Public Summary

Summary for ARTG Entry: 12299 DEPO-MEDROL methylprednisolone acetate 40mg/1mL injection vial

ARTG entry for	Medicine Registered
Sponsor	Pfizer Australia Pty Ltd
Postal Address	38-42 Wharf Road, WEST RYDE, NSW, 2114 Australia
ARTG Start Date	2/08/1991
Product category	Medicine
Status	Active
Approval area	Drug Safety Evaluation Branch

Conditions

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1. Depo-Medrol 40mg/1mL injection vial

Product Type Single Medicine Product **Effective date** 18/05/2016

Warnings

See Product Information and Consumer Medicine Information for this product

Standard Indications

Specific Indications

INDICATIONS AS AT 9 NOVEMBER 1993: A. For Intramuscular Administration: When oral therapy is not feasible and the strength, dosage form and route of administration of the drug reasonably lend the preparation to the treatment of the condition, the intramuscular use of DEPO-MEDROL is indicated as follows: 1. Endocrine Disorders: Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone acetate is the drug of choice; synthetic analogues may be used in conjunction with mineralocorticoids where applicable; in infancy, mineralocorticoid supplementation is of particular importance). Acute adrenocortical insufficiency (hydrocortisone or cortisone acetate is the drug of choice; mineralocorticoid supplementation may be necessary, particularly when synthetic analogues are used). Preoperatively and in the event of serious trauma or illness, in patients with known adrenal insufficiency or when adrenocortical reserve is doubtful. Congenital adrenal hyperplasia. Hypercalcaemia associated with cancer. Non-suppurative thyroiditis. 2. Rheumatic Disorders: As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Post-traumatic osteoarthritis. Epicondylitis. Synovitis of osteoarthritis. Acute non-specific tenosynovitis. Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy). Acute gouty arthritis. Psoriatic arthritis. Ankylosing spondylitis. Acute and subacute bursitis. 3. Collagen Diseases: During an exacerbation or as maintenance therapy in selected cases of: Systemic lupus erythematosus. Acute rheumatic carditis. Systemic dermatomyositis (polymyositis). 4. Dermatological Diseases: Pemphigus. Bullous dermatitis herpetiformis. Severe erythema multiforme (Stevens-Johnson Syndrome). Severe seborrhoeic dermatitis. Exfoliative dermatitis. Severe psoriasis. Mycosis fungoides. 5. Allergic States: Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in: Bronchial asthma. Drug hypersensitivity reactions. Contact dermatitis. Urticarial transfusion reactions. Atopic dermatitis. Acute non-infectious laryngeal oedema (adrenaline is the drug of first choice). Serum sickness. Seasonal or perennial allergic rhinitis. 6. Ophthalmic Diseases: Severe acute and chronic allergic and inflammatory processes involving the eye, such as: Herpes zoster ophthalmicus. Sympathetic ophthalmia. Iritis, Iridocyclitis. Anterior segment inflammation. Chorioretinitis. Allergic conjunctivitis. Diffuse posterior uveitis. Allergic corneal marginal ulcers. Optic neuritis. Keratitis. 7. Gastrointestinal Diseases: To tide the patient over a critical period of the disease in: Ulcerative colitis (systemic therapy). Regional enteritis (systemic therapy). 8. Respiratory Diseases: Symptomatic sarcoidosis. Berylliosis. Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate anti-tuberculous chemotherapy. Aspiration pneumonitis. Loeffler's Syndrome not manageable by other means. 9. Haematological Disorders: Acquired (autoimmune) haemolytic anaemia. Erythroblastopenia (RBC anaemia). Secondary thrombocytopenia in adults. Congenital (erythroid) hypoplastic anaemia. 10. Neoplastic Diseases: For palliative management of: Leukaemias and lymphomas in adults. Acute leukaemia in childhood. 11. Oedematous States: To induce diuresis or remission of proteinuria in the nephrotic syndrome without uraemia of the idiopathic type or that due to lupus erythematosus. 12. Nervous System: Acute exacerbations of multiple sclerosis. 13. Miscellaneous Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate anti-tuberculous chemotherapy. Trichinosis with neurological or myocardial involvement. B. For Intra-Articular Or Soft Tissue Administration: DEPO-MEDROL is indicated as adjunctive therapy for short-term administration (to tide t he patient over an acute episode or exacerbation) in: Synovitis of osteoarthritis. Epicondylitis. Rheumatoid arthritis. Acute non-specific tenosynovitis. Acute and subacute bursitis. Post traumatic osteoarthritis. Acute gouty arthritis. C. For Intralesional Administration: DEPO-MEDROL is indicated for intralesional use in the following conditions: Keloids. Discoid lupus erythematosus. Necrobiosis lipoidica diabeticorum. Alopecia areata. Localised hypertrophic, infiltrated inflammatory lesions of Licen Planus. psoriatic plaques, Granuloma Annulare and Lichen Simplex Chronicus (neurodermatitis). DEPO-MEDROL may also be useful in cystic tumours of an aponeurosis or tendon (ganglia).

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass	3 Years	Store below 30 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
1mL X 1	(S4) Prescription Only Medicine

1mL X 5	(S4) Prescription Only Medicine

Components

1. Medicine Component

Dosage Form	Injection, suspension
Route of Administration	Intraarticular Intramuscular Intralesional
Visual Identification	White to off white suspension when mixed

Active Ingredients

Methylprednisolone acetate	**40 mg/mL**