Millipred™
(Prednisolone Sodium Phosphate Oral Solution, 10 mg Prednisolone Base per 5 mL)
Rx only

DESCRIPTION
Millipred Oral Solution (10 mg Prednisolone per 5 mL) is a dye free, pale to light yellow solution. Each 5 mL (teaspoonful) of Millipred Oral Solution contains 13.4 mg prednisolone sodium phosphate (10 mg prednisolone base) in a palatable, aqueous vehicle.
Millipred Oral Solution (10 mg Prednisolone per 5 mL) also contains anti-bitter mask, corn syrup, edetate di-sodium, glyc erin, grape flavor, hydroxyethylcellulose, methylparaben, potassium phosphate dibasic, potassium phosphate monobasic, purified water, and sodium saccharin.
Prednisolone sodium phosphate occurs as white or slightly yellow, friable granules or powder. It is freely soluble in water; soluble in methanol; slightly soluble in alcohol and in chloroform; and very slightly soluble in acetone and in dioxane.

SAFETY INFORMATION
Millipred™ oral solution is contraindicated in patients with systemic fungal infections. Administration of live or live, attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of corticosteroids. Killed or inactivated vaccines may be administered, however, the response to such vaccines cannot be predicted.
Millipred Oral Solution (10 mg Prednisolone per 5 mL) should not be used in patients with active tuberculosis, latent tuberculosis infection, localized or disseminated fungal infections (except coccidioidomycosis), histoplasmosis, blastomycosis, or paracoccidioidomycosis.
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DOSAGE AND ADMINISTRATION
The initial dosage of Millipred Oral Solution (10 mg Prednisolone per 5 mL) may vary from 2.5 mL to 30 mL (5 to 60 mg prednisolone base) 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.

HOW SUPPLIED
Prednisolone oral solution is contraindicated in patients with systemic fungal infections. Administration of live or live, attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of corticosteroids. Killed or inactivated vaccines may be administered, however, the response to such vaccines cannot be predicted. Immunization procedures may be undertaken in patients who are receiving corticosteroids as replacement therapy, e.g., for Addison’s disease. Adverse reactions of Millipred™ oral solution include the following: cardiovascular (hypertrophic cardiomyopathy in premature infants); dermatologic (facial erytherma; increased sweating; impaired wound healing; may suppress reactions to skin tests; petechiae and ecchymoses; thin fragile skin; urticaria; edema); endocrine (decreased carbohydrate tolerance; development of cushingoid state; hirsutism; increased requirements for insulin or oral hypoglycemic agents in diabetic patients; manifestations of latent diabetes mellitus; menstrual irregularities; secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness; suppression of growth in children); fluid and electrolyte disturbances (negative nitrogen balance similar to protein catabolism; musculoskeletal (aseptic necrosis of femoral and humeral heads; loss of muscle mass; muscle weakness; osteoporosis; pathologic fracture of long bones; steroid myopathy; tendon rupture; vertebral compression fractures); neurological (convulsions; headache; increased intracranial pressure with papilledema (pseudotumor cerebri) usually following discontinuation of treatment; psychiatric disorders; vertigo); ophthalmic (exophthalmos; glaucoma; increased intraocular pressure; posterior subcapsular cataracts); increased appetite; malaise; nausea; and weight gain.

The National Heart, Lung, and Blood Institute (NHLBI) recommended dosing for systemic prednisone, prednisolone and dexamethasone is 40 to 60 mg/day in divided doses (4 to 60 mg/m2bsa/day).

In pediatric patients, the initial dose of Millipred Oral Solution (10 mg Prednisolone per 5 mL) may vary depending on the specific disease entity being treated. The range of initial doses is 0.14 to 2 mg/kg/day in three or four divided doses (4 to 60 mg/m2bsa/day).

The standard regimen used to treat nephrotic syndrome in pediatric patients is 60 mg/m2/day given in three divided doses for 4 weeks, followed by 4 weeks of single dose alternate-day therapy at 40 mg/m2/day.

The initial dosage of Millipred Oral Solution (10 mg Prednisolone per 5 mL) may vary depending on the specific disease entity being treated. The range of initial doses is 0.14 to 2 mg/kg/day in three or four divided doses (4 to 60 mg/m2bsa/day).

In the treatment of acute exacerbations of multiple sclerosis, daily doses of 200 mg of prednisolone for a week followed by 80 mg every other day or 4 to 8 mg dexamethasone every other day for one month have been shown to be effective.

In pediatric patients, the initial dose of Millipred Oral Solution (10 mg Prednisolone per 5 mL) may vary depending on the specific disease entity being treated. The range of initial doses is 0.14 to 2 mg/kg/day in three or four divided doses (4 to 60 mg/m2bsa/day).

The standard regimen used to treat nephrotic syndrome in pediatric patients is 60 mg/m2/day given in three divided doses for 4 weeks, followed by 4 weeks of single dose alternate-day therapy at 40 mg/m2/day.

The National Heart, Lung, and Blood Institute (NHLBI) recommended dosing for systemic prednisone, prednisolone or methylprednisolone in children whose asthma is uncontrolled by inhaled corticosteroids and long-acting bronchodilators is 1-2 mg/kg/day in single or divided doses. It is further recommended that short course, or “burst” therapy, be continued until a child achieves a peak inspiratory flow rate of 80% of his or her personal best or symptoms resolve. This usually requires 3 to 10 days of treatment, although it can take longer.

There is no evidence that tapering the dose after improvement will prevent a relapse.

For the purpose of comparison, 5 mL of Millipred Oral Solution (13.4 mg Prednisolone sodium phosphate) is equivalent to the following milligram dosage of the various glucocorticoids:

<table>
<thead>
<tr>
<th>Cortisone</th>
<th>50</th>
<th>Triamcinolone</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocortisone</td>
<td>40</td>
<td>Paramethasone</td>
<td>4</td>
</tr>
<tr>
<td>Prednisolone</td>
<td>10</td>
<td>Betamethasone</td>
<td>1.5</td>
</tr>
<tr>
<td>Prednisone</td>
<td>10</td>
<td>Dexamethasone</td>
<td>1.5</td>
</tr>
<tr>
<td>Methylprednisolone</td>
<td>8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

These dose requirements apply only to oral or intravenous administration of these compounds. When these substances or their derivatives are injected intramuscularly or into joint spaces, their relative properties may be greatly altered.

HOW SUPPLIED
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The initial dosage of Millipred Oral Solution (10 mg Prednisolone per 5 mL) may vary from 2.5 mL to 30 mL (5 to 60 mg prednisolone base) 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, Millipred Oral Solution (10 mg Prednisolone per 5 mL) should be discontinued and the patient placed on 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 drug dosage in small decrements 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 Millipred Oral Solution (10 mg Prednisolone per 5 mL) 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.

NDC 16477-510-08 8 fl oz (237 mL) bottle
Dispense in tight, light-resistant glass or PET plastic containers as defined in the USP. Store at 20°-25°C (68°-77°F). [See USP Controlled Room Temperature]. Keep tightly closed and out of the reach of children.

Manufactured for Laser Pharmaceuticals, LLC, Greenville, SC 29615 by Pharmaceutical Associates, Inc., Greenville, SC 29605
R 03/08
Millipred™ Tablets (prednisolone tablets USP, 5 mg) Rx only

DESCRIPTION
Glucocorticoids are adrenocortical steroids, both naturally occurring and synthetic, which are readily absorbed from the gastrointestinal tract. Prednisolone is a white crystalline powder, very slightly soluble in water. It is designated chemically as 1,4-diene-3,20-dione, 11,17,21-trihydroxy-(11β). The structural formula is represented below:

![Chemical Structure]

Allergic conjunctivitis; Keratitis; Allergic corneal marginal ulcers; Herpes
inflammatory processes involving the eye and its adnexa such as:

6. Ophthalmic diseases.
- Contact dermatitis; Atopic dermatitis; Drug hypersensitivity reactions.

conditions intractable to adequate trials of conventional treatment:

5. Allergic states.
- Seborrheic dermatitis.

4. Dermatologic diseases.
- Therapy in selected cases of: Systemic lupus erythematosus; Acute
traumatic osteoarthritis; Synovitis of osteoarthritis; Epicondylitis.
- Bursitis; Acute nonspecific tenosynovitis; Acute gouty arthritis; Post-

2. Rheumatic disorders.
- As adjunctive therapy for short term

importance).

CONTRAINDICATIONS
Systemic fungal infections

WARNINGS
Persons who are on drugs which suppress the immune system are more
sensitive 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 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 chickenpox or varicella zoster virus (chickenpox) mild, localized disease may appear during their use. There may be decreased resistance and infection 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 fungus or viruses.

Usage in Pregnancy
Since adequate human reproduction studies have not been done with corticosteroids in pregnant women, nursing mothers or women of childbearing potential 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 synthetic derivatives except when used in large doses. Dietary salt

reduction and potassium supplementation may be necessary. All complications of treatment with glucocorticoids are dependent on the size of the dose and the duration of treatment, a risk/benefit decision must be made in each individual case as to dose and duration of treatment and to whether or not intermittent therapy should be used.

ADVERSE REACTIONS
Fluid and Electrolyte Disturbances: Sodium retention; Fluid retention;
Congestive heart failure in susceptible patients; Potassium loss; Hypoalakmic acidosis; Hypertension.

Musculoskeletal
Muscle weakness; Steroid myopathy; Loss of muscle mass; Osteoporosis; Vertebro-lumbar 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 stomatitis.

Dermatologic
Impaired wound healing; Thin fragile skin; Petechiae and ecchymoses; Facial erythema; Increased sweating; May suppress reactions to skin tests.

Neurological
Convulsions; Increased intracranial pressure with papilledema (pseudotumor cerebri) usually after treatment; Vertigo; Headache.

Endocrine
Menstrual irregularities; Development of Cushingsoid state; Suppression
of growth in children; Secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery, or illness; Decreased carbohydrate tolerance; Manifestations of latent diabetes mellitus; Increased requirements for insulin or oral hypoglycemic agents in diabetics.

Ophthalmologic
Posterior subcapsular cataracts; Increased intracranial pressure; Glaucoma; Epiphora.

Other effects:
Negative nitrogen balance due to protein catabolism.

DOSEAGE AND ADMINISTRATION
The initial dosage of Millipred Tablets may vary from 5 mg 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 needed, a recovery period of time is a lack of satisfactory clinical response, prednisolone should be discontinued and the patient transferred to alternate 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 drug 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 in 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 prednisolone 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.

Alternate-Day Therapy
Alternate-Day Therapy is a corticosteroid dosing regimen in which twice the usual daily dose of corticosteroid is administered every other morning. The purpose of this mode of therapy is to provide the patient requiring long-term pharmacologic dose treatment with the beneficial effects of corticosteroids while minimizing certain undesirable effects, including pituitary-adrenal suppression, the Cushingoid state, corticoid withdrawal symptoms, and growth suppression in children. The rationale for this treatment schedule is based on two major premises: (a) the anti-inflammatory or therapeutic effect of corticoids persists longer than their physical presence and metabolic effects and (b) administration of the corticosteroid every other morning allows for re-establishment of more nearly normal hypothalamic-pituitary-adrenal (HPA) activity on the off-steroid day.

HOW SUPPLIED
Millipred Tablets (prednisolone tablets USP, 5 mg) are scored, round, peach tablets imprinted DAN 5059 supplied in bottles of 100 (NDC 16477-505-01) and 1000 (NDC 16477-505-10). Dispense in a well-closed container with child-resistant closure. Store at 25°C (77°F); [See USP controlled room temperature.]

Manufactured By: Watson Laboratories, Inc., Corona, CA 92880 USA
Distributed By: LASER PHARMACEUTICALS
Greenville, SC 29615

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