

DEXAMETHASONE KERN PHARMA

Dexamethasone (as sodium phosphate) 4mg/ml
solution for injection

חברת אמ.בי.איי פארמה מבקשת להודיע על שינויים שאושרו ברישום התכשיר והחמרות בעלון, כלהלן:

1. עדכון והרחבה של התוויה המאושרת.

נוסח התוויה המעודכנת:

Dexamethasone Kern Pharma is indicated in the treatment of:

Endocrine diseases such as nonsuppurative thyroiditis, hypercalcaemia associated with cancer and congenital adrenal hyperplasia.

- Allergy: Severe or disabling allergic conditions resistant to conventional treatments, as in: bronchial asthma, contact or atopic dermatitis, seasonal or perennial allergic rhinitis, hypersensitivity reactions to drugs.
- Ophthalmic: Serious inflammatory and allergic processes, acute and chronic, affecting the eyes, such as: iritis and iridocyclitis, chorioretinitis, choroiditis and diffuse posterior uveitis, optical neuritis, allergic conjunctivitis, allergic marginal corneal ulcers.
- Inflammatory Bowel dis.: Systemic treatment in exacerbations of ulcerative colitis and regional enteritis.
- Dermatological diseases (pemphigus, Stevens Johnson syndrome, exfoliative dermatitis, severe psoriasis and mycosis fungoides)
- Respiratory diseases (symptomatic sarcoidosis, berylliosis, Loeffler's syndrome)
- Haematological: acquired (autoimmune) haemolytic anaemia, idiopathic thrombocytopenic purpura in adult, pure red cell aplasia
- Nephrotic syndrome of the idiopathic type or that due to lupus erythematosus
- Cerebral oedema caused by brain tumor, neurosurgery, brain abscess, bacterial meningitis
- Collagen diseases: Active rheumatoid arthritis with severe progressive course, fast destructive remitting forms and / or extra-articular manifestations, Juvenile idiopathic arthritis with severe systemic-onset form (Still's disease) or locally with no control, rheumatic fever with carditis, dermatomyositis, polymyositis, SLE, temporal arteritis.
- Infectious Diseases: Bacterial meningitis – adjunct to antibiotics in suspected Pneumococcal meningitis and TB meningitis. Severe infectious diseases with toxic states (eg tuberculosis, typhoid, brucellosis; Only with simultaneous anti-infective therapy)
- Fetal lung maturation
- Chemotherapy – associated nausea and vomiting
- Multiple Myeloma – part of chemotherapy protocols (eg VAD)
- Prevention and treatment of acute mountain sickness/HACE

2. הוספת צורת מתן לשימוש תוך שרירי, I.M. התכשיר מאושר כעת למתן I.V, I.M.

3. החמרות בעלון לרופא, כמפורט להלן:

4.4 Special warnings and precautions for use

In post marketing experience tumor lysis syndrome (TLS) has been reported in patients with haematological malignancies following the use of dexamethasone alone or in combination with other chemotherapeutic agents. Patient at high risk of TLS, such as patients with high proliferative rate, high tumour burden, and high sensitivity to cytotoxic agents, should be monitored closely and appropriate precaution taken.

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

4.5 Interaction with other medicinal products and other forms of interaction

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects

4.8 Undesirable effects

Uncommon (between $\geq 1/1,000$ and $\leq 1/100$ of patients):

Unknown frequency (can not be estimated from the available data):

General disorders: Hiccups

Eye disorders: Chorioretinopathy; vision, blurred (see also section 4.4.)

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות. ניתן לקבל את העלון מודפס ע"י פניה לבעל הרישום, חברת אמ.בי.איי פרמה, טל. 09-7719903.

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