Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 113926 OCTAGAM normal immunoglobulin (human) 2.5g/50mL injection bottle

ARTG entry for	Medicine Registered
Sponsor	Octapharma Australia Pty Ltd
Postal Address	Jones Bay Wharf 42/26-32 Pirrama Road, PYRMONT, NSW, 2009 Australia
ARTG Start Date	16/11/2004
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. OCTAGAM normal immunoglobulin (human) 2.5g/50mL injection bottle

Product Type Single Medicine Product **Effective date** 8/10/2018

Permitted Indications

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Replacement therapy: Primary immunodeficiency syndromes: congenital agammaglobulinaemia and hypogammaglobulinaemia; common variable immunodeficiency; severe combined immunodeficiencies; Wiskott Aldrich syndrome; Myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infections. Children with congenital Acquired Immune Deficiency Syndrome (AIDS) who have repeated bacterial infections; Immunomodulatory effect: Idiopathic thrombocytopenic purpura, in adults or children with a high risk of bleeding or prior to surgery to correct platelet count. Guillain Barre syndrome. Kawasaki disease. Allogeneic bone marrow transplantation.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	2 Years	Store below 25 degrees Celsius	Not recorded	Do not Freeze Protect from Light

Pack Size/Poison information

Pack Size

50mL

Poison Schedule

(S4) Prescription Only Medicine

Components

1. Medicine Component

Dosage Form	Injection
Route of Administration	Intravenous
Visual Identification	Clear or slightly opalescent solution.

Active Ingredients

human immunoglobulin G	**50 mg/mL**

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