DESCRIPTION
Hydrocortisone Tablets, USP contain hydrocortisone which is a glucocorticoid. Hydrocortisone and cortisone are adrenocortical steroids, both naturally occurring and synthetic, which are readily absorbed from the gastrointestinal tract. Hydrocortisone (USP) is white or practically white, odorless, crystalline powder with a melting point of about 210°C (it is very slightly soluble in water and in other; sparingly soluble in acetone and in alcohol; slightly soluble in chloroform).

The chemical name for hydrocortisone is pregn-4-en-20-one,11,17,21-trihydroxy- (11β). Its molecular weight is 362.46 and the structural formula is as outlined below.

Hydrocortisone tablets are available for oral administration in three strengths: each tablet contains either 5 mg, 10 mg, or 20 mg of hydrocortisone. Inactive ingredients: colloidal silica, microcrystalline cellulose, sodium lauryl sulfate, starch, and glycollate.

ACTIONS
Naturally occurring glucocorticoids (hydrocortisone and cortisone) which also have salt-retaining properties, are used as replacement therapy in adrenocortical deficiencies. Their synthetic analogs are primarily used for their potent anti-inflammatory effects in a variety of dermatologic, ophthalmic, and other conditions. Hydrocortisone causes profound and varied metabolic effects. In addition, they modify the body’s immune responses to diverse stimuli.

INDICATIONS AND USAGE
Hydrocortisone tablets are indicated in the following conditions:

1. 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 absence of adrenal cortex
   - Adrenal hypoplasia congenita

2. Rheumatic Disorders
   - Adrenocortical insufficiency in children and adults (to counteract the deleterious effects of adrenocortical insufficiency when used in conjunction with appropriate mineralocorticoids)
   - Psoriatic arthropathy
   - Rheumatoid arthritis; including juvenile rheumatoid arthritis (selected cases may require long-term maintenance therapy)
   - Arthropathy associated with acne
   - Acne and subacute lichen planus
   - Acne nonparasitic lichen planus
   - Acne guttate
   - Posttraumatic osteoarthritis
   - Symptomatic osteoarthritis
   - Eczematoid dermatitis

3. Skin Disorders
   - During exacerbation or as maintenance therapy in selected cases of:
     - Systemic lupus erythematosus
     - Systemic dermatomyositis (polymyositis)
   - Acute rheumatic fever

4. Dermatologic Diseases
   - Periorchitis
   - Bullous dermatitis herpetiformis
   - Severe eczema
   - Stevens-Johnson syndrome
   - Exfoliative dermatitis
   - Mycosis fungoides
   - Severe psoriasis

5. Allergic States
   - Contact or photodynamic 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

6. Ophthalmic Diseases
   - Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as:
     - Keratitis
     - Allergic conjunctivitis/marginal ulcer
     - Herpes zoster ophthalmicus
     - Viral keratoconjunctivitis
     - Chronic keratitis
     - Anterior segment inflammation
     - Diffuse posterior uveitis and choroiditis
     - Optic neuritis
     - Sympathethritis

7. Respiratory Diseases
   - Symptomatic sarcoidosis
   - Intractable asthma
   - Fluid and electrolyte disturbances: huffing or disseminated pulmonary tuberculosis when used concurrently with appropriate antimycobacterial chemotherapy
   - Aspiration pneumonitis

8. Hematologic Disorders
   - Idiopathic thrombocytopenic purpura in adults
   - Secondary thrombocytopenia in adults
   - Acquired (autoimmune) hemolytic anemia
   - Myeloid sarcoma (RBC anemia)
   - Congenital (thyroid) hypoplastic anemia

9. Neoplastic Diseases
   - Carcinoma of the breast, bronchial carcinoma, and carcinoma of the lung
   - Leukemia and lymphoma in adults
   - Acute leukemias of childhood

10. Edematous States
    - To induce a diuresis or reversal of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus.

11. Gastrointestinal Diseases
    - To tide the patient over a critical period of the disease in:
      - Ulcerative colitis
      - Regional enteritis

12. Nervous System
    - Acute exacerbations of multiple sclerosis

13. Miscellaneous
    - Tuberculous meningitis with subarachnoid block or impingement block when used concurrently with appropriate antimycobacterial chemotherapy

CONTRAINDICATIONS
Systemic fungal infections and known hypersensitivity to any component

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 the signs and symptoms of infection. In patients on corticosteroid therapy, these patients should receive chemoprophylaxis.

There may be decreased resistance and liability to local infections 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 established risk of secondary adrenal insufficiency due to drug or stress.

Usage in Pregnancy: Since adequate human reproduction studies have not been done with corticosteroids, the use of these drugs to nursing mothers may be considered. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy may exhibit some signs of withdrawal. Congenital deformities, including cleft palate, have been described in infants of mothers who were on corticosteroids during the latter stages of gestation. This incidence is no greater than that for a similar population not treated with corticosteroids.

Usage in Children: Growth and development of infants and children on prolonged corticosteroid therapy should be carefully observed.

General Precautions
Drugs of this class, when used in high dosage, may cause hypokalemia with increased risk of secondary ocular infections due to fungi or viruses.

Usage during Pregnancy: Care should be taken when giving corticosteroids to pregnant women during the last months of the pregnancy, because of the risk of iatrogenic adrenal suppression in the newborn. Acute adrenal insufficiency in the newborn could result in adrenal crisis and death. Corticosteroids should be used cautiously in patients with ocular herpes simplex because they are considered to be antiviral drugs. The contribution of corticosteroids to this risk is not known.

Usage in Children: In children, symptoms of growth delay may occur. The possibility of a slight growth hormone deficiency with prolonged corticosteroid therapy should be considered. Growth and development of infants and children on prolonged corticosteroid therapy should be carefully observed.

Usage during Pregnancy: Care should be taken when giving corticosteroids to pregnant women during the last months of the pregnancy, because of the risk of iatrogenic adrenal suppression in the newborn. Acute adrenal insufficiency in the newborn could result in adrenal crisis and death.

Usage in Children: In children, symptoms of growth delay may occur. The possibility of a slight growth hormone deficiency with prolonged corticosteroid therapy should be considered.

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Usage during Pregnancy: Care should be taken when giving corticosteroids to pregnant women during the last months of the pregnancy, because of the risk of iatrogenic adrenal suppression in the newborn. Acute adrenal insufficiency in the newborn could result in adrenal crisis and death.

Usage in Children: In children, symptoms of growth delay may occur. The possibility of a slight growth hormone deficiency with prolonged corticosteroid therapy should be considered.
Gastrointestinal
- Peptic ulcer with possible perforation and hemorrhage
- Pancreatitis
- Abdominal distention
- Ulcerative esophagitis

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

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

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

Ophthalmic
- Posterior subcapsular cataracts
- Increased intraocular pressure
- Glaucoma
- Exophthalmos

Metabolic
- Negative nitrogen balance due to protein catabolism

DOSAGE AND ADMINISTRATION
The initial dosage of hydrocortisone tablets 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 of time 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 ON THE BASIS OF THE DISEASE UNDER TREATMENT AND THE RESPONSE OF THE PATIENT. After a satisfactory 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).

HOW SUPPLIED
Hydrocortisone Tablets, USP 5 mg are white, scored, round tablets debossed “5” on one side and debossed “V” on the reverse side; and are supplied as follows:
- Bottles of 10: NDC 0003-3889-10
- Bottles of 50: NDC 0003-3889-19
- Bottles of 100: NDC 0003-3889-21
- Bottles of 500: NDC 0003-3889-28
- Bottles of 1000: NDC 0003-3889-32

Hydrocortisone Tablets, USP 10 mg are white, scored, round tablets debossed “10” on one side and debossed “V” on the reverse side; and are supplied as follows:
- Bottles of 10: NDC 0003-3900-10
- Bottles of 50: NDC 0003-3900-19
- Bottles of 100: NDC 0003-3900-21
- Bottles of 500: NDC 0003-3900-28
- Bottles of 1000: NDC 0003-3900-32

Hydrocortisone Tablets, USP 20 mg are white, scored, round tablets debossed “20” on one side and debossed “V” on the reverse side; and are supplied as follows:
- Bottles of 10: NDC 0003-3901-10
- Bottles of 100: NDC 0003-3901-21
- Bottles of 500: NDC 0003-3901-28
- Bottles of 1000: NDC 0003-3901-32

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Manufactured by QUALITEST PHARMACEUTICALS
Huntsville, AL 35811

File Name: 8182192 REV 5/13 R2 Back
Date: 05/14/13
Graphic Tech.: BP
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