AUSTRALIAN PRODUCT INFORMATION
CELESTONE® CHRONODOSE® INJECTION

1 NAME OF THE MEDICINE

Betamethasone acetate and Betamethasone sodium phosphate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Celestone Chronodose Injection is a sterile aqueous suspension containing the combination of betamethasone sodium phosphate and betamethasone acetate. Each mL of Celestone Chronodose Injection contains betamethasone 5.7 mg, as betamethasone sodium phosphate 3.9 mg (in solution) and betamethasone acetate 3 mg (in suspension) in an aqueous vehicle.

Excipients with known effect:
Celestone Chronodose contains benzalkonium chloride.
For the full list of excipients, see Section 6.1 LIST OF EXCIPIENTS

3 PHARMACEUTICAL FORM

Suspension for injection.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Celestone Chronodose is indicated in the treatment of both severe and moderate conditions, in acute and chronic self-limiting diseases responsive to systemic corticosteroid therapy, especially in patients for whom treatment with oral corticosteroid medication is not feasible.

Representative conditions:

Rheumatic disorders
Rheumatoid arthritis, acute and subacute bursitis, epicondylitis, acute non-specific tenosynovitis, myositis, fibrositis, tendinitis, psoriatic arthritis.

Collagen diseases
Systemic lupus erythematosus, scleroderma, dermatomyositis.

Allergic states
Status asthmaticus, chronic bronchial asthma, seasonal or perennial allergic rhinitis, severe allergic bronchitis, contact dermatitis, atopic dermatitis, hypersensitivity reactions to drug and insect bites.

Dermatological conditions
Localised, hypertrophic, infiltrated lesions of lichen planus, psoriatic plaques, granuloma annulare and lichen simplex chronicus (neurodermatitis), keloids, discoid lupus erythematosus, necrobiosis lipoidica diabeticorum, alopecia areata.

Antepartum use in the prevention of respiratory distress syndrome in premature infants
When it is deemed necessary to induce labour prior to the thirty-second week of gestation or when premature birth before the thirty-second week of gestation becomes inevitable because of obstetric complication.

Celestone Chronodose Injection should also be considered for prophylactic treatment if the fetus is known to have a low lecithin/sphingomyelin ratio (or decreased foam stability test on amniotic fluid).

4.2 DOSE AND METHOD OF ADMINISTRATION

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

Recommended routes of administration are:

1. Intramuscular injection in allergic, dermatological, rheumatic and other conditions responsive to systemic corticosteroids, including bursitis.

2. Injection directly into the affected soft tissues in bursitis and associated inflammatory disorders of muscle such as fibrositis and myositis.

3. Intra-articular and periarticular injection in rheumatoid arthritis and osteoarthritis.

4. Intralesional injections in various dermatological conditions.

Systemic administration
Treatment of conditions requiring systemic corticoid effects can be carefully controlled by intramuscular injection of Celestone Chronodose Injection. Its rapid and prolonged action make it suitable for initiation of therapy in acute conditions in which control of inflammation must be achieved quickly and then maintained. The repository action of the drug assists in the prevention of recrudescence from irregular maintenance of corticoid effects.

Treatment is initiated with an intramuscular injection of 1 mL 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 the antepartum use in the prevention of respiratory distress syndrome in premature infants and in the prophylactic treatment of the fetus known to have a low lecithin/sphingomyelin ratio (or decreased foam stability tests on amniotic fluid), it is recommended that 2 mL be injected intramuscularly at least 24 hours before the expected time of delivery. A second dose (2 mL) should be given 24 hours later unless delivery has occurred.

Local administration
If co-administration is desired, Celestone Chronodose Injection may be mixed (in the syringe not the ampoule) with 1% or 2% lidocaine (lignocaine) hydrochloride, procaine hydrochloride, or similar local anaesthetics, using formulations which do not contain hydroxybenzoates (parabens). Anaesthetics containing methyl hydroxybenzoate, propyl hydroxybenzoate, phenol, etc. should be avoided. The required dose is first withdrawn from the ampoule into the syringe. The local anaesthetic is then drawn into the syringe and then should be shaken briefly.

In bursitis (subdeltoid, subacromial and prepatellar) an intrabursal injection of 1 mL may relieve pain and may restore 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.

In tendinitis, myositis, fibrositis, tenosynovitis, peritendinitis, and periarticular inflammatory

conditions, three or four local injections of 1 mL each at intervals of one to two weeks are recommended 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 directly 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. Dosages range from 0.25 to 2 mL, according to the size of the joint to be injected: very large joints (hip), 1 to 2 mL; large joints (knee, ankle and shoulder) 1 mL; medium joints (elbow and wrist), 0.5 to 1 mL; and small joints (hand and chest), 0.25 to 0.5 mL. Relief lasts usually from 1 to 4 or more weeks. Using a sterile technique, a 29 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 Celestone Chronodose Injection and the injection is then made into the joint.

A portion of the administered dose of Celestone Chronodose Injection is absorbed systemically following intra-articular injection. Therefore, in patients being treated concomitantly with oral or parenteral corticosteroids, especially those receiving large doses, the systemic absorption of the drug administered intra-articularly should be considered.

In intralesional treatment, 0.2 mL/cm^2 of Celestone Chronodose Injection is injected intradermally (not subcutaneously) using a tuberculin syringe with a 25 gauge, 1.27 cm needle. Care should be taken to deposit a uniform depot of medication intradermally. A total of not more than 1 mL at weekly intervals is recommended.

4.3 CONTRAINDICATIONS

As with other corticosteroids, Celestone Chronodose Injection is contraindicated in systemic fungal infections and in patients hypersensitive to betamethasone sodium phosphate, betamethasone acetate, other corticosteroids or to any component of this product. Corticosteroids should not be injected into unstable joints, infected areas or intervertebral spaces. Celestone Chronodose Injection is not recommended for epidural administration.

Relative contraindications are osteoporosis, marked emotional instability, peptic ulcer, tuberculosis, acute or chronic infections, ocular Herpes simplex, primary glaucoma, diverticulitis, recent intestinal anastomosis, Cushing's syndrome, renal insufficiency, hypertension, thromboembolic tendencies, diabetes mellitus and myasthenia gravis.

Corticosteroids are not indicated in the management of hyaline membrane disease after birth.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Celestone Chronodose Injection should not be administered intravenously. Strict aseptic technique is mandatory. Subcutaneous injection should be avoided.

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. (See 4.3 CONTRAINDICATIONS)

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.

Pheochromocytoma crisis, which may be fatal, has been reported after administration of systemic corticosteroids. Corticosteroids should only be administered to patients with suspected or identified pheochromocytoma after an appropriate risk/benefit evaluation.
Intramuscular injections of corticosteroids should be given deep into large muscle masses to avoid local tissue atrophy.

Soft tissue, intralesional and intra-articular administration of a corticosteroid may produce systemic as well as local effects.

Celestone Chronodose Injection contains two betamethasone esters, one of which, betamethasone sodium phosphate, disappears rapidly from the injection site. The potential for systemic effect produced by this soluble portion of Celestone Chronodose Injection should therefore be taken into account by the physician when using this preparation.

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

Drug induced secondary adrenocortical insufficiency may result from too rapid corticosteroid withdrawal and may be minimised by gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy; therefore, if stress occurs during that period, corticotherapy should be reinstituted. If the patient is receiving corticosteroids already, the dosage may have to be increased.

Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticosteroid should be administered concurrently.

In certain conditions ordinarily considered contraindications to corticosteroid therapy, the physician must weigh anticipated clinical improvement against the possibility of undesirable corticosteroid effects.

Corticosteroids may mask the signs of infection and enhance the dissemination of an infecting organism. Hence, patients receiving corticosteroids should be watched for evidence of intercurrent infection. Should infection occur, vigorous, appropriate anti-infective therapy should be initiated. Abrupt withdrawal of corticosteroids should be avoided.

Celestone Chronodose Injection should not be administered to patients with an acute or chronic infection unless the condition is severe and unless appropriate anti-infective agents are administered concurrently. When corticosteroids are used, decreased resistance and inability to localise infection may occur.

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 anti-microbial therapy should be instituted.

While on corticosteroid therapy patients should not be vaccinated against smallpox. Other immunisation 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, immunisation procedures may be undertaken in patients who are receiving corticosteroids as replacement therapy, e.g. for Addison's 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.

Corticosteroid therapy 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 anti-tuberculous 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 rifampicin 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.

Prolonged corticosteroid use may produce posterior subcapsular cataracts (especially in children), glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections due to fungi or viruses. 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.

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

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.

Celestone Chronodose Injection should be administered intramuscularly with caution to patients with idiopathic thrombocytopenic purpura.

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

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.

Corticosteroid effect is enhanced in patients with hypothyroidism or in those with cirrhosis.

Cautious use of corticosteroids is advised in patients with ocular herpes simplex because of possible corneal perforation.

Psychic derangements may appear with corticosteroid therapy. Existing emotional instability, or psychotic tendencies may be aggravated by corticosteroids.

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.

Corticosteroids should be used with caution in: non-specific ulcerative colitis, if there is a probability of impending perforation, abscess, or other pyogenic infection; diverticulitis; fresh intestinal anastomoses; active or latent peptic ulcer; renal insufficiency; hypertension; osteoporosis; and myasthenia gravis.

Since complications of glucocorticosteroid treatment are dependent on dose, size and duration of treatment, a risk/benefit decision must be made with each patient.

Corticosteroids may alter the motility and number of spermatozoa in some patients.

Results from a single, multicentre, randomised, controlled study with another corticosteroid, methylprednisolone hydrogen succinate, 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.

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.

Use in the elderly
No data available.

Paediatric use
Since corticosteroid administration can disturb growth rates and inhibit endogenous corticosteroid production in infants and children, the growth and development of these patients receiving prolonged therapy should be followed carefully.

Effects on laboratory tests
Corticosteroids may affect the nitro-blue tetrazolium test for bacterial infection and produce false negative results.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Concurrent use of corticosteroids with potassium-depleting diuretics may enhance hypokalaemia. Concurrent use of corticosteroids with cardiac glycosides may enhance the possibility of arrhythmias or digitalis toxicity associated with hypokalaemia. Corticosteroids may enhance the potassium depletion caused by amphotericin B (amphotericin). 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 anti-coagulants may increase or decrease the anti-coagulant effects, possibly requiring adjustment in dosage.

Antidiabetics
The hyperglycaemic effect of betamethasone may offset the hypoglycaemic effect of oral antidiabetic drugs. Dosage adjustments of an anti-diabetic drug may be necessary when corticosteroids are given to diabetics

Estrogens, Including Oral Contraceptives
Patients receiving both a corticosteroid and an estrogen should be observed for excessive corticosteroid effects.

Hepatic Enzyme Inducers

Concurrent use of phenobarbital (phenobarbitone), phenytoin, rifampicin or ephedrine may enhance the metabolism of corticosteroids, reducing their therapeutic effects.

Interactions with Strong CYP3A4 Inhibitors
Corticosteroids (including betamethasone) are metabolized by CYP 3A4.

Coadministration with strong CYP3A4 inhibitors, (e.g. **ketoconazole,** 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.

Nonsteroidal Anti-Inflammatory Agents (NSAIDs)
Plasma levels of salicylates may be reduced. Aspirin should be used cautiously in conjunction with corticosteroids in hypoprothrombinaemia.

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

Somatotropin
Concomitant glucocorticosteroid therapy may inhibit the response to somatotropin. Doses of betamethasone in excess of 0.3 to 0.45 mg per m^2 of body surface per day should be avoided during the administration of somatotropin.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility
No data available.

Use in Pregnancy (Category C)
The use of corticosteroids in pregnancy or in women of childbearing potential requires that the possible benefits of the drug be weighed against the potential hazards to the mother and fetus.

In the prophylactic treatment of hyaline membrane disease in premature infants, corticosteroids should not be administered to pregnant women with pre-eclampsia, eclampsia or evidence of placental damage.

Since use of prophylactic corticosteroids beyond the 32nd week of gestation is still controversial, the physician should weigh the benefits against the potential hazards to the mother and the fetus when using corticosteroids beyond this period of gestation.

In animal experiments, corticosteroids have been found to cause malformations of various kinds (cleft palate, skeletal malformations) and abortion. These findings do not seem to be relevant to humans. Reduced placental and birth weight have been recorded in animals and humans after long-term treatment. Since the possibility of suppression of the adrenal cortex in the newborn baby after long-term treatment must be considered, the needs of the mother must be carefully weighed against the risk to the fetus when prescribing these drugs. The short-term use of corticosteroids antepartum for the prevention of respiratory distress syndrome does not seem to pose a risk to the fetus or the newborn infant.

Maternal pulmonary oedema has been reported with tocolysis and fluid overload.

Infants born of mothers who received substantial doses of corticosteroids during pregnancy should be observed carefully for signs of hypo-adrenalism. When mothers were given

betamethasone injections pre-natally, 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.

Since transplacental passage of corticosteroids occurs, newborn and young infants born of mothers who were dosed with corticosteroids throughout most or some portion of their pregnancy should be examined carefully for the possible very rare occurrence of congenital cataracts.

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

Use in lactation
The drug is excreted in breast milk and may be harmful to young children because it could suppress growth or cause other adverse effects such as hypo-adrenalism. Potential benefits to the mother should outweigh these possible hazards to the infant.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Adverse reactions to Celestone Chronodose Injection relate both to dose and to duration of therapy. These reactions can usually be reversed or minimised by a reduction in dosage; this is generally preferable to withdrawal of drug treatment.

Adverse reactions have been the same as those reported to other corticosteroids: fluid and electrolyte, musculoskeletal, gastrointestinal, dermatological, neurological, endocrine, ophthalmic, metabolic and psychiatric disturbances.

Cardiovascular:
Congestive heart failure in susceptible patients; hypertension.

Fluid and electrolyte disturbances:
Sodium retention, potassium loss, hypokalaemic alkalosis; fluid retention.

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).

Gastrointestinal:
Hiccups; peptic ulcer with possible subsequent perforation and haemorrhage; pancreatitis; abdominal distention; ulcerative oesophagitis.

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, angioedema.

Neurologic:

Convulsions; increased intracranial pressure with papilloedema (pseudotumour cerebri) usually after treatment; vertigo; headache.

Endocrine:
Menstrual irregularities; development of cushingoid state; suppression of fetal intrauterine and childhood growth; 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 hypoglycaemic agents in diabetics.

Ophthalmic:
Posterior subcapsular cataracts; increased intraocular pressure, glaucoma; exophthalmos, vision blurred.

Metabolic:
Negative nitrogen balance due to protein catabolism.

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

Other:
Anaphylactoid or hypersensitivity and hypotensive or shock-like reactions.

Neonatal hypoglycemia has been reported after antenatal administration.

Additional adverse reactions related to parenteral corticosteroid therapy include rare instances of blindness associated with intralesional therapy around the face and head; hyperpigmentation or hypopigmentation; subcutaneous and cutaneous atrophy; sterile abscess; post-injection flare (following intra-articular use); charcot-like arthropathy.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at http://www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

A single overdose of a corticosteroid would not be expected to produce acute symptoms. Hypercorticoid effects are not anticipated unless there has been repeated administration of high doses.

Symptoms
Systemic effects of chronic overdosage with steroids include effects on sodium and water retention, increased appetite, mobilisation of calcium and phosphorus with osteoporosis, nitrogen depletion, hyperglycaemia, effects on tissue repair, increased susceptibility to infection, adrenal insufficiency, adrenal cortex hyperactivity, mental and neurological disturbances and muscular weakness.

Treatment
In case of an acute overdose, maintain adequate fluid intake and monitor electrolytes in serum and urine, with particular attention to sodium and potassium balance. In case of chronic toxicity,

slowly withdraw drug. Treat electrolyte imbalance if necessary.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Celestone Chronodose is an injectable preparation containing both soluble and slightly soluble esters of betamethasone that provides anti-inflammatory, anti-rheumatic and anti-allergic effects in the treatment of corticosteroid-responsive disorders.

Mechanism of action
No data available.

Clinical trials
No data available.

5.2 PHARMACOKINETIC PROPERTIES

Prompt therapeutic activity in conditions responsive to corticosteroids is initiated by betamethasone sodium phosphate, a soluble ester that is absorbed quickly into tissues after injection.

Sustained activity is provided by betamethasone acetate, which is only slightly soluble and affords a repository for slow absorption.

The combined rapid and depot actions of these forms of betamethasone facilitate rapid control as well as steady maintenance of corticosteroid effects.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity
No data available**.**

Carcinogenicity
No data available**.**

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

benzalkonium chloride
disodium edetate
dibasic sodium phosphate
monobasic sodium phosphate
water for injections

Inactive ingredients
Nitrogen

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

The expiry date can be found on the packaging. In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG).

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Protect ampoules from light.
Store below 25^{O}C.

6.5 NATURE AND CONTENTS OF CONTAINER

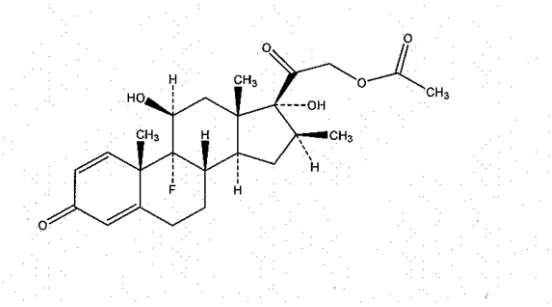
Injection, suspension in flint glass (Type I) ampoule with rubber stopper.
Ampoules, 1 mL: 5s, 2s.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

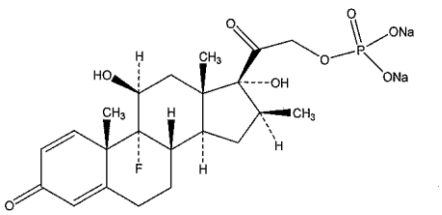
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure



betamethasone acetate
9-fluoro-11β,17-dihydroxy-16β-methyl-3,20-dioxopregna-1,4diene-21-yl acetate)
Molecular formula: $C_{24}H_{31}FO_6$ MW: 434.5 CAS registry number: 987-24-6



betamethasone sodium phosphate
9-fluoro-11β,17-dihydroxy-16β-methyl-3,20-dioxopregna-1,4diene-21-yl disodium phosphate
Molecular formula: $C_{22}H_{28}FNa_2O_8P$ MW: 516.4 CAS registry number: 151-73-5

7 MEDICINE SCHEDULE (POISONS STANDARD)

S4 – Prescription Only Medicine

8 SPONSOR

Organon Pharma Pty Ltd
Building A, 26 Talavera Road,
Macquarie Park, NSW 2113 Australia

9 DATE OF FIRST APPROVAL

8 October 1991

10 DATE OF REVISION

24 February 2022

Summary table of changes

Section Changed	Summary of new information
4.4	Update to the Special Warnings and Precautions for use section for Pheochromocytoma crisis.
4.8	Update to Adverse Effect (Undesirable Effects) section for Neonatal hypoglycemia.

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