CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 83-009

PRINTED LABELING

NDC 0032-2808-10

ORASONE 1™ PREDNISONE USP

1 mg.

CAUTION: Federal law prohibits dispensing without prescription.

Licensed under Pat. No. 3,134,718.

USUAL DOSAGE: See package insert.

See accompanying literature for more information.

Expires:

3E0127 3

ORASONE 1™
PREDNISONE
USP
1 mg.
1000 Tablets
ROWELL
LABORATORIES, INC.
BAUDETTE, MN 56623

JAN 29 1974

APPROVED

NDC 0032-2808-01

ORASONE 1™
PREDNISONE
USP
1 mg.

CAUTION: Federal law prohibits dispensing without prescription.

Licensed under Pat. No. 3,134,718.

USUAL DOSAGE: See package insert.

See accompanying literature for more information.

Expires:

3E0873

ORASONE 1™
PREDNISONE
USP
1 mg.
100 Tablets
ROWELL
LABORATORIES, INC.
BAUDETTE, MN 56623

JAN 29 1974

APPROVED

NDC 32-2812-10

1000 TABLETS

ORASONE 10™ PREDNISONE USP

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:

ORASONE 10™
PREDNISONE
10 mg.
ROWELL
LABORATORIES, INC.
BAUDETTE, MN 56623

JAN 29 1974

APPROVED

NDC 32-2812-01

ORASONE 10™
PREDNISONE
USP
10 mg.

CAUTION: Federal law prohibits dispensing without prescription.

Licensed under Pat. No. 3,134,718.

USUAL DOSAGE: See package insert.

See accompanying literature for more information.

Expires:

4E0673

ORASONE 10™
PREDNISONE
USP
10 mg.
100 Tablets
ROWELL
LABORATORIES, INC.
BAUDETTE, MN 56623

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 scored to prevent confusion or mixing. Glucocorticosteroids are adrenocortical steroids, both naturally occurring and synthetic, which are readily absorbed from the gastrointestinal tract. Prednisone is a white to practically white, odorless, 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.
Ankylosing spondylitis.
Acute and subacute bursitis.
Acute nonspecific tenosynovitis.
Acute gouty arthritis.

3. Collagen Diseases:

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

4. Dermatologic Diseases:

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

5. Allergic States:

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

6. Opthalmic Diseases:

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

flammatory 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

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Acute gouty arthritis.

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During an exacerbation or as maintenance therapy in selected cases of:
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Pemphigus.
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Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as:
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Herpes zoster ophthalmicus.
Anterior segment inflammation.
Diffuse posterior uveitis and choroiditis.
Sympathetic ophthalmia.
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Keratitis.
Chorioretinitis.
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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.

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 postprandial 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

Osteoporosis.

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.
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Endocrine.

Menstrual irregularities.
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Ophthalmic.

Posterior subcapsular cataracts.
Increased intraocular pressure.

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Negative nitrogen balance due to protein catabolism.

DOSAGE AND ADMINISTRATION

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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.

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HOW SUPPLIED

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110110M01172

ROWELL LABORATORIES, INC.
BAUDETTE, MINN. 56623

ORASONE

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

DESCRIPTION

ORASONE Prednisone Tablets, [illegible] 20 mg., provide dosage flexibility [illegible] maintenance [illegible]. The tablets [illegible] prednisone [illegible] white [illegible] crystalline powder [illegible] very slightly soluble in water, soluble in [illegible], sparingly soluble in acetone and in [illegible] but 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: Psoriatic arthritis.
Rheumatoid arthritis (selected cases may require low-dose maintenance therapy).
Ankylosing spondylitis.
Acute and subacute bursitis.
Acute nonspecific tenosynovitis.
Acute gouty arthritis.

3. Collagen Diseases:

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

4. Dermatologic Diseases:

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

5. Allergic States:

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

6. Ophthalmic Diseases:

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

(Continued on reverse side)

ORASONE

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

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.

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 postprandial 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 following dosage recommendations are suggested initial daily doses and are intended as guides. In general, the required daily dose can be estimated to be about one fifth the required daily dose of cortisone (or about one third the required daily dose of hydrocortisone). As with other orally administered corticosteroids, the total daily dose of prednisone should be given in four divided doses, preferably after meals and with a snack at bedtime.

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 rheumatic diseases (except for acute rheumatic carditis), allergic conditions affecting the skin or respiratory tract, and ocular inflammatory diseases. If a satisfactory response is not obtained in 7 days, re-evaluation of the case to confirm the original diagnosis should be made. As soon as a satisfactory clinical response is obtained, the daily dose should be reduced gradually, either to termination of treatment in the case of acute conditions (e.g., seasonal asthma, exfoliative dermatitis, acute ocular inflammations) or to the minimal effective maintenance dose level in the case of chronic conditions (e.g., rheumatoid arthritis, systemic lupus erythematosus, bronchial asthma, atopic 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 not more than 2.5 mg. at intervals of 7 to 10 days are suggested. In rheumatoid arthritis, maintenance steroid therapy should be at the lowest possible level. The recommendations of some rheumatologists regarding the maximally tolerated maintenance dose levels for long-term therapy are as follows: 2 to 3 mg. or less daily for children and adolescents, 5 to 6.5 mg. daily for young women, 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:

Adrenocortical insufficiency	2.5 to 5 mg.
Congenital adrenal hyperplasia	5 to 20 mg.
Nonsuppurative thyroiditis	20 to 30 mg.
Hypercalcemia associated with cancer	40 to 60 mg.

2. Rheumatic Disorders:

Psoriatic arthritis	10 to 20 mg.
Rheumatoid arthritis	10 to 20 mg.
Ankylosing spondylitis	10 to 20 mg.
Acute and subacute bursitis	20 to 30 mg.
Acute nonspecific tenosynovitis	20 to 40 mg.
Acute gouty arthritis	10 to 60 mg.

3. Collagen Diseases:

Systemic lupus erythematosus	20 to 120 mg.
Acute rheumatic carditis	0.6 mg./lb./day

4. Dermatologic Diseases:

Pemphigus	120 to 180 mg.
Bullous dermatitis herpetiformis	60 to 120 mg.
Severe erythema multiforme (Stevens Johnson syndrome)	60 to 120 mg.
Exfoliative dermatitis	20 to 60 mg.
Mycosis fungoides	60 to 120 mg.
Severe psoriasis	10 to 20 mg.

5. Allergic States:

Seasonal or perennial allergic rhinitis	20 to 60 mg.
Bronchial asthma	20 to 60 mg.
Contact dermatitis	20 to 60 mg.
Atopic dermatitis	15 to 50 mg.
Serum sickness	60 to 80 mg.

6. Ophthalmic Diseases:

[illegible]	15 to 60 mg.

7. Respiratory Diseases:

Symptomatic sarcoidosis	20 to 40 mg.
Loeffler's syndrome	50 to 60 mg.
Berylliosis	40 to 60 mg.
Fulminating or disseminated pulmonary tuberculosis	60 to 120 mg.

8. Hematologic Disorders:

Idiopathic and secondary thrombocytopenia in adults	20 to 120 mg.
Acquired (autoimmune) hemolytic anemia	20 to 120 mg.
Erythroblastopenia (RBC anemia)	20 to 120 mg.
Congenital (erythroid) hypoplastic anemia	20 to 120 mg.

9. Neoplastic Diseases:

Leukemias and lymphomas in adults	20 to 120 mg.
Acute leukemia of childhood	20 to 120 mg.

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	[illegible] mg.

11. Miscellaneous:

Tuberculous meningitis with subarachnoid block or impending block when concurrently accompanied by appropriate antituberculous chemotherapy	[illegible]
[illegible]	[illegible] mg.
Systemic dermatomyositis (polymyositis)	[illegible] mg.