ANNEXURE – IV

Patient Information Leaflet

(Enclosed)

PATIENT INFORMATION LEAFLET
(DEEXA) DEXAMETHASONE SODIUM PHOSPHATE INJECTION USP 4 MG
[Dexamethasone Sodium Phosphate USP]

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your physician, health care provider or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist.

WHAT IS IN THIS LEAFLET:

1. WHAT DEXAMETHASONE SODIUM PHOSPHATE INJECTION IS AND WHAT IT IS USED FOR

It contain active ingredient dexamethasone sodium phosphate is an adrenocortical steroid anti-inammatory drug. It is a sterile, preserved, aqueous liquid injection of dexamethasone sodium phosphate in water for injection for intravenous (IV), intramuscular (IM), intra-articular, soft-tissue or intralesional use. It is used primarily as an anti-inflammatory or immunosuppressant agent in the treatment of a variety of diseases including those of allergic, dermatologic endocrine, hematologic, inflammatory, neoplastic, nervous system, renal, respiratory, rheumatic, and autoimmune origin. It may be used in management of cerebral edema, chronic swelling, as a diagnostic agent, diagnosis of Cushing's syndrome, antiemetic.

2. BEFORE YOU USE DEXAMETHASONE SODIUM PHOSPHATE INJECTION

Do not use it if you are allergic to dexamethasone sodium phosphate or any of the other ingredients of this medicine. It is contraindicated if you suffer from systemic fungal infections, cerebral malaria. Local injection of a glucocorticoid is contraindicated in bacteraemia and systemic fungal infections, unstable joints, infection at the injection site e.g. septic arthritis resulting form. If you are not sure, talk to your physician, pharmacist or nurse before having dexamethasone sodium phosphate injection. **Take special care with dexamethasone sodium phosphate injection:**

Warnings and Precautions: Talk to your physician before taking dexamethasone sodium phosphate injection. If you have now or have had in the past. **Adrenal suppression:** May cause hypercorticisni or suppression of hypothalamic-pituitary adrenal (HPA) axis, particularly in younger children or in patients receiving high doses for prolonged periods. Particular care is required when patients are transferred from systemic corticosteroids to inhaled products due to possible adrenal insufficiency or withdrawal from steroids, including an increase in allergic symptoms. **Immunosuppression:** Prolonged use of corticosteroids may also increase the incidence of secondary infection, mask acute infection (including fungal infections), prolong or exacerbate viral infections, or limit response to vaccines. **Adrenal insufficiency:** Dexamethasone does not provide adequate mineralocorticoid activity in adrenal insufficiency. The lowest possible

dose should be used during treatment; discontinuation and/or dose reductions should be gradual. **Cardiovascular disease:** Use with caution in patients with heart failure; long-term use has been associated with fluid retention and hypertension. **Diabetes:** Use with caution in patients with diabetes mellitus; may alter glucose production or regulation leading to hyperglycaemia. **Gastrointestinal disease:** Use with caution in patients with GI diseases (peptic ulcer, ulcerative colitis) due to perforation risk. **Head injury:** High-dose corticosteroids should not be used for the management of head injury. **Hepatic impairment**: Use with caution in patients with hepatic impairment, cirrhosis; long-term use has been associated with fluid retention. **Myasthenia gravis:** Use with caution in patients with myasthenia gravis; exacerbation of symptoms has occurred especially during initial treatment with corticosteroids. **Myocardial infarction (MI):** Use with caution following acute MI; corticosteroids have been associated with myocardial rupture. **Ocular disease:** Use with caution in patient with cataracts and/or glaucoma; increased intraocular pressure, open-angle glaucoma and cataracts have occurred with prolonged use. Consider routine eye exams in chronic use. **Osteoporosis:** Use with caution in patients with osteoporosis; high doses and/or long-term use of corticosteroids have been associated with increased bone loss and osteoporotic fractures. **Renal impairment:** Use with caution in patients with renal impairment; fluid retention may occur. **Seizure disorders:** Use with caution in patients with a history of seizure disorder; seizures have been reported with adrenal crisis. **Thyroid disease:** Changes in thyroid status may necessitate dosage adjustments; metabolic clearance of corticosteroids increases in hyperthyroid patients and decreases in hypothyroid ones.**Discontinuation of therapy:** Withdraw therapy with gradual tapering of dose. **Elderly**: Because of the risk of adverse effects, systemic corticosteroids should be used cautiously in the elderly in the smallest possible effective dose for the shortest duration. **Pediatrics:** It should not be recommended, it may affect growth velocity; growth should be routinely monitored in pediatric patients.

Using other medicines: It can affect or be affected by other medicines you are using, some medicines may increase the effects of dexamethasone sodium phosphate injection. Rifampicin, rifabutin, ephedrine, carbamazepine, phenylbutazoe, phenobarbital, phenytoin, primidone, and aminoglutethimide enhance the metabolism of corticosteroids and its therapeutic effects may be reduced. The effects of anticholinesterases are antagonised by corticosteoids in myasthenia gravis. The desired effects of hypoglycaemic agents (including insulin, antihypertensive, cardiac glycosides and diuretics are antagonised by corticosteroids, an the hypokalaemic effects of acetazolamide, loop diuretics, thiazide diuretics and carbenoxol ne are enhanced. The effect of coumarin anticoagulants may be enhanced by concurrent corticosteroid therapy. The renal clearance of salicylates is increased by corticosteroid and steroid withdrawal may result in salicylate intoxication. There may be interaction with salicylates in patients with hypoprothrombinaemia. 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. **Using dexamethasone sodium phosphate injection with food and drink:** None. **Pregnancy and breast-feeding:** Before taking any medicine for advice consult to direction of physician. Pregnancy: It crosses the placenta; and is part ally metabolized to inactive metabolites by placental enzyme. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Use in breast-feeding:** Corticosteroids may pass into breast milk, although no data are available for dexamethasone. Infants of mothers taking high doses of systemic corticosteroids for prolonged periods may have a degree of adrenal suppression. Therefore, use is not recommended in women breast- feeding infants.

Driving and using machines: patients should not drive or use machinery if you are affected by the administration of dexamethasone sodium phosphate injection. **Important information about some of the ingredients of dexamethasone sodium phosphate injection** contain excipients with

known side effect: Each ml contains, Propyl-hydroxybenzoate and methyl-hydroxybenzoate: which may cause allergic reactions (possibly delayed) and exceptionally, bronchospasm. Sodium metabisulphate may rarely cause severe hypersensitivity reactions.

3. HOW TO USE DEXAMETHASONE SODIUM PHOSPHATE INJECTION

Always take your dose of dexamethasone sodium phosphate injection exactly as qualified person, like a physician or a nurse has told you, you should check with your physician, health care provider or pharmacist if you are not sure. Do not change your usual dose without talking to your physician. **How dexamethasone sodium phosphate injection will be given to you:** Dosage must be individualized on the basis of the disease and the response of the patient. **Method of administration:** For Intravenous (IV), Intramuscular (IM) Use Only. **Adults:** Usual adult initial dosage is 0.5 mg-20 mg a day. In emergencies, the usual dose of Dexamethasone sodium phosphate 4 mg/ml solution for injection by intravenous or intramuscular injection is 4 mg-20 mg (in shock use only the I.V. route). This dose may be repeated until adequate response is noted. After initial improvement, single doses of 2 mg-4 mg, repeated as necessary, should be sufficient. The total daily dosage usually need not exceed 80 mg, even in severe conditions. Cerebral oedema associated with malignancy: I.V.10 mg initially, then 4 mg by intramuscular injection every 6 hours as required for 2-4 days then gradually reduced and stopped over 5-7 days. **Mildly emetogenic therapy:** I.M or I.V.: 4 mg every 4-6 hours. **Treatment of shock:** Addisonian crisis/shock (e.g. adrenal insufficiency/responsive to steroid therapy): I.V: 4-10 mg as a single dose, which may be repeated if necessary. **Pediatric:** 200-400 micrograms/kg daily. **If you more dexamethasone sodium phosphate injection than you should:** Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much or that you will miss a dose. If you are concerned, talk to your doctor or nurse. **If you forget to dexamethasone sodium phosphate injection:** It is important to take dexamethasone sodium phosphate injection as prescribed by your physician. If you miss a dose. Do not take a double dose to make up for the forgotten dose. **If you stop using dexamethasone sodium phosphate injection:** It can be dangerous to have your treatment with dexamethasone Injection stopped abruptly. If you have any further questions on the use of this product, ask your physician, health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist. Following less frequent adverse effects have been reported with I.V/IM administration of dexamethasone sodium phosphate: Arrhythmia, bradycardia, cardiac arrest, cardiomyopathy, CHF, circulatory collapse, edema, hypertension, myocardial rupture (post-MI), syncope, thromboembolism, vasculitis. Depression, emotional instability, euphoria, headache, intracranial pressure increased, insomnia, malaise, mood swings, neuritis, personality changes, pseudotumor cerebr (usually following discontinuation), psychic disorders, seizure, vertigo. Acne, allergic dermatitis, alopecia, angioedema, bruising, dry skin, erythema, fragile skin, hirsutism, perianal pruritus (following LV. injection), petechiae, rash, skin atrophy, urticaria, wound healing impaired. Adrenal suppression, carbohydrate tolerance decreased, Cushing's syndrome, diabetes mellitus, glucose intolerance decreased, growth suppression (children), hyperglycemia, hypokalemic alkalosis, menstrual irregularities, negative nitrogen balance, pituitary-adrenal axis suppression, protein catabolism, sodium retention. Abdominal distention, appetite increased, gastrointestinal haemorrhage, gastrointestinal perforation, nausea, pancreatitis, peptic ulcer, ulcerative esophagitis, weight gain. Altered (increased or decreased) spermatogenesis. Post injection flare (intra-articular use),

thrombophlebitis. Arthropathy, aseptic necrosis (femoral and humoral heads), fractures, muscle mass loss, myopathy (particularly in conjunction with neuromuscular disease or neuromuscular-blocking agents), neuropathy, osteoporosis, parasthesia, tendon rupture, vertebral compression fractures, weakness. Cataracts, exophthalmos, glaucoma, and intraocular pressure increased. Miscellaneous: Abnormal fat deposition, anaphylactoid reaction, anaphylaxis, avascular necrosis, diaphoresis, hiccups, hypersensitivity, impaired wound healing, infections, Kaposi's sarcoma, moon face, secondary malignancy.

5. HOW TO STORE DEXAMETHASONE SODIUM PHOSPHATE INJECTION

Keep this medicine out of the sight and reach of children. Store below 30°C. Protect from light. Do Not Freeze. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. The aqueous liquid injection should be use immediately after first opening. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

6. FURTHER INFORMATION

It contain active substances as Dexamethasone sodium phosphate Eq. to dexamethasone phosphate USP. Methyl-hydroxybenzoate BP, Propyl-hydroxybenzoate BP, Sodium citrate BP, Sodium metabisulphite BP, Disodium edetate BP, Creatinine USP NF, Sodium hydroxide BP, Water for injections BP. Pack size: A clear colourless liquid filled in 2 ml transparent glass ampoule. Such 10 ampoules are packed in Paper-PVC blister pack. Such 10 Paper-PVC blister blisters are packed in a plain inner pack with packaging insert.

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