CLINICAL PHARMACOLOGY

Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have physiologic and pathophysiologic activities mediating those of the adrenal cortex, have little or no mineralocorticoid activity. Generally, the synthetic glucocorticoids are 5- to 100-fold more potent than cortisone, although individual responses may vary. Systemic absorption of topical (cutaneous) glucocorticoids is insufficient to alter systemic metabolism or mineralocorticoid activity.

Prednisolone tablets are indicated for treatment in conditions responsive to systemic steroids.

INDICATIONS AND USAGE

1. Endocrine disorders. Primary or secondary adrenal insufficiency (adrenocortical crisis) is the first choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy or children with hypopituitarism, mineralocorticoids may be required for the first few years of life. Secondary adrenal insufficiency is also treated with mineralocorticoid therapy while the adrenal cortex is recovering from adrenocortical failure or corticosteroid suppression.

2. Rheumatic disorders. As adjunctive therapy for short term treatment (no longer than 10 days) in rheumatoid arthritis, acute lupus erythematosus, and Sjogren’s syndrome.

3. Dermatologic disorders. Pemphigus, Bullous dermatitis herpetiformis, Severe pemphigus erythematosus (Stevens-Johnson syndrome) and Toxic epidermal necrolysis.

4. Ophthalmic disorders.

5. Allergic states. Control of severe, acute or chronic allergic conditions intractable to adequate trials of conventional treatment; Seasonal or perennial allergic rhinitis; Atopic dermatitis; Asthma; Contact dermatitis; Atopic dermatitis; Drug hypersensitivity reactions.

6. Respiratory diseases. Asthma, bronchitis, emphysema, bronchial or pulmonary edema caused by bronchial asthma or pulmonary heart disease; Pneumonia; Acute exacerbations of chronic bronchitis; Adult respiratory distress syndrome; Acute respiratory distress syndrome (ARDS).

7. Respiratory diseases. Seasonal or perennial allergic rhinitis; Serum sickness; Bronchial asthma; Contact dermatitis; Atopic dermatitis; Drug hypersensitivity reactions.

8. Hematologic disorders. Idiopathic thrombocytopenic purpura in adults; Acquired (autoimmune) hemolytic anemia; Acquired (autoimmune) aplastic anemia.

9. Neoplastic diseases. For palliative management of: Leukemias and lymphomas; Melanomas; Carcinomas of gastrointestinal tract and genitourinary tract; Lymphosarcoma.

10. Edematous states. Congestive heart failure, nephrotic syndrome, hepatic edema, acute attack of gout, pericardial effusion, incipient diabetic coma, myxedema, myxedematous or diabetic edema.

11. Gastrointestinal. To tide the patient over a critical period of the disease (i.e., during surgery or other periods of intense physical stress).

12. Nervous system.


14. Other uses. Secondary thrombocytopenia in adults; Idiopathic thrombocytopenic purpura in adults; Acquired (autoimmune) hemolytic anemia; Acquired (autoimmune) aplastic anemia; Secondary thrombocytopenia in adults; Acquired (autoimmune) hemolytic anemia; Acquired (autoimmune) aplastic anemia; Acute renal failure; Metabolic alkalosis; Myasthenia gravis; Osteoporosis and myasthenia gravis.

15. Growth and development of infants and children on prolonged corticosteroid therapy should be monitored periodically. See PRECAUTIONS.

16. Unlabeled Use: Treatment of life-threatening or moderately severe childhood asthma when inhaled beta blockers are not sufficient.

WARNINGs

Persons who are on drugs which suppress the immune system are more susceptible to infections than healthy individuals. Chickenpox and measles, for example, can have a more serious or even fatal course in non-immune children or adults on corticosteroids. In such children or adults who have not had these diseases, particular care should be taken to avoid exposure. How the dose, route and duration of corticosteroid administration affects the risk for developing a disseminated infection is not known. The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known.

If exposed to chickenpox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. If exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IMIG) may be indicated. [See the respective package inserts for further information on dosage and IG, prescribing information.] If chickenpox develops, treatment with antiviral agents may be considered.

In patients on corticosteroid therapy subjected to unusual stress during or after steroid therapy, the usual dose of corticosteroid should be maintained or increased, and, if necessary, a stress dose of a synthetic glucocorticoid may be necessary.

SEROLOGIC HYPERSensitivity

SEROLOGIC HYPERSensitivity is caused by all synthetic glucocorticoids. SEROLOGIC HYPERSensitivity results in an increase in antibody formation against synthetic glucocorticoids. In patients who have been treated with synthetic glucocorticoids for 10 or more days, the appearance of antibodies to other synthetic glucocorticoids is more likely to occur. The likelihood of the appearance of antibodies and the severity of any adverse effects are related to the dose and duration of therapy. Except in rare instances, these antibodies do not interfere with the pharmacologic activity of the related glucocorticoids.

PRECAUTIONS

Information for Patients

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HOW SUPPLIED

Prednisolone tablets (prednisolone tablets USP, 5 mg) are scored, round, peach tablets imprinted DAN 5059 supplied in bottles of 100 (NDC 16477-505-01).


Manufactured By: Laser Pharmaceuticals, LLC
Distributed By: Laser Pharmaceuticals, LLC

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Millipred Tablets
(prednisolone USP, 5 mg)

“Many indications...only one Millipred”

Millipred Tablets are indicated for the control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment including:

- Asthma
- Seasonal or Perennial Allergic Rhinitis
- Atopic Dermatitis
- Contact Dermatitis

Millipred Tablets are indicated as adjunctive therapy for short term administration in patients experiencing exacerbation or an acute episode of:

- Arthritis; including rheumatoid and juvenile rheumatoid arthritis
- Post-traumatic osteoarthritis
- Bursitis

Millipred Tablets are contraindicated in patients with systemic fungal infections. 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.

Scored tablet allows more flexibility in your dosing regimen

Most economical prednisolone tablet available

No bitter aftertaste

No refrigeration required

Please consult accompanying full prescribing information for usual dosage and important safety information.