# Oradexon Chapha

**paediatric elixir**

**for oral use**

**Composition**
Each ml contains:
0,05 mg dexamethasone.

**Characteristics**
Dexamethasone is a synthetic glucocorticoid which is easily absorbed from the gastro-intestinal tract. It has 7 times the anti-inflammatory potency of prednisolone. Like other glucocorticoids, dexamethasone also has anti-allergic, anti-toxic, anti-shock, anti-pyretic and immunosuppressive properties. Dexamethasone has practically no water and salt-retaining properties. Because of the long biological half-life (36–54 hours), dexamethasone is especially indicated in conditions where continuous glucocorticoid action is desired.
Oradexon Chapha elixir is a pleasant-tasting liquid. Moreover, the active ingredient can be accurately dosed. This makes product especially suitable for paediatric use, e.g. in the treatment of adrenogenital syndromes.

**Indications**
Oradexon Chapha elixir has the same indications as the other glucocorticoids, though chiefly in the paediatric field, including:
congenital and acquired adrenal cortical insufficiency, adrenogenital syndrome, in serious cases of rheumatoid arthritis (Still's disease), acute rheumatic carditis, nephrotic syndrome with minimal change lesions, hypersensitivity reactions to drugs or chemicals, insect stings and bites, severe hay-fever, Stevens-Johnson syndrome, prevention of scars and sympathetic ophthalmia caused by eye surgery and eye injuries, oesophagitis corrosiva, thrombocytopenic purpura, auto-immune haemolytic anaemia, acute lymphocytic leukaemia, Hodgkin's disease, aplastic anaemia, in selected cases of myastenia gravis, in tuberculous meningitis to prevent obstruction of the flow of cerebrospinal fluid, severe hypervitaminosis-D, idiopathic infantile hypercalcaemia, persistent hypoglycaemia of the newborn.

**Dosage**
The following dosages are given as a guide for children up to 5 years of age. In certain conditions (e.g. nephrotic syndrome) a much higher dosage may be needed.

| Age in years | Day of treatment | | | | |
|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | After the 4th day |
| 1 | 4 x 2,5 ml<br>10 ml | 3 x 2,5 ml<br>7,5 ml | 2 x 2,5 ml<br>5 ml | 1 x 2,5 ml<br>2,5 ml | Continued treatment with a maintenance dose is necessary |
| 2 | 4 x 4 ml<br>16 ml | 3 x 4 ml<br>12 ml | 2 x 4 ml<br>8 ml | 1 x 4 ml<br>4 ml | in many cases. This dose should be determined |
| 5 | 4 x 8 ml<br>32 ml | 3 x 8 ml<br>24 ml | 2 x 8 ml<br>16 ml | 1 x 8 ml<br>8 ml | by the attending physician. |

Older children are preferably given Oradexon Organon tablets. If for any reason (such as intolerance to tablets or difficulty in swallowing) they are given Oradexon Chapha elixir, the following dosages are advised:

| Age in years | Day of treatment | | | | |
|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | After the 4th day |
| 8 | 4 x 12 ml<br>48 ml | 3 x 12 ml<br>36 ml | 2 x 12 ml<br>24 ml | 1 x 12 ml<br>12 ml | Continued treatment with a maintenance dose is necessary |
| 12 | 4 x 15 ml<br>60 ml | 3 x 15 ml<br>45 ml | 2 x 15 ml<br>30 ml | 1 x 15 ml<br>15 ml | in many cases. This dose should be determined by the attending physician. |

**Administration**
Oradexon Chapha elixir should be taken orally.
Inside the small measuring beaker on this bottle of Oradexon Chapha elixir is a plastic collar which enables the contents to be poured without spilling.
The beaker is marked at 2, 2.5, 3, 4, 5, 8, 10, 12 and 15 ml for the accurate measurement of all prescribed doses. When the bottle is first opened attach the pouring collar inside the neck of the bottle. After measuring out the required quantity close the bottle by replacing the screw-cap leaving the pouring collar in position.
Unless the attending physician prescribes otherwise, one should – according to the daily rhythm of the adrenal cortex – preferably give the total daily dosage once, between 8 and 10 o'clock in the morning.

**Contra-indications**
- Gastric and duodenal ulcers.
- Systemic fungal infections.
- Certain viral infections, e.g. varicella and herpes genitales infections.
- Glaucoma.
- Hypersensitivity to glucocorticoids.

In general no contra-indications apply in conditions where the use of glucocorticoids may be life-saving.

**Warning and precautions**

- Patients with the following conditions should be monitored:
  - latent or overt cardiac failure, renal dysfunction, hypertension, epilepsy or migraine, since glucocorticoids may induce fluid retention;
  - osteoporosis, since glucocorticoids have a negative effect on the calcium balance;
  - a history of psychotic illness;
  - latent tuberculosis, since glucocorticoids may induce reactivation;
  - certain parasitic infestations, in particular amoebiasis;
  - incomplete statural growth, since glucocorticoids on prolonged administration may accelerate epiphyseal closure.
- Glucocorticoid therapy is non-specific, suppresses the symptoms and signs of disease and decreases the resistance to infections. Appropriate antimicrobial therapy should accompany glucocorticoid therapy when necessary, e.g. in tuberculosis, and viral and fungal infections of the eye.
- If a live vaccine is to be administered it should be borne in mind that glucocorticoids exert an immunosuppressive effect.
- Patients on long-term glucocorticoid therapy should be regularly examined for increased intra-ocular pressure and posterior subcapsular cataracts.
- Patients on long-term glucocorticoid therapy should be regularly examined with respect to their glucose metabolism.
- Before, during and after stressful situations, dosage may need to be increased in patients currently on glucocorticoids or resumed in patients who have undergone prolonged glucocorticoid treatment in the previous year.
- Discontinuation of prolonged therapy should be carried out by gradual reduction of dosage and under strict medical supervision, since withdrawal may result in acute exacerbation of the disease and acute adrenocortical insufficiency.

**Interactions**

- Patients treated concomitantly with glucocorticoids and one of the following drugs should be monitored:
  - diuretics and/or cardiac glucosides, since potassium loss may be enhanced. This is a particular risk in patients using cardiac glucosides, since hypokalaemia increases the toxicity of these drugs;
  - antidiabetics, since glucocorticoids may impair glucose tolerance, thereby increasing the need for antidiabetic drugs;
  - non-steroidal anti-inflammatory drugs, since the incidence and/or severity of gastro-intestinal ulceration may increase;
  - oral anticoagulants, since glucocorticoids may alter the need for these drugs.
- Glucocorticoids may be less effective when used concomitantly with liver enzyme-inducing drugs, such as rifampicin, ephedrine, barbiturates, phenytoin and primidone.
- If patients undergoing long-term therapy with glucocorticoids are concomitantly given salicylates, any reduction in glucocorticoid dosage should be made with caution, since salicylate intoxication has been reported in such cases.
- Antacids, especially those containing magnesium trisilicate, have been reported to impair the gastro-intestinal absorption of glucocorticoids.
  Therefore, doses of one agent should be spaced as far as possible from the other.

**Adverse reactions**

- Adverse reactions, associated with prolonged systemic glucocorticoid therapy, are unlikely when high doses are administered over a short period of time. Nevertheless, gastric and duodenal ulceration, with possible perforation and haemorrhage, may occasionally occur.
- The following adverse reactions have been associated with prolonged systemic glucocorticoid therapy:
  - Endocrine and metabolic disturbances: Cushing-like syndrome, hirsutism, menstrual irregularities, premature epiphyseal closure, secondary adrenocortical and pituitary unresponsiveness, decreased glucose tolerance, negative nitrogen and calcium balance.
  - Fluid and electrolyte disturbances: sodium and fluid retention, hypertension, potassium loss, hypokalaemic alkalosis.
  - Musculo-skeletal effects: myopathy, abdominal distention, osteoporosis, aseptic necrosis of femoral and humeral heads.
  - Gastro-intestinal effects: gastric and duodenal ulceration, perforation and haemorrhage.
  - Dermatologic effects: impaired wound healing, skin atrophy, striae, petechiae and ecchymoses, bruising, facial erythema, increased sweating, acne.
  - C.N.S. effects: psychic disturbances ranging from euphoria to frank psychotic manifestations, convulsions, in children pseudotumor cerebri (benign intracranial hypertension) with vomiting and papilloedema.
  - Ophtalmic effects: glaucoma, increased intraocular pressure, posterior subcapsular cataracts.
  - Immunosuppressive effects: increased susceptibility to infections, decreased responsiveness to vaccination and skin tests.

**Note**

The pleasant taste of Oradexon Chapha elixir makes it imperative to keep the bottle out of reach of children.

Préparé au Liban par
**CHAPHA ( Chalhoub Pharmaceuticals) S.A.L.**
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