

CAUTION: Federal law prohibits dispensing without prescription.
Licensed under Pat. No. 3,134,718.

ROWELL
LABORATORIES, INC.
BAUDETTE, MN 56623

CM
JAN 29 1974
APPROVED

ORASONE[®] PREDNISONE USP

1 mg., 5 mg., 10 mg. & 20 mg.

DESCRIPTION

ORASONE Prednisone Tablets, available in four strengths up to 20 mg., provide dosage flexibility over the entire range from high initial to low maintenance doses. The tablets are embossed for strength identification and colored to prevent confusion or mixing. Glucocorticoids are steroid hormones, both naturally occurring and synthetic, which are secreted by the adrenal cortex from the gastrointestinal tract. Prednisone is a white to practically white, crystalline powder. It is very slightly soluble in water; soluble in methanol and in dioxane; sparingly soluble in acetone and in alcohol; slightly soluble in chloroform.

ACTIONS:

Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have salt-retaining properties, are used as replacement therapy in adrenocortical deficiency states. Their synthetic analogs are primarily used for their potent anti-inflammatory effects in disorders of many organ systems.

Glucocorticoids cause profound and varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli.

INDICATIONS

1. Endocrine Disorders:

Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the first choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy mineralocorticoid supplementation is of particular importance).

Congenital adrenal hyperplasia.
Nonsuppurative thyroiditis.

Hypercalcemia associated with cancer.

2. Rheumatic Disorders:

As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:

Rheumatoid arthritis (selected cases may require low-dose maintenance therapy).
Psoriatic arthritis. Acute nonspecific tenosynovitis.
Ankylosing spondylitis. Acute gouty arthritis.
Acute and subacute bursitis.

3. Collagen Diseases:

During an exacerbation or as maintenance therapy in selected cases of:
Systemic lupus erythematosus. Acute rheumatic carditis.

4. Dermatologic Diseases:

Pemphigus. Exfoliative dermatitis.
Bullous dermatitis herpetiformis. Mycosis fungoides.
Severe erythema multiforme (Stevens-Johnson syndrome). Severe psoriasis.

5. Allergic States:

Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment:
Seasonal or perennial allergic rhinitis. Atopic dermatitis.
Bronchial asthma. Serum sickness.
Contact dermatitis.

6. Ophthalmic Diseases:

Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as:
Allergic corneal marginal ulcers. Allergic conjunctivitis.
Herpes zoster ophthalmicus. Keratitis.
Anterior segment inflammation. Chorioretinitis.
Diffuse posterior uveitis and choroiditis. Optic neuritis.
Sympathetic ophthalmia. Iritis and iridocyclitis.

7. Respiratory Diseases:

Symptomatic sarcoidosis.
Loeffler's syndrome not manageable by other means.
Berylliosis.
Fulminating or disseminated pulmonary tuberculosis when concurrently accompanied by appropriate antituberculous chemotherapy.

8. Hematologic Disorders:

Idiopathic and secondary thrombocytopenia in adults.
Acquired (autoimmune) hemolytic anemia.
Erythroblastopenia (RBC anemia).
Congenital (erythroid) hypoplastic anemia.

9. Neoplastic Diseases:

For palliative management of:
Leukemias and lymphomas in adults. Acute leukemia of childhood.

10. Edematous States:

To induce a diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus.

11. Miscellaneous:

Tuberculous meningitis with subarachnoid block or impending block when concurrently accompanied by appropriate antituberculous chemotherapy.
Systemic Dermatomyositis (polymyositis).

CONTRAINDICATIONS

Systemic fungal infections.

WARNINGS

In patients on corticosteroid therapy subjected to unusual stress, increased dosage of rapidly acting corticosteroids before, during, and after the stressful situation is indicated.

Corticosteroids may mask some signs of infection, and new infections may appear during their use. There may be decreased resistance and inability to localize infection when corticosteroids are used.

Prolonged use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections due to fungi or viruses.

Usage in pregnancy: Since adequate human reproduction studies have not been done with corticosteroids, the use of these drugs in pregnancy, nursing mothers or women of childbearing potential requires that the possible benefits of the drug be weighed against the potential hazards to the mother and embryo or fetus. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy, should be carefully observed for signs of hypoadrenalism.

Average and large doses of hydrocortisone or cortisone can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium. These effects are less likely to occur with the synthetic derivatives except when used in large doses. Dietary salt restriction and potassium supplementation may be necessary. All corticosteroids increase calcium excretion.

WHILE ON CORTICOSTEROID THERAPY PATIENTS SHOULD NOT BE VACCINATED AGAINST SMALLPOX. OTHER IMMUNIZATION PROCEDURES SHOULD NOT BE UNDERTAKEN IN PATIENTS WHO ARE ON CORTICOSTEROIDS ESPECIALLY ON HIGH DOSE, BECAUSE OF POSSIBLE HAZARDS OF NEUROLOGICAL COMPLICATIONS AND A LACK OF ANTIBODY RESPONSE.

The use of prednisone in active tuberculosis should be restricted to those cases of fulminating or disseminated tuberculosis in which the corticosteroid is used for the management of the disease in conjunction with an appropriate antituberculous chemotherapy.

Inflammatory effects in disorders of many organ systems.
Glucocorticoids cause profound and varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli.

INDICATIONS

1. Endocrine Disorders:

Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the first choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy mineralocorticoid supplementation is of particular importance).
Congenital adrenal hyperplasia. Hypercalcemia associated with cancer.
Nonsuppurative thyroiditis.

2. Rheumatic Disorders:

As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:
Rheumatoid arthritis (selected cases may require low-dose maintenance therapy).
Psoriatic arthritis. Acute nonspecific tenosynovitis.
Ankylosing spondylitis. Acute gouty arthritis.
Acute and subacute bursitis.

3. Collagen Diseases:

During an exacerbation or as maintenance therapy in selected cases of:
Systemic lupus erythematosus. Acute rheumatic carditis.

4. Dermatologic Diseases:

Pamphigus. Exfoliative dermatitis.
Bullous dermatitis herpetiformis. Mycosis fungoides.
Severe erythema multiforme. Severe psoriasis.
(Stevens-Johnson syndrome).

5. Allergic States:

Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment:
Seasonal or perennial allergic rhinitis. Atopic dermatitis.
Bronchial asthma. Serum sickness.
Contact dermatitis.

6. Ophthalmic Diseases:

Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as:
Allergic corneal marginal ulcers. Allergic conjunctivitis.
Herpes zoster ophthalmicus. Keratitis.
Anterior segment inflammation. Chorioretinitis.
Diffuse posterior uveitis and choroiditis. Optic neuritis.
Sympathetic ophthalmia. Iritis and iridocyclitis.

7. Respiratory Diseases:

Symptomatic sarcoidosis.
Loeffler's syndrome not manageable by other means.
Berylliosis.
Fulminating or disseminated pulmonary tuberculosis when concurrently accompanied by appropriate antituberculous chemotherapy.

8. Hematologic Disorders:

Idiopathic and secondary thrombocytopenia in adults.
Acquired (autoimmune) hemolytic anemia.
Erythroblastopenia (RBC anemia).
Congenital (erythroid) hypoplastic anemia.

9. Neoplastic Diseases:

For palliative management of:
Leukemias and lymphomas in adults. Acute leukemia of childhood.

10. Edematous States:

To induce a diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus.

11. Miscellaneous:

Tuberculous meningitis with subarachnoid block or impending block when concurrently accompanied by appropriate antituberculous chemotherapy.
Systemic Dermatomyositis (polymyositis).

CONTRAINDICATIONS

Systemic fungal infections.

WARNINGS

In patients on corticosteroid therapy subjected to unusual stress, increased dosage of rapidly acting corticosteroids before, during, and after the stressful situation is indicated.

Corticosteroids may mask some signs of infection, and new infections may appear during their use. There may be decreased resistance and inability to localize infection when corticosteroids are used.

Prolonged use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections due to fungi or viruses.

Usage in pregnancy: Since adequate human reproduction studies have not been done with corticosteroids, the use of these drugs in pregnancy, nursing mothers or women of childbearing potential requires that the possible benefits of the drug be weighed against the potential hazards to the mother and embryo or fetus. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy, should be carefully observed for signs of hypoadrenalism.

Average and large doses of hydrocortisone or cortisone can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium. These effects are less likely to occur with the synthetic derivatives except when used in large doses. Dietary salt restriction and potassium supplementation may be necessary. All corticosteroids increase calcium excretion.

WHILE ON CORTICOSTEROID THERAPY PATIENTS SHOULD NOT BE VACCINATED AGAINST SMALLPOX. OTHER IMMUNIZATION PROCEDURES SHOULD NOT BE UNDERTAKEN IN PATIENTS WHO ARE ON CORTICOSTEROIDS, ESPECIALLY ON HIGH DOSE, BECAUSE OF POSSIBLE HAZARDS OF NEUROLOGICAL COMPLICATIONS AND A LACK OF ANTIBODY RESPONSE.

The use of prednisone in active tuberculosis should be restricted to those cases of fulminating or disseminated tuberculosis in which the corticosteroid is used for the management of the disease in conjunction with an appropriate antituberculous regimen.

If corticosteroids are indicated in patients with latent tuberculosis or tuberculin reactivity, close observation is necessary as reactivation of the disease may occur. During prolonged corticosteroid therapy, these patients should receive chemoprophylaxis.

PRECAUTIONS

Drug-induced secondary adrenocortical insufficiency may be minimized by gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy; therefore, in any situation of stress occurring during that period, hormone therapy should be reinstituted. Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently. There is an enhanced effect of corticosteroids on patients with hypothyroidism and in those with cirrhosis.

Corticosteroids should be used cautiously in patients with ocular herpes simplex because of possible corneal perforation.

The lowest possible dose of corticosteroid should be used to control the condition under treatment, and when reduction in dosage is possible, the reduction should be gradual.

Psychic derangements may appear when corticosteroids are used, ranging from euphoria, insomnia, mood swings, personality changes, and severe depression, to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated by corticosteroids.

Aspirin should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia.

Steroids should be used with caution in nonspecific ulcerative colitis, if there is a probability of impending perforation, abscess or other pyogenic infection; diverticulitis; fresh intestinal anastomoses; active or latent peptic ulcer; renal insufficiency; hypertension; osteoporosis; and myasthenia gravis.

Growth and development of infants and children on prolonged corticosteroid therapy should be carefully observed.

ADVERSE REACTIONS

Fluid and Electrolyte Disturbances.

Sodium retention.

Fluid retention.

Congestive heart failure in susceptible patients.

Potassium loss.

Hypokalemic alkalosis.

Hypertension.

Musculoskeletal.

Muscle weakness.

Steroid myopathy.

Loss of muscle mass.

Osteoporosis.

Vertebral compression fractures.

Aseptic necrosis of femoral and humeral heads.

Pathologic fracture of long bones.

Gastrointestinal.

Peptic ulcer with possible perforation and hemorrhage.

Pancreatitis.

Abdominal distention.

Ulcerative esophagitis.

Dermatologic.

Impaired wound healing.

Thin fragile skin.

Petechiae and ecchymoses.

Facial erythema.

Increased sweating.

May suppress reactions to skin tests.

Neurological.

Increased intracranial pressure with papilledema (pseudo-tumor cerebri) usually after treatment.

Convulsions.

Vertigo.

Headache.

Endocrine.

Menstrual irregularities.

Development of Cushingoid state.

Secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness.

Suppression of growth in children.

Decreased carbohydrate tolerance.

Manifestations of latent diabetes mellitus.

Increased requirements for insulin or oral hypoglycemic agents in diabetics.

Ophthalmic.

Posterior subcapsular cataracts.

Increased intraocular pressure.

Glaucoma.

Exophthalmos.

Metabolic.

Negative nitrogen balance due to protein catabolism.

DOSEAGE AND ADMINISTRATION

1. Dosage should be individualized according to the severity of the disease and the response of the patient. For infants and children, the recommended dosage should be governed by the same considerations rather than by strict adherence to the ratio indicated by age or body weight.

2. Hormone therapy is an adjunct to, and not a replacement for, conventional therapy.

3. Dosage should be decreased or discontinued gradually when the drug has been administered for more than a few days.

4. The severity, prognosis and expected duration of the disease and the reaction of the patient to medication are primary factors in determining dosage.

5. If a period of spontaneous remission occurs in a chronic condition, treatment should be discontinued.

6. Blood pressure, body weight, routine laboratory studies, including 2-hour post-prandial blood glucose and serum potassium, and a chest X-ray should be obtained at regular intervals during prolonged therapy. Upper GI X-rays are desirable in patients with known or suspected peptic ulcer disease.

The initial dosage of ORASONE Prednisone may vary from 5 to 60 mg. per day depending on the specific disease entity being treated. In situations of less severity lower doses will generally suffice while in selected patients higher initial doses may be required. The initial dosage should be maintained or adjusted until a satisfactory response is noted. If after a reasonable period of time there is a lack of satisfactory clinical response, prednisone should be discontinued and the patient transferred to other appropriate therapy. IT SHOULD BE EMPHASIZED THAT DOSAGE REQUIREMENTS ARE VARIABLE AND MUST BE INDIVIDUALIZED ON THE BASIS OF THE DISEASE UNDER TREATMENT AND THE RESPONSE OF THE PATIENT.

After a favorable response is noted, the proper maintenance dosage should be determined by decreasing the initial dosage in small increments at appropriate time intervals until the lowest dosage which will maintain an adequate clinical response is reached. It should be kept in mind that constant monitoring is needed in regard to drug dosage. Included in the situations which may make dosage adjustments necessary are changes in clinical status secondary to remissions or exacerbations in the disease process, the patient's individual drug responsiveness, and the effect of patient exposure to stressful situations not directly related to the disease entity under treatment; in this latter situation it may be necessary to increase the dosage of prednisone for a period of time consistent with the patient's condition. If after long-term therapy the drug is to be stopped, it is recommended that it be withdrawn gradually rather than abruptly.

HOW SUPPLIED

ORASONE Prednisone Tablets: 1 mg. pink scored, 5 mg. white scored; 10 mg. blue scored, and 20 mg. yellow scored - all in bottles of 100 and 1000.

6E01172

110110M01172



ROWELL LABORATORIES, INC.
BAUDETTE, ILL. 60023

Osteoporosis.	numeral heads.
Gastrointestinal.	Pathologic fracture of long bones.
Peptic ulcer with possible perforation and hemorrhage.	Abdominal distention.
Pancreatitis.	Ulcerative esophagitis.
Dermatologic.	
Impaired wound healing.	Facial erythema.
Thin fragile skin.	Increased sweating.
Petechiae and ecchymoses.	May suppress reactions to skin tests.
Neurological.	
Increased intracranial pressure with papilledema (pseudo-tumor cerebri) usually after treatment.	Convulsions.
	Vertigo.
	Headache.
Endocrine.	
Menstrual irregularities.	Suppression of growth in children.
Development of Cushingoid state.	Decreased carbohydrate tolerance.
Secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness.	Manifestations of latent diabetes mellitus.
	Increased requirements for insulin or oral hypoglycemic agents in diabetics.
Ophthalmic.	
Posterior subcapsular cataracts.	Glaucoma.
Increased intraocular pressure.	Exophthalmos.
Metabolic.	
Negative nitrogen balance due to protein catabolism.	

DOSAGE AND ADMINISTRATION

1. Dosage should be individualized according to the severity of the disease and the response of the patient. For infants and children, the recommended dosage should be governed by the same considerations rather than by strict adherence to the ratio indicated by age or body weight.
2. Hormone therapy is an adjunct to, and not a replacement for, conventional therapy.
3. Dosage should be decreased or discontinued gradually when the drug has been administered for more than a few days.
4. The severity, prognosis and expected duration of the disease and the reaction of the patient to medication are primary factors in determining dosage.
5. If a period of spontaneous remission occurs in a chronic condition, treatment should be discontinued.
6. Blood pressure, body weight, routine laboratory studies, including 2-hour post-prandial blood glucose and serum potassium, and a chest X-ray should be obtained at regular intervals during prolonged therapy. Upper GI X-rays are desirable in patients with known or suspected peptic ulcer disease.

The initial dosage of ORASONE Prednisone may vary from 5 to 60 mg. per day depending on the specific disease entity being treated. In situations of less severity lower doses will generally suffice while in selected patients higher initial doses may be required. The initial dosage should be maintained or adjusted until a satisfactory response is noted. If after a reasonable period of time there is a lack of satisfactory clinical response, prednisone should be discontinued and the patient transferred to other appropriate therapy. IT SHOULD BE EMPHASIZED THAT DOSAGE REQUIREMENTS ARE VARIABLE AND MUST BE INDIVIDUALIZED ON THE BASIS OF THE DISEASE UNDER TREATMENT AND THE RESPONSE OF THE PATIENT.

After a favorable response is noted, the proper maintenance dosage should be determined by decreasing the initial dosage in small increments at appropriate time intervals until the lowest dosage which will maintain an adequate clinical response is reached. It should be kept in mind that constant monitoring is needed in regard to drug dosage. Included in the situations which may make dosage adjustments necessary are changes in clinical status secondary to remissions or exacerbations in the disease process, the patient's individual drug responsiveness, and the effect of patient exposure to stressful situations not directly related to the disease entity under treatment; in this latter situation it may be necessary to increase the dosage of prednisone for a period of time consistent with the patient's condition. If after long-term therapy the drug is to be stopped, it is recommended that it be withdrawn gradually rather than abruptly.

HOW SUPPLIED

ORASONE Prednisone Tablets; 1 mg. pink scored; 5 mg. white scored; 10 mg. blue scored; and 20 mg. yellow scored - all in bottles of 100 and 1000.

6E01172
110110M01172



ROWELL LABORATORIES, INC.
BAUDETTE, MINN. 56623

PREDNISONE TABLETS USP 1 mg., 5 mg., 10 mg., 20 mg.

PRECAUTIONS

The usual treatment of a nonfatal disease is usually to institute the use of a combination of a diuretic and tuberculin in which the latter is used in the management of the disease in conjunction with an anti-tubercular regimen.

If contraindications are indicated in patients with latent tuberculosis, tuberculin reactions, close observation is necessary as reactivation of the disease may occur. During prolonged corticosteroid therapy, these patients should receive chemotherapy.

PRECAUTIONS

Drug-induced secondary adrenocortical insufficiency may be minimized by gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy; therefore, in any situation of stress, occurring during this period, hormone therapy should be reinstated. Since mineralocorticoid secretion may be impaired, salt and/or mineralocorticoid should be administered concurrently. There is an enhanced effect of corticosteroids on patients with hypothyroidism and in those with diabetes.

ried cautiously in par

The lowest possible dose of corticosteroid should be used to control the condition under treatment, and when reduction in dosage is possible, the reduction should be gradual.

Psychic derangements may appear when corticosteroids are used ranging from euphoria, insomnia, mood swings, personality changes, and severe depression to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated by corticosteroids.

Growth and development of infants and children on prolonged corticosteroid therapy should be monitored.

ADVERSE REACTIONS:
FLUID AND ELECTROLYTE IMBALANCES: Na⁺ retention. Fluid retention. Congestive heart failure in susceptible patients. Potassium loss. Hypochloremia and
leuk. Hypertension. - **SHOCK AND ECTAL:** Muscle weakness. Steroid myopathy.

Loss of muscle mass, Osteoporosis, Vertebral compression fractures, Avascular necrosis of femoral and humeral heads, Pathologic fracture of long bones. = GASTRO-INTESTINAL, Peptic ulcer with possible perforation and hemorrhage, Pancreatitis, Abdominal distention, Ulcerative esophagitis. = GASTRO-INTESTINAL Impaired acid healing, Thin fragile skin, Petechiae and ecchymosis, HEMATOLOGICAL Increased

sweating. May exhibit reactions to skin tests - **NEUROLOGICAL**: Increased intracranial pressure with papilloedema; ataxic gait; **ENDOCRINE**: hypercalcaemia; convulsions; vertigo; headache. - **ENDOCRINE**: Menstrual irregularities. Unimpaired Cushingoid state. Secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness. Suppression of growth in children. Decreased carbohydrate tolerance. Manifestations of latent diabetes mellitus. Increased requirements for insulin and oral hypoglycaemic agents in diabetics. - **Genitourinary**: Urinary incontinence. Deepened vaginal furrows.

diabetics. - OPHTHALMIC: Posterior subcapsular cataracts, increased intraocular pressure, Glaucoma, Exophthalmos. - METABOLIC: Negative nitrogen balance due to protein catabolism.

1. Dosage should be individualized according to the severity of the disease and the response of the patient. For infants and children the recommended dosage should be governed by the same considerations rather than by strict adherence to the ratio indicated by age or body weight.

3. Dosage should be decreased or discontinued gradually when the drug has been administered for more than a few days.
4. The severity, prognosis and expected duration of the disease and the reaction of the patient to medication are primary factors in determining dosage.

6. Blood pressure, body weight, routine laboratory studies, including a 2-hour orthostatic blood glucose and serum potassium, and a chest X-ray should be obtained at regular intervals during prolonged therapy. Upper GI X-rays are desirable in

The following dosage recommendations are suggested initial daily doses and are intended as guides. In general, the required daily dose can be estimated to be 20-30% of the required daily dose of cortisone or 20-30% of the required daily dose of hydrocortisone. As with other orally administered corticosteroids, the

The initial suppressive dose level is continued until a satisfactory clinical response is obtained, a period usually of 3 to 7 days in the case of the more severe (except for acute rheumatic carditis, allergic conjunctivitis, streptococcal scarlet fever, tonsillitis, and acute inflammation of the ear). It is important, regardless of

piratory tract and ocular inflammatory diseases. If a satisfactory response is obtained in 7 days, re-evaluation of the case to confirm the original diagnosis may be made. As soon as a satisfactory clinical response is obtained, the dose should be reduced gradually, either by termination of treatment in the case of some conditions (e.g. seasonal asthma, exfoliative dermatitis, acute allergic inflammation) or by the gradual effective maintenance dose level in the case of chronic conditions.

(e.g., rheumatoid arthritis, systemic lupus erythematosus, bronchial asthma, chronic dermatitis). In chronic conditions, and in rheumatoid arthritis especially, it is important that the reduction in dosage from initial to maintenance dose levels be accomplished slowly. Decrements of no more than 25% at intervals of 2 to 3 days are suggested in rheumatoid arthritis; maintenance steroid therapy should be continued

lowest possible level. The recommendations for some medium cysts regimens - maximally tolerated maintenance dose levels for long-term therapy are 20 to 30 mg, 2 to 3 mg, or less daily for children and adolescents; 5 to 6.5 mg, daily for men; 3.5 to 5 mg, daily for postmenopausal women, and 6.5 to 9 mg, daily for men.

INITIAL DOSES
See preceding discussion for directions for gradual withdrawal and for maintenance therapy in chronic conditions.

1. Endocrine Disorders:	7. Respiratory Diseases:
--------------------------------	---------------------------------

Adrenocortical insufficiency	2.5 to 5 mg.	Symptomatic	
Congenital adrenal hyperplasia	5 to 20 mg.	bacterial	40 to 45 mg.
Non suppressive	5 to 10 mg.	Larrier's syndrome ...	50 to 70 mg.
		Bertrams	40 to 50 mg.
		Fulminating or dis-	
		seminating	50 to 70 mg.

Hyperbilirubinemia	20 to 30 mg.	serum- and sputum	
Hypercalcemia associated		hypercalcemia	60 to 120 mg.
with cancer	40 to 60 mg.		

2. Rheumatic Disorders:

Psoriatic arthritis	10 to 20 mg.	mycobacteremia in psoriasis	25 to 100 mg.
Rheumatoid arthritis	10 to 20 mg.	Acute sarcoidosis	25 to 100 mg.
Ankylosing spondylitis ...	10 to 20 mg.	Chronic anemia ...	25 to 100 mg.
Acute and subacute dermatitis	20 to 30 mg.	Erythema multiforme SBC anemia	25 to 100 mg.

Acute nonspecific rheumatismis	20 to 40 mg.	Compensated erythremia	20 to 40 mg.
Acute gouty arthritis	10 to 60 mg.	Dehydrated anemia	20 to 40 mg.

3. Collagen Diseases:

9. Neoplastic Diseases:

Leukemias and lymphomas

4. Dermatologic Diseases: 10. Edematous States:

Pomptropus 120 to 180 mg.
Bullus demands
..... 60 to 120 mg.
Severe dysrhythmia multiplying
Steven Johnson

To induce a dysrhythmia design him
stimulate in the apical
system without stimuli
the diagnosis is that due
to larynx dysrhythmia.

Exhalative desmopressin ...	60 to 120 mg.
Exhalative desmopressin ...	20 to 60 mg.
Exhalative desmopressin ...	60 to 120 mg.
Exhalative desmopressin ...	10 to 20 mg.

5. Allergic Status:

Serum or serumal	
allergic reactions	20 to 60 mg.
allergic status	20 to 60 mg.

Conjunctivitis	20 to 40 mg	Conjunctivitis	20 to 40 mg
Cornea	20 to 40 mg	Cornea	20 to 40 mg
Iris	15 to 30 mg	Iris	15 to 30 mg
Sclera	20 to 40 mg	Sclera	20 to 40 mg

6. Ophthalmic Diseases:

19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100 101 102 103 104 105 106 107 108 109 110 111 112 113 114 115 116 117 118 119 120 121 122 123 124 125 126 127 128 129 130 131 132 133 134 135 136 137 138 139 140 141 142 143 144 145 146 147 148 149 150 151 152 153 154 155 156 157 158 159 160 161 162 163 164 165 166 167 168 169 170 171 172 173 174 175 176 177 178 179 180 181 182 183 184 185 186 187 188 189 190 191 192 193 194 195 196 197 198 199 200 201 202 203 204 205 206 207 208 209 210 211 212 213 214 215 216 217 218 219 220 221 222 223 224 225 226 227 228 229 230 231 232 233 234 235 236 237 238 239 240 241 242 243 244 245 246 247 248 249 250 251 252 253 254 255 256 257 258 259 260 261 262 263 264 265 266 267 268 269 270 271 272 273 274 275 276 277 278 279 280 281 282 283 284 285 286 287 288 289 290 291 292 293 294 295 296 297 298 299 300 301 302 303 304 305 306 307 308 309 310 311 312 313 314 315 316 317 318 319 320 321 322 323 324 325 326 327 328 329 330 331 332 333 334 335 336 337 338 339 340 341 342 343 344 345 346 347 348 349 350 351 352 353 354 355 356 357 358 359 360 361 362 363 364 365 366 367 368 369 370 371 372 373 374 375 376 377 378 379 380 381 382 383 384 385 386 387 388 389 390 391 392 393 394 395 396 397 398 399 400 401 402 403 404 405 406 407 408 409 410 411 412 413 414 415 416 417 418 419 420 421 422 423 424 425 426 427 428 429 430 431 432 433 434 435 436 437 438 439 440 441 442 443 444 445 446 447 448 449 450 451 452 453 454 455 456 457 458 459 460 461 462 463 464 465 466 467 468 469 470 471 472 473 474 475 476 477 478 479 480 481 482 483 484 485 486 487 488 489 490 491 492 493 494 495 496 497 498 499 500 501 502 503 504 505 506 507 508 509 510 511 512 513 514 515 516 517 518 519 520 521 522 523 524 525 526 527 528 529 530 531 532 533 534 535 536 537 538 539 540 541 542 543 544 545 546 547 548 549 550 551 552 553 554 555 556 557 558 559 560 561 562 563 564 565 566 567 568 569 570 571 572 573 574 575 576 577 578 579 580 581 582 583 584 585 586 587 588 589 590 591 592 593 594 595 596 597 598 599 600 601 602 603 604 605 606 607 608 609 610 611 612 613 614 615 616 617 618 619 620 621 622 623 624 625 626 627 628 629 630 631 632 633 634 635 636 637 638 639 640 641 642 643 644 645 646 647 648 649 650 651 652 653 654 655 656 657 658 659 660 661 662 663 664 665 666 667 668 669 670 671 672 673 674 675 676 677 678 679 680 681 682 683 684 685 686 687 688 689 690 691 692 693 694 695 696 697 698 699 700 701 702 703 704 705 706 707 708 709 710 711 712 713 714 715 716 717 718 719 720 721 722 723 724 725 726 727 728 729 730 731 732 733 734 735 736 737 738 739 740 741 742 743 744 745 746 747 748 749 750 751 752 753 754 755 756 757 758 759 760 761 762 763 764 765 766 767 768 769 770 771 772 773 774 775 776 777 778 779 780 781 782 783 784 785 786 787 788 789 790 791 792 793 794 795 796 797 798 799 800 801 802 803 804 805 806 807 808 809 810 811 812 813 814 815 816 817 818 819 820 821 822 823 824 825 826 827 828 829 830 831 832 833 834 835 836 837 838 839 840 841 842 843 844 845 846 847 848 849 850 851 852 853 854 855 856 857 858 859 860 861 862 863 864 865 866 867 868 869 870 871 872 873 874 875 876 877 878 879 880 881 882 883 884 885 886 887 888 889 890 891 892 893 894 895 896 897 898 899 900 901 902 903 904 905 906 907 908 909 910 911 912 913 914 915 916 917 918 919 920 921 922 923 924 925 926 927 928 929 930 931 932 933 934 935 936 937 938 939 940 941 942 943 944 945 946 947 948 949 950 951 952 953 954 955 956 957 958 959 960 961 962 963 964 965 966 967 968 969 970 971 972 973 974 975 976 977 978 979 980 981 982 983 984 985 986 987 988 989 990 991 992 993 994 995 996 997 998 999 1000 1001 1002 1003 1004 1005 1006 1007 1008 1009 1010 1011 1012 1013 1014 1015 1016 1017 1018 1019 1020 1021 1022 1023 1024 1025 1026 1027 1028 1029 1030 1031 1032 1033 1034 1035 1036 1037 1038 1039 1040 1041 1042 1043 1044 1045 1046 1047 1048 1049 1

ORASONE 1  ORASONE 10 
ORASONE 5  ORASONE 20 

...contributing to the good life...



ROWELL LABORATORIES, INC.
DAQUETTE, MN 56422