Deltasone®

Prednisolone Sodium Phosphate BP

Oral Solution

COMPOSITION:

Deltasone® Oral Solution: Each 5mL oral solution contains Prednisolone 5mg. **DESCRIPTION:**

Deltasone® is the preparation of prednisolone, a glucocorticoid, which is readily absorbed from the gastrointestinal tract.

INDICATIONS:

Treatment of palpebral and bulbar conjunctivitis; corneal injury from chemical, radiation, or foreign body penetration; endocrine disorders, rheumatic disorders, collagen diseases, dermatological diseases, allergic states, ophthalmic diseases; respiratory diseases, hematological disorders, neoplastic diseases, edematous states, and pastrointestinal diseases.

DOSAGE AND ADMINISTRATION:

Dosage depends upon condition being treated and response of patients; dosage for children and infants should be based on severity of the disease and response of the patient rather than on strict adherence to dosage indicated by age, weight or body surface area.

Children:

Acute asthma: Oral: 1-2 mg/kg/day in divided dosage 1-2 times per day for 3-5 days. Anti-inflammatory or immunosuppressive dose: Oral: 0.1-2 mg/kg/day in divided doses 1-4 times per day.

Nephrotic syndrom: Oral:

Initial (first 3 episodes): 2 mg/kg/day (maximum: 80 mg per day) in divided doses 3 - 4 times per day until urine is protein free for 3 consecutive days (maximum 28 days); followed by 1-1.5 mg /kg/day given every other day for 4 weeks. Maintenance: 0.5-1 mg /kg/day given every other day for 3-6 months

Adults:

Oral: 5-60 mg/day

Rheumatoid arthritis: Oral: Initial, 5 -7.5 mg/day; adjust dose as necessary. Elderly: Use lowest effective dose.

Alter 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.

SIDE-EFFECTS:

>10%

Central nervous system: Insomnia, nervousness.

Gastrointestinal: Increased appetite, indigestion.

1% to 10%

Dermatologic: Hirsutism

Endocrine and metabolic: Diabetes mellitus Neuromuscular & skeletal: Arthralgia

Ocular. Glaucoma Respiratory: Epistaxis

DRUG INTERACTIONS:

Increased Effect: Systemic: The combined use of cyclosporin and Prednisolone may result, in elevated levels of both agents.

Decreased effect: Systemic: Decreased effect of corticosteroids with barbiturates, amino-glutethimide phenytoin and rifampicin. Decreased effect of salicylates. Vaccine and toxoids. Prednisolone may decrease the effect of isoniazid, warferin or IUD contraceptives.

WARNINGS:

Persons who are on drugs which suppress the immune system are more susceptible 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.

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 childbearing 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 hypoadrenalism.

CONTRAINDICATIONS:

Systemic fungal infections.

PHARMACEUTICAL PRECAUTION:

Store in a cool and dry place, away from light. Keep all medicines out of the reach of children.

PACKAGE QUANTITIES:

Deltasone® Oral Solution: Each bottle contains 50 ml & 100ml oral solution.



Updated : December, 2015 C-Code : 105214233/V 01

Deltasone®

Prednisolone USP

DESCRIPTION:

Deltasone* is the Preparation of prednisolone, a glucocorticoid, which is readily absorbed from the gastrointestinal tract.

Deltasone® 5 mg: Each tablet contains 5 mg Prednisolone USP

Deltasone®10 mg: Each tablet contains 10 mg Prednisolone USP

Deltasone® 20 mg: Each tablet contains 20 mg Prednisolone USP

INDICATIONS:

Treatment of palpebral and bulbar conjunctivitis; corneal injury from chemical, radiation or foreign body penetration, endocrine disorders, rheumatic disorders, collagen diseases, dermatological diseases, allergic states, ophthalmic diseases, respiratory diseases, hematological disorders, neoplastic diseases, edematous states and gastrointestinal diseases.

DOSAGE AND ADMINISTRATION:

Dosage depends upon condition being treated and response of patients; dosage for children and infants should be based on severity of the disease and response of the patient rather than on strict adherence to dosage indicated by age, weight or body surface area.

Childrer

Acute asthma: Oral: 1-2 mg/Kg/day in divided dosage 1-2 times per day for 3-5 days. Anti-inflammatory or immunosuppressive dose: Oral: 0.1-2 mg/kg/day in divided doses 1-4 times per day.

Nephrotic syndrom: Oral:

Initial (first 3 episodes): 2 mg/Kg/day (maximum: 80 mg per day) in divided doses 3 - 4 times per day until urine is protein free for 3 consecutive days (maximum 28 days); followed by 1-1.5 mg/Kg/day given every other day for 4 weeks.

Maintenance: 0.5-1 mg /Kg/day given every other day for 3-6 months

Adults:

Oral: 5-60 mg/day

Rheumatoid arthritis: Oral: Initial: 5 -7.5 mg/day; adjust dose as necessary.

Elderly: Use lowest effective dose.

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.

SIDE EFFECTS:

>10%

Central nervous system: Insomnia, nervousness.

Gastrointestinal: Increased appetite, indigestion.

1% to 10%

Dermatologic: Hirsutism

Endocrine and metabolic: Diabetes mellitus

Neuromuscular & skeletal: Arthralgia

Ocular: Glaucoma

Respiratory: Epistaxis

DRUG INTERACTIONS:

Increased Effect: Systemic: The combined use of cyclosporine and prednisolone may result in elevated levels of both agents.

Decreased Effect: Systemic: Decreased effect of corticosteroids with barbiturates, amino-glutethimide phenytoin and rifampicin. Decreased effect of salicylates, vaccine and toxoids. Prednisolone may decrease the effect of isoniazid, warferin or IUD contraceptives.

WARNINGS:

Persons who are on drugs which suppress the immune system are more susceptible 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.

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 funqi 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 childbearing 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 hypoadrenalism.

CONTRAINDICATIONS:

Systemic fungal infections.

Pharmaceutical Precaution:

Store in a cool and dry place, away from light. Keep all medicines out of the reach of children.

Package Quantities:

Deltasone* 5 mg tablet: Box containing 10 X 50's, 10 X 25's tablets in blister pack.

Deltasone* 10 mg tablet: Box containing 10 X 10's tablets in blister pack.

Deltasone* 20 mg tablet: Box containing 5 X 10's tablets in blister pack.



Updated: April, 2015 C-Code: 105212523/V01