Nervous System
Acute exacerbations of multiple sclerosis, cerebral edema associated with primary or metastatic brain tumor, craniotomy, or head injury.

Ophthalmic Diseases
Sympathetic ophthalmia, temporal arteritis, uveitis, and ocular inflammatory conditions unresponsive to topical corticosteroids.

Renal Diseases
To induce a diuresis or remission of proteinuria in idiopathic nephrotic syndrome or that due to lupus erythematosus.

Respiratory Diseases
As an adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis, acute rheumatic carditis, ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis, in steroid responsive asthma, and multiple forms of collagen vascular disease. For the treatment of dermatomyositis, polymyositis, and systemic lupus erythematosus.

CONTRAINDICATIONS
Systemic fungal infections (see WARNINGS: Fungal Infections). Dexamethasone tablets are contraindicated in patients who are hypersensitive to any components of this product.

WARNINGS
Rare instances of anaphylactoid reactions have occurred in patients receiving corticosteroids (see ADVERSE REACTIONS). Increased dosage of rapidly acting corticosteroids is indicated in patients on corticosteroid therapy subjected to any unusual stress before, during, and after the stressful situation.

Cardio-Renal:
Average or large doses of corticosteroids can cause elevation of blood pressure, sodium 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.

Endocrine:
Corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for corticosteroid insufficiency after withdrawal of treatment. Adrenocortical insufficiency may result from too rapid withdrawal of corticosteroids and 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 reinstated.

Terminal stage corticosteroid therapy may obviate the need for additional therapy. If the patient is receiving steroids already, dosage may have to be increased.

Metabolic clearance of corticosteroids is decreased in hyperthyroid patients and increased in hyperthyroid patients. Changes in thyroid status of the patient may necessitate adjustment in dosage.

Infections:
Patients who are on corticosteroids are more susceptible to infections than individuals not receiving corticosteroids. In pediatric or adult patients who have not had these diseases, particular care should be taken to avoid exposure. Patients receiving corticosteroids should receive prophylaxis.

Viral infections:
Chickenspox and measles can have a more serious or even fatal course in patients receiving corticosteroids (see ADVERSE REACTIONS). In pediatric or adult patients who have not had these diseases, particular care should be taken to avoid exposure.

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of response to warfarin, although there have been some conflicting reports. Therefore, coagulation indices should be monitored frequently to maintain the desired anticoagulant effect.

**Antibiotics:** Because corticosteroids may increase blood glucose concentrations, dosage adjustments of antidiabetic agents may be required.

**Serum Drugs:** Serum levels of immunosuppressants may be decreased.

**Cholesteramine:** Cholesteramine may increase the clearance of corticosteroids.

**Cytopsirine:** Increased activity of both cyclopsirine and corticosteroids may occur when the two are used concurrently. Convulsions have been reported with this concurrent use.

**WARNINGS:** Infections, Vaccination

- Patients on corticosteroid therapy may exhibit a diminished response to toxoids and live or inactivated vaccines due to inhibition of antibody response.
- In post-marketing experience, there have been reports of both increases and decreases in the incidence of malignancy in patients treated with corticosteroids.
- Co-administration with thalidomide should be employed cautiously, as toxic effects may be noted.
- Inhibition of skin test reactions by corticosteroids increases the risk of gastrointestinal side effects. Aspirin should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia.
- Concomitant use of aspirin (or other nonsteroidal anti-inflammatory agents) and corticosteroids may result in increased plasma concentrations of aspirin and decreased motility and number of spermatozoa, malaise, moon face, weight gain.

**OVERDOSE**

- Treatment of overdose is by supportive and symptomatic therapy. In the case of acute overdose, according to the patient's condition, supportive therapy may include gastric lavage or emesis.
- For greater accuracy, give 0.5 mg of dexamethasone orally every 6 hours for 48 hours. Twenty-four hour urine collections are made for determination of 17-hydroxycorticosteroid excretion.
- To distinguish Cushing's syndrome due to pituitary ACTH excess from Cushing's syndrome due to other causes.
- Give 2.0 mg of dexamethasone orally every 6 hours for 48 hours. Twenty-four hour urine collections are made for determination of 17-hydroxycorticosteroid excretion.

**HUMAN SUPPLIES**

Decadron® tablets are available as:

- 0.5 mg tablets scored (yellow), debossed “Par-084” and supplied in bottles of 300 NDC 1406-014-00.
- 0.75 mg tablets scored (blue), debossed “Par-085” and supplied in bottles of 100 NDC 1406-015-01.
- 1 mg tablets scored (white), debossed “Par-087” and supplied in bottles of 100 NDC 1406-016-16.
- 2 mg tablets scored (white), debossed “Par-129” and supplied in bottles of 100 NDC 1406-017-01.
- Store at 20° to 25°C (68° to 77°F) (See USP Controlled Room Temperature). Dispense in a tight, light resistant container as defined in the USP./NF.

**Distributed by:**

- Fera Pharmaceuticals, LLC
- for Pragma Pharmaceuticals, LLC
- La Crosse, N.Y. 11560
- PPI-014
- Revised: 01/18

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