

PRESCRIBING INFORMATION

^{Pr}BETAJECT

Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension USP

(6mg/mL)

Sterile

Glucocorticoid

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THERAPEUTIC CLASSIFICATION

Glucocorticoid

PHARMACOLOGY

Betamethasone sodium phosphate and betamethasone acetate injectable suspension is a combination of soluble and slightly soluble betamethasone esters that provides potent anti-inflammatory, antirheumatic and antiallergic effects in the treatment of corticosteroid-responsive disorders. Prompt therapeutic activity is achieved by betamethasone sodium phosphate, which is absorbed quickly after injection. Sustained activity is provided by betamethasone acetate, which is only slightly soluble and becomes a repository for slow absorption, thereby controlling symptoms over a prolonged period.

INDICATIONS AND CLINICAL USE

BETAJECT is indicated as follows:

- IM injection in allergic, dermatologic, rheumatic, and other conditions responsive to systemic corticosteroids, including bursitis;
- Local injection into the affected tissues in bursitis and associated inflammatory disorders of tendons such as tenosynovitis, and inflammatory disorders of muscle such as fibrosis and myositis
- Intra-articular and periarticular injection in rheumatoid arthritis and osteoarthritis;
- Intralesional injection in various dermatologic conditions; and
- Local injection in certain inflammatory and cystic disorders of the foot.

CONTRAINDICATIONS

Betaject is contraindicated in patients:

- who are hypersensitive to any components of this product (see DOSAGE FORMS, COMPOSITION AND PACKAGING).
- with herpes simplex of the eye
- with systemic fungal infections.
- with vaccinia
- with cerebral malaria
- in idiopathic thrombocytopenia purpura when administered intramuscularly

Regional corticosteroid therapy is contraindicated in areas that are locally infected, although infection elsewhere in the body is not a contraindication to the use of corticosteroid regionally.

WARNINGS AND PRECAUTIONS

General

Strict aseptic technique is mandatory in the use of betamethasone sodium phosphate and betamethasone acetate injectable suspension. Betamethasone sodium phosphate and betamethasone acetate injectable suspension is not intended for intravenous or subcutaneous use.

Following intra-articular injection, a portion of the administered dose of betamethasone sodium phosphate and betamethasone acetate injectable suspension is absorbed systemically. In patients being treated concomitantly with peroral and parenteral corticosteroids, especially those receiving large doses, the systemic absorption of the drug should be considered in determining intra-articular dosage.

In patients on corticosteroid therapy subjected to unusual stress, increased dosage of rapidly acting corticosteroids before, during and after the stressful situation may be recommended.

The lowest possible dose of corticosteroid should be used to control the condition under treatment; when dosage reduction is possible, the reduction should be gradual.

With long-term corticosteroid therapy, transfer from parenteral to oral administration should be considered after weighing the potential benefits and risks.

Advise patients to inform subsequent physicians of the prior use of corticosteroids.

Corticosteroids should not be injected into unstable joints, infected areas or intervertebral spaces. Repeated injections into joints of osteoarthritis may increase joint destruction. Avoid injecting corticosteroids directly into the substance of tendons because delayed appearance of tendon rupture has resulted.

Following intra-articular corticosteroid therapy, care should be taken by the patient to avoid overuse of the joint in which symptomatic benefit has been obtained.

Examination of any joint fluid present is necessary to exclude a septic process. Local injection into a previously infected joint is to be avoided. A marked increase in pain and local swelling, further restriction of joint motion, fever and malaise are suggestive of septic arthritis. If the diagnosis of sepsis is confirmed, appropriate antimicrobial therapy should be instituted.

Cardiovascular/Renal

Literature reports suggest an apparent association between use of corticosteroids and left ventricular free wall rupture after a recent myocardial infarction; therefore, therapy with corticosteroids should be used with great caution in these patients.

As sodium retention with resultant edema and potassium loss may occur in patients receiving corticosteroids, these agents should be used with caution in patients with congestive heart failure, hypertension, or renal insufficiency.

Carcinogenesis

Kaposi's sarcoma has been reported to occur in patients receiving corticosteroid therapy, most often for chronic conditions. Discontinuation of corticosteroids may result in clinical improvement.

Endocrine and Metabolism

Average and large doses of corticosteroids can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium. These effects are less likely to occur with the synthetic derivatives except when used in large doses. Dietary salt restriction and potassium supplementation may be considered. All corticosteroids increase calcium excretion.

Drug-induced secondary adrenocortical insufficiency may be minimized by gradual dosage reduction. Such relative insufficiency may persist for months after discontinuation of therapy; therefore, if stress occurs during that period, corticotherapy should be reinstated. If the patient is receiving corticosteroids already, dosage may have to be increased. Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticosteroid should be administered concurrently.

There is an enhanced effect of corticosteroids in patients with hypothyroidism. Metabolic clearance of corticosteroids is decreased in hypothyroid patients and increased in hyperthyroid patients. Changes in thyroid status of the patient may necessitate adjustment in dosage.

Corticosteroids decrease bone formation and increase bone resorption both through their effect on calcium regulation (ie, decreasing absorption and increasing excretion) and inhibition of osteoblast function. This, together with a decrease in the protein matrix of the bone secondary to an increase in protein catabolism, and reduced sex hormone production, may lead to inhibition of bone growth in pediatric patients and the development of osteoporosis at any age. Special consideration should be given to patients at increased risk of osteoporosis (ie, postmenopausal women) before initiating corticosteroid therapy.

Fat embolism has been reported as a possible complication of hypercorticism.

Gastrointestinal

Corticosteroids should be used with caution in: nonspecific ulcerative colitis, if there is a probability of impending perforation, abscess or other pyogenic infection; diverticulitis, fresh intestinal anastomoses; active or latent peptic ulcer.

Hematologic

Use acetylsalicylic acid (ASA, Aspirin) cautiously in conjunction with corticosteroids in hypoprothrombinemia.

Hepatic/Biliary/Pancreatic

There is an enhanced effect of corticosteroids in patients with cirrhosis.

Immune

Rare instances of anaphylactoid/anaphylactic reactions with a possibility of shock have occurred in patients receiving parenteral corticosteroid therapy. Appropriate precautionary measures should be taken with patients who have a history of allergic reactions to corticosteroids.

While on corticosteroid therapy, patients should not be vaccinated against smallpox because of potential complications. Other immunization procedures should not be undertaken in patients receiving corticosteroids, especially high doses, because of possible hazards of neurological complications and lack of antibody response. However, immunization procedures may be undertaken in patients who are receiving corticosteroids as replacement therapy, e.g., for Addison disease.

Patients who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chickenpox or measles and, if exposed, to obtain medical advice. This is of particular importance in children.

Patients who are on corticosteroids are more susceptible to infections than are healthy individuals. Corticosteroids may mask some signs of infection and new infections may appear during use. There may be decreased resistance and inability to localize infection when corticosteroids are used. If corticosteroids have to be used in the presence of bacterial infections, institute appropriate vigorous anti-infective therapy.

Infection with any pathogen (viral, bacterial, fungal, protozoan, or helminthic) in any location of the body may be associated with the use of corticosteroids alone or in combination with other immunosuppressive agents. These infections may be mild to severe. With increasing doses of corticosteroids, the rate of occurrence of infectious complications increases.

Corticosteroids may exacerbate systemic fungal infections and therefore should not be used in the presence of such infections unless they are needed to control drug reactions. There have been cases reported in which concomitant use of amphotericin B and hydrocortisone was followed by cardiac enlargement and congestive heart failure.

Corticosteroid use may lead to activation of latent disease or an exacerbation of intercurrent infections due to pathogens, including those caused by Amoeba, Candida, Cryptococcus, Mycobacterium, Nocardia, Pneumocystis, and Toxoplasma.

It is recommended that latent amebiasis or active amebiasis be ruled out before initiating corticosteroid therapy in any patient who has spent time in the tropics or in any patient with unexplained diarrhea.

Similarly, corticosteroids should be used with great care in patients with known or suspected Strongyloides (threadworm) infestation. In such patients, corticosteroid-induced immunosuppression may lead to Strongyloides hyperinfection and dissemination with widespread

larval migration, often accompanied by severe enterocolitis and potentially fatal gram-negative septicemia.

Chickenpox and measles can have a more serious or even fatal course in patients on corticosteroids. In patients who have not had these diseases, particular care should be taken to avoid exposure. The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known. If exposed to chickenpox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. If exposed to measles, prophylaxis with immunoglobulin (IG) may be indicated. (See the respective package inserts for complete VZIG and IG prescribing information.) If chickenpox develops, treatment with antiviral agents should be considered.

The use of corticosteroids in active tuberculosis should be restricted to those cases of fulminating or disseminated tuberculosis in which the corticosteroid is used for management in conjunction with an appropriate antituberculous regimen. If corticosteroids are indicated in patients with latent tuberculosis or tuberculin reactivity, close observation is necessary since reactivation of the disease may occur. During prolonged corticosteroid therapy, patients should receive chemoprophylaxis. If rifampin is used in a chemoprophylactic program, its enhancing effect on metabolic hepatic clearance of corticosteroids should be considered; adjustment in corticosteroid dosage may be required.

Neurologic

Serious neurologic events, some resulting in death, have been reported with epidural injection of corticosteroids. Specific events reported include, but are not limited to, spinal cord infarction, paraplegia, quadriplegia, cortical blindness, and stroke. These serious neurologic events have been reported with and without use of fluoroscopy. The safety and effectiveness of epidural administration of corticosteroids have not been established, and corticosteroids are not approved for this use.

Results from a single, multicenter, randomized, controlled study with another corticosteroid, methylprednisolone hemisuccinate, showed an increase of early mortality (at 2 weeks) and late mortality (at 6 months) in patients with cranial trauma who had received methylprednisolone, compared to placebo. The causes of mortality in the methylprednisolone group have not been established. Of note, this study excluded patients who were felt to have a clear indication for corticosteroids.

Corticosteroids should be used with caution in patients with myasthenia gravis.

Ophthalmologic

Prolonged corticosteroid use may produce posterior subcapsular cataracts (especially in children), increased intraocular pressure and glaucoma with possible damage to the optic nerves, and may enhance secondary ocular infections due to fungi or viruses. Ophthalmologic examination should be done periodically, especially in patients on long-term therapy (more than six weeks). Patients on long-term therapy should have intraocular pressure monitored.

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) 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 of visual disturbances 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.

The use of oral corticosteroids is not recommended in the treatment of optic neuritis and may lead to an increase in the risk of new episodes.

Psychiatric

Psychic derangement may appear when corticosteroids are used, ranging from euphoria, insomnia, mood swings, personality changes, and severe depression to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated by corticosteroids.

Sensitivity / Resistance

Because rare instances of anaphylactoid reactions have occurred in patients receiving parenteral corticosteroid therapy, appropriate precautionary measures should be taken prior to administration, especially when the patient has a history of allergy to any drug.

Special Populations

Fertility

Corticosteroids have been shown to impair fertility in animal studies. Steroids may increase or decrease motility and number of spermatozoa in some patients.

Pregnancy

Since adequate human reproduction studies have not been done with corticosteroids, the use of these drugs in pregnancy, or in women of childbearing potential requires that the possible benefits of the drug be weighed against the hazards to the mother and embryo, fetus or infant.

Corticosteroids cross the placental barrier.

When mothers were given betamethasone injections prenatally, the infants had transient suppression of fetal growth hormone and presumably of those pituitary hormones which regulate corticosteroid production by both the definitive and fetal zones of the fetal adrenal glands.

However, the suppression of fetal hydrocortisone did not interfere with the pituitary-adrenocortical responses to stress after birth.

Infants born of mothers who were dosed with corticosteroids throughout most or some portion of their pregnancy should be examined carefully for signs of adrenal insufficiency and the possible very rare occurrence of congenital cataracts.

Women who have been on corticosteroids during pregnancy should be monitored during and after labor and delivery for any indication of adrenal insufficiency because of the stresses associated with childbirth.

Corticosteroids are not indicated in the management of hyaline membrane disease after birth and should not be administered to pregnant women with pre-eclampsia, eclampsia, or evidence of placental damage.

Breastfeeding

Corticosteroids appear in breast milk of nursing mothers. Because of the potential for adverse effects from betamethasone sodium phosphate and betamethasone acetate injectable suspension in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatrics (< 18 years of age)

Growth and development of infants and children on prolonged corticosteroid therapy should be carefully observed (see PRECAUTIONS, Endocrine and Metabolism, and Ophthalmologic).

Monitoring and Laboratory Test:

Corticosteroids may suppress reactions to skin tests.

Corticosteroids may affect the nitroblue tetrazolium test for bacterial infection and produce false negative results.

Dosage adjustments may be required with remission or exacerbation of the disease process, the patient's individual response to therapy and exposure of the patient to emotional or physical stress such as serious infection, surgery or injury. Monitoring may be necessary for up to one year following cessation of long-term or high-dose corticosteroid therapy.

DRUG INTERACTIONS

Drug-Drug Interactions

Hepatic Enzyme Inducers (e.g., barbiturates, phenytoin, carbamazepine, rifampin)

Concurrent use of phenobarbital, phenytoin, rifampin or ephedrine may enhance the metabolism and clearance of corticosteroids, reducing their therapeutic effects.

Estrogens, including Oral Contraceptives

Patients receiving both a corticosteroid and an estrogen should be observed for excessive corticosteroid effects.

Amphotericin B injection and Potassium-Depleting Agents

Concurrent use of corticosteroids with potassium-depleting diuretics may enhance hypokalemia. Concurrent use of corticosteroids with cardiac glycosides may enhance the possibility of arrhythmias or digitalis toxicity associated with hypokalemia. Corticosteroids may enhance the potassium depletion caused by amphotericin B. In all patients taking any of these drug therapy combinations, serum electrolyte determinations, particularly potassium levels, should be monitored closely.

Anticoagulants, Oral

Concurrent use of corticosteroids with coumarin-type anticoagulants may increase or decrease the anticoagulant effects, possibly requiring adjustment in dosage.

Nonsteroidal anti-Inflammatory Agents (NSAIDs)

Combined effects of non-steroidal anti-inflammatory drugs with glucocorticosteroids may result in an increased occurrence or increased severity of gastrointestinal ulceration.

Corticosteroids may decrease blood salicylate concentrations. Acetylsalicylic acid should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia.

Antidiabetics

Because corticosteroids may increase blood glucose concentration, dosage adjustments of antidiabetic agents may be required.

Somatotropin

Concomitant glucocorticosteroid therapy may inhibit the response to somatotropin.

Aminoglutethimide

Aminoglutethimide may lead to a loss of corticosteroid-induced adrenal suppression.

Antibiotics

Macrolide antibiotics have been reported to cause a significant decrease in corticosteroid clearance.

Anticholinesterases

Concomitant use of anticholinesterase agents and corticosteroids may produce severe weakness in patients with myasthenia gravis. If possible, anticholinesterase agents should be withdrawn at least 24 hours before initiating corticosteroid therapy.

Antitubercular Drugs

Serum concentrations of isoniazid may be decreased.

Cholestyramine

Cholestyramine may increase the clearance of corticosteroids.

Cyclosporine

Increased activity of both cyclosporine and corticosteroids may occur when the two are used concurrently. Convulsions have been reported with this concurrent use.

Interactions with Strong CYP3A4 Inhibitors

Corticosteroids (including betamethasone) are metabolized by CYP 3A4.

Ketoconazole has been reported to decrease the metabolism of certain corticosteroids by up to 60%, leading to an increased risk of corticosteroid side effects.

Coadministration with strong CYP3A4 inhibitors, (e.g. itraconazole, clarithromycin, ritonavir, cobicistat-containing products) may lead to increased exposures of corticosteroids and therefore the potential for increased risk of systemic corticosteroid side effects.

Consider the benefit of coadministration versus the potential risk of systemic corticosteroid effects, in which case patients should be monitored for systemic corticosteroid side-effects.

Vaccines

Patients on prolonged corticosteroid therapy may exhibit a diminished response to toxoids and live or inactivated vaccines due to inhibition of antibody response. Corticosteroids may also potentiate the replication of some organisms contained in live attenuated vaccines. Routine administration of vaccines or toxoids should be deferred until corticosteroid therapy is discontinued if possible (see PRECAUTIONS, Immune).

Drug-Laboratory Test Interactions

Corticosteroids may suppress reactions to skin tests.

Drug-Lifestyle Interactions

The intake of alcohol with corticosteroids may result in an increased occurrence or increased severity of gastrointestinal ulceration.

ADVERSE EFFECTS

There have been a few cases of crystal deposition but no reports of dimpling of the skin after intradermal injection. Nevertheless, because dimpling of the skin is attributable to atrophy of subcutaneous fat and is seen with other injectable corticosteroids, subcutaneous injection should be avoided. Pain has not been reported.

Dermatologic: impaired wound healing; skin atrophy; thin fragile skin; petechiae and ecchymoses; facial erythema; increased sweating; suppressed reactions to skin tests; reactions such as allergic dermatitis, urticaria, angioneurotic edema, hyperpigmentation, hypopigmentation, subcutaneous atrophy, cutaneous atrophy; Kaposi's sarcoma.

Endocrine: menstrual irregularities; development of cushingoid state; suppression of growth in children; secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness; decreased carbohydrate tolerance, manifestations of latent diabetes mellitus, increased requirements of insulin or oral hypoglycemic agents in diabetics.

Fluid and electrolyte disturbances: sodium retention, potassium loss, hypokalemic alkalosis; fluid retention; congestive heart failure in susceptible patients; hypertension.

Gastrointestinal: hiccups, peptic ulcer with possible perforation and hemorrhage; pancreatitis; abdominal distention; ulcerative esophagitis.

General disorders and administration site conditions: sterile abscess, post injection flare (following intraarticular use).

Immune system disorders: hypersensitivity, anaphylactoid and hypotensive or shock like reactions.

Metabolic: negative nitrogen balance due to protein catabolism.

Musculoskeletal: muscle weakness, corticosteroid myopathy, loss of muscle mass; aggravation of myasthenic symptoms in myasthenia gravis; osteoporosis; vertebral compression fractures; aseptic necrosis of femoral and humeral heads; pathologic fracture of long bones; tendon rupture; joint instability (from repeated intra-articular injections), charcot-like arthropathy.

Neurologic: convulsions; increased intracranial pressure with papilledema (pseudotumor cerebri) usually after treatment; vertigo; headache.

Ophthalmic: posterior subcapsular cataracts; increased intraocular pressure, glaucoma; exophthalmos, instances of blindness associated with intralesional therapy around the face and head, vision blurred.

Psychiatric: euphoria, mood swings; severe depression to frank psychotic manifestations; personality changes; hyperirritability; insomnia.

Vascular disorders: thromboembolism.

OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Centre.

Treatment of acute overdose is by supportive and symptomatic therapy. For chronic overdosage in the face of severe disease requiring continuous steroid therapy, the dosage of the corticosteroid may be reduced only temporarily.

Complications resulting from the metabolic effects of the corticosteroid or from deleterious effects of the basic or concomitant illnesses or resulting from drug interactions should be handled as appropriate. Maintain adequate fluid intake and monitor electrolytes in serum and urine, with particular attention to sodium and potassium balance. Treat electrolyte imbalance if necessary.

DOSAGE AND ADMINISTRATION

Intramuscular injections of corticosteroids should be given deep into large muscle masses to avoid local tissue atrophy.

Shake well before using.

Dosage must be adjusted according to the severity of the condition, the response obtained, and the patient's tolerance to the corticosteroid.

For systemic effect, treatment is initiated with 1 mL IM in most conditions and repeated weekly, or more often, if necessary. In severe illness such as status asthmaticus or disseminated lupus erythematosus, 2 mL might be required initially. In dermatologic disorders, including neurodermatitis, psoriasis, hypertrophic lichen planus, lichen simplex, eczema, contact dermatitis,

and dermatitis medicamentosa, IM dosage is usually 1 mL at intervals of 3 days to a week. In respiratory tract disorders, including bronchial asthma, hay fever, allergic bronchitis, and perennial allergic rhinitis, IM dosage is usually 1 to 2 mL at weekly intervals. Bursitis may be treated with IM injections of 1 mL repeated weekly, if necessary.

The initial dose should be maintained or adjusted until a satisfactory response is observed. If a satisfactory clinical response does not occur after a reasonable period of time, treatment with BETAJECT should be discontinued and other appropriate therapy initiated.

For local effect, in acute bursitis (subdeltoid, subacromial and prepatellar), one intrabursal injection of 1 mL relieves pain and restores the full range of movement in a few hours. Several intrabursal injections at intervals of 1 to 2 weeks are usually required in recurrent acute bursitis and in acute exacerbations of chronic bursitis. Partial relief of pain and some increase in mobility may be expected in both conditions after 1 or 2 injections. In tendonitis, myositis, fibrositis, tenosynovitis, peritendonitis and periarticular inflammatory conditions, 3 or 4 local injections of 1 mL each at intervals of 1 to 2 weeks between injections are given in most cases. Injection should be made into the affected tendon sheaths rather than into the tendons themselves. In periarticular inflammatory conditions, the painful area should be infiltrated. In ganglions of joint capsules, 0.5 mL is injected into the ganglion cysts. In rheumatoid arthritis and osteoarthritis, relief of pain, soreness, and stiffness may be experienced in 2 to 4 hours after intra-articular injection. Using sterile technique, a 20 to 24 gauge needle on an empty syringe for aspiration is inserted into the synovial cavity, and a few drops of synovial fluid are withdrawn to confirm that the needle is in the joint. The aspirating syringe is replaced by the syringe containing BETAJECT and the injection is then made into the joint (see Table 1).

Table 1 BETAJECT

Intra-articular Injection

Size of Joint	Location	Dose (mL)
Very large	Hip	1.0 – 2.0
Large	Knee Ankle Shoulder	1.0
Medium	Elbow Wrist	0.5 – 1.0
Small (Metacarpophalangeal, intraphalangeal) (Sternoclavicular)	Hand Chest	0.25 – 0.5

Pain with intra-articular injection of BETAJECT has not been a problem. However, should the physician want to administer it with a local anaesthetic, it can be mixed in the syringe with an equal volume of 1% or 2% lidocaine hydrochloride, procaine hydrochloride or similar local anesthetics using formulations which do not contain parabens. Anesthetics containing methylparaben, propylparaben, phenol, etc. should be avoided. The required dose of BETAJECT is first withdrawn from the vial into the syringe. The local anaesthetic is then drawn in, and the syringe shaken briefly. Do not inject local anaesthetics into the vial of BETAJECT.

Dermatologic conditions that have responded to intralesional treatment with BETAJECT include: localised neurodermatitis, psoriasis, nummular eczema, alopecia areata, hypertrophic lichen planus, circumscribed lichen simplex, keloids, and chronic discoid lupus erythematosus.

In intralesional treatment, 0.2 mL of BETAJECT is injected intradermally (not SC) per cm² of lesion using a tuberculin syringe with a 25 gauge, 13 mm needle. Care should be taken to deposit a uniform depot of medication intradermally. A total of no more than 1 mL at weekly intervals is recommended.

Disorders of the foot responsive to corticosteroids injected locally: For most injections into the foot, a tuberculin syringe with a 25 gauge, 2 cm needle is used. Treatment is given at intervals of 3 days to a week. In bursitis under heloma durum (hard corn), bursitis under heloma molle (soft corn), synovial cysts, and Morton's neuralgia (metatarsalgia) 0.25 to 0.5 mL are recommended. For bursitis under calcaneal spurs, bursitis under hallux rigidus (flexion deformity of the great toe), bursitis over digiti quinti varus (inward deviation of the fifth toe), tenosynovitis, and periostitis of the cuboid, 0.5 mL is recommended; in acute gouty arthritis, 0.5 to 1 mL are recommended.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Each mL of sterile, aqueous suspension contains: betamethasone acetate 3 mg, betamethasone sodium phosphate equivalent to 3 mg betamethasone, dibasic sodium phosphate 7.1 mg, monobasic sodium phosphate 3.4 mg, disodium edetate 0.1 mg, benzalkonium chloride 0.02% (as preservative), sodium hydroxide and/or hydrochloric acid to adjust pH and water for injection.

BETAJECT is available in multidose vials of 1 mL, boxes of 10, and 5 mL, boxes of 1.

Store between 2 and 30°C. Protect from freezing. Protect from light

Discard 28 days after initial use.

Latex-Free Stoppers: Stoppers contain no dry natural rubber.

REFERENCES

1. Merck Canada Inc., CELESTONE[®] SOLUSPAN[®] Product Monograph. Control no. 210219, Date of Revision: December 11, 2017.