A cute exacerbations of multiple sclerosis
Ulcerative colitis Regional enteritis
To induce a diuresis or remission of proteinuria in the nephrotic syndrome,
Leukemias and lymphomas in adults A cute leukemia of childhood
For palliative management of:
Loeffler's syndrome not manageable by other means
Iritis and iridocyclitis
A cute rheumatic carditis (polymyositis)
B ullous dermatitis herpetiformis Exfoliative dermatitis
A cute rheumatic carditis (polymyositis)
C ontrol of severe or incapacitating allergic conditions intractable to adequate
A nterior segment inflammation Diffuse posterior uveitis and
S erum sickness B ronchial asthma
C ontact dermatitis A topic dermatitis
A cute exacerbation or as maintenance therapy in selected cases of:
Systemic lupus erythematosus Systemic dermatomyositis
Acute rheumatic carditis (polymyositis)
4. Dermatologic Diseases
B ulbous dermatitis herpetiformis Exfoliative dermatitis
Severe erythema multiforme (Stevens-Johnson syndrome) Mycosis fungoides
Severe seborrheic dermatitis Severe psoriasis
5. Allergic Diseases
C ontrolled, severe or excruciating allergic conditions irritable to inadequate
trials of conventional treatment:
S erum sickness B rochial asthma
Contact dermatitis Atopic dermatitis
6. Ophthalmic Diseases
S evere acute and chronic allergic and inflammatory processes involving the eye
S evere chronic or perennial allergic rhinitis Drug hypersensitivity reactions
S evere cataracts Drug hypersensitivity reactions
7. Respiratory Diseases
S ymptomatic sarcoidosis B erylliosis
L eifier's syndrome not manageable by other means
F ulminating or disseminated pulmonary tuberculosis when concurrently
T hrombotic antiphospholipid syndrome
8. Hematologic Diseases
I dioptic thrombocytopenia purpura in adults Secondary thrombocytopenia
A cquired (immune) hemolytic anemia Thrombotic thrombocytopenia purpura
C ongenital (erythroid) hypoplastic anemia Erythroblastopenia (RBC anemia)
9. Neoplastic Diseases
F or palliative management of:
L eukemias and lymphomas in adults Acute leukemia of childhood
10. Endematus States
To induce a diuresis or remission of proteinuria in the nephrotic syndrome,
without uraemia, of the idiopathic type or due to lupus erythematosus.
11. Gastrointestinal Diseases
To tide over a patient critical over a period of the disease in:
Ulcerative colitis Regional enteritis
12. Nervous System
A cute exacerbations of multiple sclerosis
T uberous meningitis with subarachnoid block or impeding block when
used concurrently with appropriate antituberculosis chemotherapy.
Neurotic or myoclonic involvement
CONTRAINDICATIONS
Systemic fungal infections and known hypersensitivity to components.

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. Infections with any pathogen including viral, bacterial, fungal,
protozoan or helminthic infections, in any location of the body, may be associated
with the use of corticosteroids alone or in combination with other immunosuppressive
agents that affect cellular immunity, humoral immunity, or neutrophil function.

These infections may be mild, but can be severe and at times fatal. With increasing
doses of corticosteroids, the rate of occurrence of infectious complications
increases. 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 child-bearing 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 hypoadrenalinism.

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.

Administration of live or live, attenuated vaccines is contraindicated in patients
receiving immunosuppressive doses of corticosteroids. Killed or inactivated vaccines
may be administered to patients receiving immunosuppressive doses of corticosteroids;
however, the response to such vaccines may be diminished. Indicated immunization
procedures may be undertaken in patients receiving nonimmunosuppressive doses of corticosteroids.

The use of MethylPREDNISolone Tablets 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 tuberculosis
reactivity, close observation is necessary to detect the appearance of the disease.
During prolonged corticosteroid therapy, these patients should receive chemoprophylaxis.

Persons who are on drugs which suppress the immune system are more
susceptible to infections than healthy individuals. Chicken pox 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 of 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
chicken pox, prophylaxis with varicella zoster immune globulin (VZIG) may be
indicated. If exposed to measles, prophylaxis with pooled intramuscular
immunoglobulin (Ig) may be indicated. (See the respective package inserts for
complete VZIG and IG prescribing information.) If chicken pox develops,
treatment with antiviral agents may be considered. Similarly, corticosteroids
should be used with great care in patients with known or suspected
Strongyloides hyperinfection and dissemination with widespread larval migration, often accompanied by severe enterocolitis and potentially fatal gran-negative septicemia.

PRECAUTIONS
General 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 cataracts.

Corticosteroids should be used cautiously in patients with herpetic 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.

Psychiatric disorders 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.

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.
Alternate Day Therapy:

3) In less severe disease processes in which corticosteroid therapy is indicated, it may be possible to initiate treatment with alternate day therapy. More severe disease states usually will require daily divided dose therapy for initial control of the disease process. The initial suppressive dose as brief as possible is satisfactory clinical response is obtained, usually four to ten days in the case of many allergic and collagen diseases. It is important to tell the patient that the initial suppressive dose as brief as possible is satisfactory for alternate day therapy. Once control has been established, two courses are available: (a) change to alternate day therapy and then gradually reduce the amount of corticosteroid given every other day or (b) following control of the disease process reduce the daily dose of corticosteroid to the lowest effective level as rapidly as possible and then change over to an alternate day schedule. Thrombocytopenia (a) may be preferable.

4) Because of the advantages of alternate day therapy, it may be desirable to try patients on this form of therapy who have been on daily corticosteroids for long periods of time (e.g., patients with rheumatoid arthritis). Since these patients may already have a suppressed HP axis, establishing them on alternate day therapy may be difficult and not always successful. However, it is recommended that regular attempts be made to change them over to alternate day therapy. Even quadruple the daily maintenance dose and administer this every other day rather than just doubling the daily dose if control is not achieved, an attempt should be made to reduce this dose to a minimum.

5) As indicated above, certain corticosteroids, because of their prolonged suppressive effect on adrenal activity, are not recommended for alternate day therapy (e.g., dexamethasone and betamethasone).

6) The maximal activity of the adrenal cortex is between 2 am and 8 am, and it is minimal between 10 pm and midnight. Exogenous corticosteroids do not supress an adrenocortical activity the least, when given at the time of maximal activity (am).

7) In using alternate day therapy it is important that the patient individualize and tailor the therapy to each patient. Complete control of symptoms will not be possible in all patients. An advantage of alternate day therapy will help the patient to understand and tolerate the possible flare-up in symptoms which may occur in the latter part of the off-steroid day. Other symptomatic therapy may be added or increased at this time if needed.

8) In the event of an acute flare-up of the disease process, it may be necessary to return to a full suppressive daily divided corticosteroid dose. Once control is again established alternate day therapy may be reinstituted.

9) Although many of the undesirable features of corticosteroid therapy can be minimized by alternate day therapy, the physician must carefully weight the benefit-risk ratio for each patient in whom corticosteroid therapy is being considered.

HOW SUPPLIED
MethylPREDNISOLONE Tablets, 4 mg are white, oval, quadrant tablets debossed “16” or “16” and “4” in black. They are supplied in bottles of 100, 500, 1000 and in unit of use packs of 21 tablets. Dispense in a tight-light resistant container as defined in the USP. Store at 20°–25°C (68°–77°F) [see USP Controlled Room Temperature].

REFERENCES