Public Summary

Summary for ARTG Entry:	201877 M-M-R II powder for injection vial with pre-filled diluent syringe, single dose
ARTG entry for	Medicine Registered
Sponsor	Merck Sharp & Dohme (Australia) Pty Ltd
Postal Address	North Ryde Post Business Centre, Locked Bag 2234, NORTH RYDE BC, NSW, 1670 Australia
ARTG Start Date	12/12/2012
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"

Except where the sponsor has been contracted by an overseas partry to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

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, other than condition No. 8 and condition No. 9.

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, other than condition No.11

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.

The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:

Products

1 . M-M-R II powder for injection vial with diluent pre-filled syringe, single dose

Product Type	Composite Pack	**Effective Date**	2/11/2022

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

M-M-R II is indicated for simultaneous immunisation against measles, mumps and rubella.,Refer to the NHMRC Australian Immunisation Handbook (AIH) for vaccination recommendations and schedule.,There is some evidence to suggest that infants immunised against measles at less than 12 months of age, or who are born to mothers who had wild-type measles and who are vaccinated at less than one year of age may not develop sustained antibody levels when later revaccinated. The advantage of early protection must be weighed against the chance for failure to respond adequately on reimmunisation.,Infants who are less than 12 months of age may fail to respond to one or more components of the vaccine due to presence in the circulation of residual antibodies of maternal origin, the younger the infant, the lower the likelihood of seroconversion. In geographically isolated or other relatively inaccessible populations for whom immunisation programmes are logistically difficult, and in population groups in which wild-type measles infections may occur in a significant proportion of infants before 15 months of age, it may be desirable to give the vaccine to infants at an earlier age. Infants vaccinated under these conditions at less than 12 months of age should be revaccinated after reaching 12 to 15 months of age.,Previously unvaccinated children older than 12 months who are in contact with susceptible pregnant women should receive live attenuated rubella vaccine to reduce the risk of exposure of the pregnant woman.,Non-Pregnant Adolescent and Adult Females:
Immunisation of susceptible non-pregnant adolescent and adult females of childbearing age with live attenuated rubella virus vaccine is indicated if certain precautions are observed (See 4.4 Special Warnings and Precautions for Use and 4.6 Fertility, Pregnancy and Lactation). Vaccinating susceptible postpubertal females confers individual protection against subsequently acquiring rubella infection during pregnancy, which in turn prevents infection of the foetus and consequent congenital rubella injury. Congenital malformations do occur in up to seven percent of all live births, and their chance appearance after vaccination should be borne in mind.,Women of childbearing age should be advised not to become pregnant for one month after vaccination against rubella (which is included in M-M-R II) and should be informed of the reasons for this precaution (See 4.6 Fertility, Pregnancy and Lactation, Use in

Pregnancy).,The Australian Immunisation Handbook recommends that effort should be made to identify and immunise non-pregnant seronegative women of child-bearing age.,Women of childbearing age who are potential candidates for vaccination can have serologic tests to determine susceptibility to rubella. However, rubella vaccination of a woman who is not known to be pregnant and has no history of vaccination is justifiable without serologic testing. Please refer to AIH for recommendations for further information regarding serological testing for immunity to rubella.,Postpubertal females should be informed of the frequent occurrence of generally self-limited arthralgia and/or arthritis beginning 2 to 4 weeks after vaccination against rubella (see 4.8 Adverse Effects (Undesirable Effects)).,Post-Partum Women
It has been found convenient in many instances to vaccinate rubella-susceptible women in the immediate postpartum period using an appropriate rubella-containing vaccine. (See 4.6 Fertility, Pregnancy and Lactation, Use in Lactation).,Revaccination
Children vaccinated when younger than 12 months of age should be revaccinated at 12 to 15 months of age. Persons who were vaccinated originally when 12 months of age or older should be revaccinated with a MMR-containing vaccine, as per the recommended vaccination schedule. Revaccination is intended to seroconvert those who did not respond to the first dose. However, data on long term persistence of antibodies are limited and continued surveillance will be required to allow firm recommendations to be made on revaccination. However, persons should be revaccinated if there is evidence to suggest that initial immunisation was ineffective.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Multiple containers	Glass Type I Clear	2 Years	Store at 2 to 8 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
10 vials of powder and 10 syringes of diluent	(S4) Prescription Only Medicine
1 vial of powder and 1 syringe of diluent	(S4) Prescription Only Medicine

Components

1 . powder

Dosage Form	Injection, powder for
Route of Administration	Subcutaneous
Visual Identification	Lyophilised powder

Active Ingredients

Measles virus	**1000 TCID50**
Mumps virus	**12500 TCID50**
Rubella virus	**1000 TCID50**

Other Ingredients (Excipients)

adenine sulfate dihydrate
adenosine phosphate
adenosine triphosphate disodium
aminobenzoic acid
arginine hydrochloride
arginine
ascorbic acid
Biotin
calcium chloride dihydrate
calcium pantothenate
cholesterol
choline chloride
cysteine hydrochloride
cystine dihydrochloride
cystine
deoxyribose
dibasic potassium phosphate
dibasic sodium phosphate dihydrate
dibasic sodium phosphate

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dl-alanine
dl-alpha-tocopheryl phosphate disodium
dl-aspartic acid
dl-glutamic acid
dl-leucine
dl-methionine
dl-phenylalanine
dl-serine
dl-threonine
dl-tryptophan
dl-valine
ergocalciferol
ferric nitrate nonahydrate
folic acid
glucose monohydrate
glutamine
glutathione
glycine
guanine hydrochloride monohydrate
histidine hydrochloride
histidine
hydrolysed gelatin
hydroxyproline
inositol
isoleucine
leucine
lysine hydrochloride
lysine
magnesium sulfate heptahydrate
menadione
methionine
monobasic potassium phosphate
monobasic sodium phosphate
monosodium glutamate monohydrate
neomycin
nicotinamide
nicotinic acid
phenolsulfonphthalein
phenylalanine
polysorbate 80
potassium chloride
proline
pyridoxal hydrochloride
pyridoxine hydrochloride
retinol acetate
riboflavine
ribose
serine
sodium acetate
sodium bicarbonate
sodium chloride
sodium hypoxanthine
sodium pyruvate

sodium xanthine
sorbitol
sucrose
thiamine hydrochloride
threonine
thymine
tryptophan
tyrosine disodium
tyrosine
uracil
valine
water for injections

2 . Diluent

Dosage Form	Diluent, not applicable
Route of Administration	Subcutaneous Intramuscular
Visual Identification	Clear colourless solution

Active Ingredients	
water for injections	**.75 mL**

Other Ingredients (Excipients)

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