MSD

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September 2019

# MMR II Vaccine (Measles, mumps and rubella vaccine)

# Supply of Singapore-labelled MMR II to New Zealand

Dear Health Professional,

This communication is intended for Healthcare Professionals (HCPs) who perform the administration of the MMR II Vaccine to patients.

# **Summary**

MSD is supplying the following batch of Singapore-labelled MMR II Vaccine to the New Zealand market upon request from PHARMAC to address the measles outbreak in New Zealand:

Batch Number: S021856 Expiry Date: 16-July 2021

Please note the following:

# Comparison of Singapore and New Zealand label

A side-by-side comparison of the Singapore and New Zealand labels (vaccine carton, vaccine vial label, diluent vial label, package insert) are appended to this letter.

## New Zealand Data Sheet and CMI

The New Zealand Data Sheet and Consumer Medicine Information for MMR II may be accessed at www.medsafe.govt.nz

# Classification and dosage form

The classification 'Prescription Medicine' and the dosage form 'Powder for injection with diluent' are not present on the Singapore product.

# **Excipients**

The following excipients, which are present in the New Zealand product, are also present in the Singapore product:

Dibasic potassium phosphate
Dibasic sodium phosphate
Monobasic potassium phosphate
Monobasic sodium phosphate
Monosodium glutamate monohydrate
Phenolsulfonphthalein
Sodium bicarbonate
Sorbitol
Sucrose
Hydrolysed gelatin
Neomycin
Other buffer and media ingredients

# Storage condition

The Medsafe-approved instructions for storage must be followed:

Store at 2-8 °C. (REFRIGERATE. DO NOT FREEZE.) Protect from light.

# Pregnancy Warning

The Medsafe-approved pregnancy warning must be followed:

WARNING: NOT TO BE ADMINISTERED TO PREGNANT WOMEN. A woman must not become pregnant within 3 months after having the vaccine.

# Adverse Event, Product Quality Complaint reporting and Company Contact Point

If you have any questions regarding MMR II or if you wish to report any suspected Adverse Events and/or Product Quality Complaints with the use of MMR II to MSD:

Email: dpoc.australia@merck.com

T: 0800 500 673

Yours faithfully,

Chad Woodcock NZ Medical Director

# **Comparison of Singapore and New Zealand label**



# **New Zealand**

# **Vaccine Package Insert New Zealand Instruction For Use**



#### M-M-R® II

The New Zealand Data Shoot and Consumer Medicine Information may be accessed at: www.medsafe.govt.nz

The following information is intended for healthcare professionals only:

#### Dosage and Administration

FOR SUBCUTANEOUS ADMINISTRATION

Do not inject intravascularly. Do not give immune globulin (IG) concurrently with M-M-R II.

The dose for any age is 0.5 mL administered subcutaneously, preferably into the outer aspect of the upper arm.

CAUTION: A storile syringe free of preservatives, antisoptics, and detergents should be used for each injection and/or reconstitution of the vaccine because these substances may inactivate the live virus vaccine. A 25 gauge, 5/8" needle is recommended.

To reconstitute, use only the diluent supplied, since it is free of preservatives or other antiviral substances which might inactivate the vaccine

Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration whe never solution and container permit. Before reconstitution, the lyophilised vaccine is a light yellow compact crystalline plug. M-M-R II, when reconstituted, is clear yellow.

# Recommended Vaccination Schedule

Individuals first vaccinated at 12 months of age or older, should be revaccinated at 4 to 6 years of age since increased risk of exposure typically occurs around primary school entry. Revaccination is intended to seroconvert those who do not respond to the first dose.

#### Single Dose Vial

Single Loss Viai.

First withdraw the entire volume of diluent into the syringe to be used for seconstitution. Inject all the diluent in the syringe into the vial of lyophilised vaccine, and agitate to mix thoroughly. If the lyophilised vaccine cannot be dissolved, discard, Withdraw the entire contents into a syringe and inject the total volume of reconstituted vaccine

It is important to use a separate sterile syringe and needle for each individual patient to prevent transmission of hepatitis B and other infectious agents from one person to another.

#### Special precautions for storage

To maintain potency, M.-M. R. II must be stored between -50°C and +8°C (-58°F to +46°F). Use of day los may subject M.-M. R. II to temperatures colder than -50°C (-58°F). Protect the vaccine from light at all times, since such exposure may inactivate the viruses.

Before reconstitution, store the worbilised vaccine at 2°C to 8°C (36°F to 46°F). The diluent may be stored in the refrigerator with the lyophilised vaccine or separately at room temperature. eze the diluent

Combination pack containing lyophilised vaccine and diluent together should be stored at 2°C to 8°C (36°F to 46°F).

It is recommended that the vaccine be used as soon as possible after reconstitution. Store reconstituted vaccine in the vaccine vial in a dark place at 2°C to 8°C (36°F to 46°F) and discard if not

Prior to reconstitution the vaccine has a shelf life of 24 months when stored at 2°C to 8°C and protected from light.



# Singapore

# **Vaccine Package Insert** Singapore's Physician's Circular



# M-M-R II®

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