Public Summary

Summary for ARTG Entry: 50691 SOLU-MEDROL methylprednisolone 500mg (as sodium succinate) powder for 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	22/11/1994
Product category	Medicine
Status	Active
Approval area	Drug Safety Evaluation Branch

Conditions

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. SOLU-MEDROL methylprednisolone 500mg (as sodium succinate) powder for injection vial

Product Type Single Medicine Product **Effective date** 11/08/2017

Warnings

See Product Information and Consumer Medicine Information for this product

Standard Indications

Specific Indications

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, SOLU-MEDROL Powder for Injection is indicated only for intravenous or intramuscular use in the following conditions: 1. ENDOCRINE DISORDERS: Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone 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 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. Shock unresponsive to conventional therapy if adrenocortical insufficiency exists or is suspected. Congenital adrenal hyperplasia; Nonsuppurative thyroiditis; Hypercalcaemia associated with cancer. 2. RHEUMATIC DISORDERS: As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Ankylosing spondylitis; Psoriatic arthritis; Acute and subacute bursitis; Epicondylitis; Synovitis of osteoarthritis; Acute gouty arthritis; Acute nonspecific tenosynovitis; Post-traumatic osteoarthritis. Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy). 3. COLLAGEN DISEASE: During an exacerbation or as maintenance therapy in selected cases of: Systemic lupus erythematosus; Systemic dermatomyositis (polymyositis); Acute rheumatic carditis. 4. DERMATOLOGICAL DISEASES: Bullous dermatitis herpetiformis; Pemphigus; Severe psoriasis; Severe seborrhoeic dermatitis; Exfoliative dermatitis; Mycosis fungoides; Severe erythema multiforme (Stevens-Johnson Syndrome). 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; Serum sickness; Seasonal or perennial allergic rhinitis; Acute noninfectious laryngeal oedema (adrenaline is the drug of first choice). 6. OPHTHALMIC DISEASES: Severe acute and chronic allergic and inflammatory processes involving the eye, such as : Allergic corneal marginal ulcers; Allergic conjunctivitis; Chorioretinitis; Anterior segment inflammation; Herpes zoster ophthalmicus; Iritis, iridocyclitis; Diffuse posterior uveitis and choroiditis; Keratitis; Optic neuritis; Sympathetic ophthalmia. 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; Aspiration pneumonitis; Loeffler's syndrome not manageable by other means; Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy. 9. HAEMATOLOGIC DISORDERS: Idiopathic thrombocytopenic purpura in adults (IV only; IM administration is contraindicated); Secondary thrombocytopenia in adults; Acquired (autoimmune) haemolytic anaemia; Erythroblastopenia (RBC anaemia); Congenital (erythroid) hypoplastic anaemia. 10. NEOPLASTIC DISEASES: For palliative management of: Leukaemias and lymphomas in adults; Acute leukaemia of 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 antituberculous chemotherapy.Trichinosis with neurologi
c or myocardial involvement. SOLU-MEDROL is beneficial as adjunctive therapy in the treatment of AIDS patients with moderate to severe Pneumocystis carinii pneumonia (PCP) when given within the first 72 hours of initial anti-pneumocystis treatment.

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass	3 Years	Store below 25 degrees Celsius	Not recorded	Protect from Light

Pack Size/Poison information

Pack Size	Poison Schedule
1 x 1 vial powder - 500mg	(S4) Prescription Only Medicine
1 x 5 vials of powder - 500mg	(S4) Prescription Only Medicine

Components

1. Medicine Component

Dosage Form	Injection, powder for
Route of Administration	Intravenous Rectal Intramuscular
Visual Identification	White freeze dried cake.

Active Ingredients	
methylprednisolone sodium succinate	**663.13 mg**

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