

## HYDROCORTISONE 10 MG

Tablets

### Composition

Each tablet contains 10 mg hydrocortisone.

### Action

Hydrocortisone is the main glucocorticoid secreted by the adrenal cortex. It exhibits anti-inflammatory and immunosuppressant properties inhibiting the clinical manifestations of disease in a wide range of disorders.

### Pharmacokinetics

Hydrocortisone is well absorbed after oral administration achieving peak blood concentrations after one hour. Plasma protein binding is greater than 90%. Hydrocortisone is primarily bound to plasma globulin. Globulins have a high affinity for hydrocortisone but low binding capacity. Plasma albumin may also bind hydrocortisone. Although albumin has a low affinity for hydrocortisone, it does have a high binding capacity.

Only unbound form of hydrocortisone is pharmacologically active. Hydrocortisone is metabolised in the liver by hydrogenation to tetrahydrocortisone and other degraded forms. These are then excreted in the urine as glucuronide conjugates, with a small proportion of unchanged hydrocortisone. The biological half-life of hydrocortisone is about 100 minutes.

### Indications

Hydrocortisone tablets are indicated in the following conditions:

#### 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.

#### Rheumatic Disorders

As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:

- Psoriatic arthritis.
- Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy).
- Ankylosing spondylitis.
- Acute and subacute bursitis.
- Acute nonspecific tenosynovitis.
- Acute gouty arthritis.
- Post-traumatic osteoarthritis.
- Synovitis of osteoarthritis.
- Epicondylitis.

#### Collagen Diseases

During an exacerbation or as maintenance therapy in selected cases of:

- Systemic lupus erythematosus.
- Systemic dermatomyositis (polymyositis).
- Acute rheumatic carditis.

#### Dermatologic Diseases

- Pemphigus.

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

### **Allergic States**

Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment:

- Seasonal or perennial allergic rhinitis.
- Serum sickness.
- Bronchial asthma.
- Contact dermatitis.
- Atopic dermatitis.
- Drug hypersensitivity reactions.

### **Ophthalmic Diseases**

Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa as:

- Allergic conjunctivitis.
- Keratitis.
- Allergic corneal marginal ulcers.
- Herpes zoster ophthalmicus.
- Iritis and iridocyclitis.
- Chorioretinitis.
- Anterior segment inflammation.
- Diffuse posterior uveitis and choroiditis.
- Optic neuritis.
- Sympathetic ophthalmia.

### **Respiratory Diseases**

- Symptomatic sarcoidosis.
- Loeffler's syndrome not manageable by other means.
- Berylliosis.
- Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy.
- Aspiration pneumonitis.

### **Hematologic Disorders**

- Idiopathic thrombocytopenic purpura in adults.
- Secondary thrombocytopenia in adults.
- Acquired (autoimmune) hemolytic anemia.
- Erythroblastopenia (RBC anemia).
- Congenital (erythroid) hypoplastic anemia.

### **Neoplastic Diseases**

For palliative management of:

- Leukemias and lymphomas in adults.
- Acute leukemia of childhood.

### **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.

### **Gastrointestinal Diseases**

To tide the patient over a critical period of the disease in:

- Ulcerative colitis.
- Regional enteritis.

### **Nervous System**

Acute exacerbations of multiple sclerosis.

### **Miscellaneous**

Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy.

Trichinosis with neurologic or myocardial involvement.

### **Contraindications**

Systemic fungal infections and known hypersensitivity to components.

Administration of live or live, attenuated vaccines are 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.

### **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.

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.

The use of hydrocortisone 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.

Persons who are on drugs that 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 unknown. If exposed to chicken pox, prophylaxis with varicella zoster immunoglobulin (VZIG) may be indicated.

If exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be indicated information for complete VZIG and IG for complete 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* (threadworm) infestation. In such patients, corticosteroid-induced immunosuppression may lead to *Strongyloides* hyperinfection and dissemination with widespread larval migration, often accompanied by severe enterocolitis and potentially fatal gram-negative septicemia.

### **Pregnancy**

#### *Category C*

Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

### **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, Tendon rupture, particularly of the Achilles tendon, 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.

Increases in alanine transaminase (ALT, SGPT), aspartate transaminase (AST, SGOT) and alkaline phosphatase have been observed following corticosteroid treatment. These changes are usually small, not associated with any clinical syndrome and are reversible upon discontinuation.

### **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 reinstated. 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, to severe depression, to frank psychotic manifestations. In addition, 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.

Growth and development of infants and children on prolonged corticosteroid therapy should be carefully observed.

Kaposi's sarcoma has been reported to occur in patients receiving corticosteroid therapy. Discontinuation of corticosteroids may result in clinical remission.

Although controlled clinical trials have shown corticosteroids to be effective in speeding the resolution of acute exacerbations of multiple sclerosis, they do not show that corticosteroids affect the ultimate outcome or natural history of the disease. The studies do show that relatively high doses of corticosteroids are necessary to demonstrate a significant effect.

Since complications of treatment with glucocorticosteroids 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 as to whether daily or intermittent therapy should be used.

Information for the Patient: Persons who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chicken pox or measles.

Patients should also be advised that if they are exposed, medical advice should be sought immediately.

### **Drug Interactions**

The pharmacokinetic interactions listed below are potentially clinically important. Drugs that induce hepatic enzymes such as phenobarbital, phenytoin, and rifampin may increase the clearance of corticosteroids and may require increases in corticosteroid dose to achieve the desired response.

Drugs such as troleandomycin and ketoconazole may inhibit the metabolism of corticosteroids and thus decrease their clearance. Therefore, the dose of corticosteroid should be titrated to avoid steroid toxicity.

Corticosteroids may increase the clearance of chronic high dose aspirin. This could lead to decreased salicylate serum levels or increase the risk of salicylate toxicity when corticosteroid is withdrawn. Aspirin should be used cautiously in conjunction with corticosteroids in patients suffering from hypoprothrombinemia.

The effect of corticosteroids on oral anticoagulants is variable. There are reports of enhanced as well as diminished effects of anticoagulants when given concurrently with corticosteroids. Therefore, coagulation indices should be monitored to maintain the desired anticoagulant effect.

### **Dosage and Administration**

The initial dosage may vary from 20 mg to 240 mg of hydrocortisone 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, there is a lack of satisfactory clinical response, hydrocortisone should be discontinued, and the patient transferred to other appropriate therapy. It should be emphasized that dosage requirements are variable and must be individualized based on 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 hydrocortisone 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.

**Multiple Sclerosis**

In treatment of acute exacerbations of multiple sclerosis, daily doses of 200 mg of Prednisolone for a week followed by 80 mg every other day for 1 month have been shown to be effective (20 mg of hydrocortisone is equivalent to 5 mg of Prednisolone).

**Presentation**

Box of 50 Tablets