רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

XX 2022

Dexamethasone Kern pharma
Solution for injection/infusion

חברת אמ.בי.איי פארמה בע"מ מבקשת להודיע על הוספת גודל אריזה של 5mg/20ml עבור התכשיר שבנדון.
עלון התכשיר עודכן בהתאם.
כמו-כן, נבקש להודיע על עדכונים בעלון התכשיר, אשר כוללים מידע בטיחותי חדש.

התכשיר מכיל:

DEXAMETHASONE PHOSPHATE (AS SODIUM PHOSPHATE) 4MG/ML

צורת המתן: I.M, I.V

התווית התכשיר:

By intramuscular or intravenous route

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).
- Hematological: acquired (autoimmune) hemolytic anemia, idiopathic thrombocytopenic purpura in adult, pure red cell aplasia.
- Nephrotic syndrome of the idiopathic type or that due to lupus erythematosus.
- Cerebral edema 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 (e.g tuberculosis, typhoid, brucellosis; Only with simultaneous anti-infective therapy).
- Fetal lung maturation.
- Chemotherapy – associated nausea and vomiting.
- Multiple Myeloma – part of chemotherapy protocols (e.g VAD).
- Prevention and treatment of acute mountain sickness/HACE.

בהודעה זו כלולים העדכונים המהותיים בלבד. החמרות מסומנות בצהוב, תוספת טקסט מסומנת בקו תחתון, מחיקת טקסט מסומנת בקו חוצה.

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עדכונים בעלון לרופא נעשו בסעיפים הבאים

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml ampoule of Dexamethasone Kern Pharma contains dexamethasone phosphate 4 mg (as dexamethasone sodium phosphate, 4.37 mg), which is equivalent to 3.33 mg dexamethasone base.

Each 5 ml ampoule of Dexamethasone Kern Pharma contains dexamethasone phosphate 20 mg (as dexamethasone sodium phosphate, 21.85 mg) which is equivalent to 16.65 mg dexamethasone base.

4.4 Special warnings and precautions for use

The presence of joint effusion during corticosteroid treatment requires examination to exclude a septic process. A marked increase in pain accompanied by local swelling, extensive restriction of joint mobility, fever, and malaise is suggestive of septic arthritis. If this complication occurs and the diagnosis of joint infection is confirmed, appropriate antimicrobial therapy should be instituted.

Systemic corticosteroids should not be discontinued in patients who are already being treated with systemic (oral) corticosteroids for other reasons (e.g. patients with chronic obstructive pulmonary disease), but who do not require supplemental oxygen.

Hypertrophic cardiomyopathy

Cases of hypertrophic cardiomyopathy have been reported after systemic administration of corticosteroids, including dexamethasone, to premature infants. In most reported cases, this effect was reversible after withdrawal of treatment. Preterm infants treated with systemic dexamethasone should undergo diagnostic evaluation and monitoring of cardiac structure and function (section 4.8).

4.5 Interaction with other medicinal products and other forms of interaction

Dexamethasone can increase plasma levels of albendazole with possible inhibition of its effect, by inducing its hepatic metabolism.

4.6 Fertility, pregnancy and lactation

Pregnancy

Studies have shown an increased risk of neonatal hypoglycemia following pre-natal administration of a short course of corticosteroids, including dexamethasone, to women at risk of late pre-term delivery.

4.8 Undesirable effects

Unknown frequency (cannot be estimated from the available data):

Cardiac disorders: hypertrophic cardiomyopathy in premature babies (see section 4.4).

העלון מפורסם במאגר התרופות שבאתר משרד הבריאות: https://data.health.gov.il/drugs/index.html#!/byDrug
לחילופין, ניתן לקבלו מודפס באמצעות פניה לבעל הרישום, חברת אמ.בי.איי פארמה, ת.ד. 5061, קדימה
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