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

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<thead>
<tr>
<th>New Zealand</th>
<th>Singapore</th>
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<tr>
<td>Vaccine Carton</td>
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<td>[Image: Vaccine Carton New Zealand]</td>
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<td><strong>Vaccine Package Insert</strong>&lt;br&gt;&lt;br&gt;&lt;strong&gt;New Zealand Instruction For Use**&lt;br&gt;&lt;br&gt;<strong>M-M-R</strong> II&lt;br&gt;&lt;br&gt;The New Zealand Data Sheet and Consumer Medicine Information may be accessed at: <a href="http://www.medicines.govt.nz">www.medicines.govt.nz</a>. The following information is intended for healthcare professionals only:&lt;br&gt;&lt;br&gt;Dosage and Administration&lt;br&gt;&lt;br&gt;For subcutaneous administration&lt;br&gt;&lt;br&gt;Do not inject intra muscularly. 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. &lt;br&gt;&lt;br&gt;CAUTION: A sterile syringe free of preservatives, antioxidants, and detergents should be used for each injection and for reconstitution of the vaccine because these substances may inactivate the live virus vaccine. A 25 gauge 5/8” needle is recommended. To reconstitute, add only the diluent supplied, since it is free of preservatives or other antiviral substances which might inactivate the vaccine. &lt;br&gt;&lt;br&gt;Penicillin drug products should be inspected visually for particulate matter and discoloration prior to administration when no 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. &lt;br&gt;&lt;br&gt;Recommended vaccination schedule&lt;br&gt;&lt;br&gt;Individuals first vaccinated at 12 months of age or older, should be revaccinated at 4 to 6 years of age since an increased risk of adverse events typically occurs around primary school entry. Revaccination is intended to occur with those who do not respond to the first dose. &lt;br&gt;&lt;br&gt;Single Dose Visit&lt;br&gt;&lt;br&gt;First withdraw the desired volume of diluent into a syringe to be used for reconstitution. Inject the diluent in the syringe into the vial of lyophilised vaccine and mix thoroughly. If the lyophilised vaccine cannot be dissolved, discard. Withdraw the contents into a syringe and inject the total volume of reconstituted vaccine subcutaneously. &lt;br&gt;&lt;br&gt;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. &lt;br&gt;&lt;br&gt;Special precautions for storage&lt;br&gt;&lt;br&gt;Merck and Co. recommends that the vaccine be stored between 15°C and 18°C (59°F to 65°F). Use of the diluent may affect M-M-R II to a temperature colder than 15°C (59°F). &lt;br&gt;&lt;br&gt;The diluent may be stored in the refrigerator with the lyophilised vaccine or separately at room temperature. Do not freeze the diluent. &lt;br&gt;&lt;br&gt;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. Some reconstituted vaccine in the vial may be used at a different location in a patient’s arm at a dark place at 2°C to 8°C (36°F to 46°F) and discard if not used within 6 hours. &lt;br&gt;&lt;br&gt;Prior to reconstitution the vaccine has a shelf life of 24 months when stored at 2°C to 8°C and protected from light.</td>
<td><strong>Vaccine Package Insert</strong>&lt;br&gt;&lt;br&gt;&lt;strong&gt;Singapore’s Physician’s Circular**&lt;br&gt;&lt;br&gt;M-M-R® II&lt;br&gt;&lt;br&gt;(MEASLES, MUMP, and RUBELLA VIRUS VACCINE LIVE)&lt;br&gt;&lt;br&gt;THE NEW ZEALAND DATA SHEET AND CONSUMER MEDICINE INFORMATION MAY BE ACCESED AT: <a href="http://WWW.MEDICINES.GOVTT.ZNZ">WWW.MEDICINES.GOVTT.ZNZ</a>. THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY:&lt;br&gt;&lt;br&gt;DOSAGE AND ADMINISTRATION&lt;br&gt;&lt;br&gt;FOR SUBCUTANEOUS ADMINISTRATION&lt;br&gt;&lt;br&gt;DO NOT INJECT INTRAMUSCULARLY. DO NOT GIVE IMMUNE GLOBULIN (IG) CONCURRENTLY WITH M-M-R II.&lt;br&gt;&lt;br&gt;THE DOSE FOR ANY AGE IS 0.5 mL ADMINISTERED SUBCUTANEOUSLY, PREFERABLY INTO THE OUTER ASPECT OF THE UPPER ARM.&lt;br&gt;&lt;br&gt;CAUTION: A STERILE SYRINGE FREE OF PRESERVATIVES, ANTIOXIDANTS, AND DETERGENTS SHOULD BE USED FOR EACH INJECTION AND FOR RECONSTITUTION OF THE VACCINE BECAUSE THESE SUBSTANCES MAY INACTIVATE THE LIVE VIRUS VACCINE. A 25 GAUGE 5/8” NEEDLE IS RECOMMENDED.&lt;br&gt;&lt;br&gt;TO RECONSTITUTE, ADD ONLY THE DILUENT SUPPLIED, SINCE IT IS FREE OF PRESERVATIVES OR OTHER ANTIVIRAL SUBSTANCES WHICH MIGHT INACTIVATE THE VACCINE.&lt;br&gt;&lt;br&gt;PEenicillin DRUG PRODUCTS SHOULD BE INSPECTED VISUALLY FOR PARTICULATE MATTER AND DISCOLORATION PRIOR TO ADMINISTRATION WHEN NO SOLUTION AND CONTAINER PERMIT.&lt;br&gt;&lt;br&gt;BEBFORE RECONSTITUTION, THE LYOPHILIZED VACCINE IS A LIGHT YELLOW COMPACT CRYSSTALINE PLUG. M-M-R II, WHEN RECONSTITUTED, IS CLEAR YELLOW.&lt;br&gt;&lt;br&gt;RECOMMENDED VACCINATION SCHEDULE&lt;br&gt;&lt;br&gt;INDIVIDUALS FIRST VACCINATED AT 12 MONTHS OF AGE OR OLDER, SHOULD BE REVACCINATED AT 4 TO 6 YEARS OF AGE SINCE AN INCREASED RISK OF ADVERSE EVENTS TYPICALLY OCCURS AROUND PRIMARY SCHOOL ENTRY. REVACCINATION IS INTENDED TO OCCUR WITH THOSE WHO DO NOT RESPOND TO THE FIRST DOSE.&lt;br&gt;&lt;br&gt;SINGLE DOSE VISIT&lt;br&gt;&lt;br&gt;FIRST WITHDRAW THE DESIRED VOLUME OF DILUENT INTO A SYRINGE TO BE USED FOR RECONSTITUTION. INJECT THE DILUENT IN THE SYRINGE INTO THE VIAL OF LYOPHILIZED VACCINE AND MIX THOROUGHLY. IF THE LYOPHILIZED VACCINE CANNOT BE DISSOLVED, DISCARD. WITHDRAW THE CONTENTS INTO A SYRINGE AND INJECT THE TOTAL VOLUME OF RECONSTITUTED VACCINE SUBCUTANEOUSLY.&lt;br&gt;&lt;br&gt;IT IS IMPORTANT TO USE A SEPARATE STERILE SYRINGE AND NEEDLE FOR EACH INDIVIDUAL PATIENT TO PREVENT TRANSMISSION OF HEPATITIS B AND OTHER INFECTIONOUS AGENTS FROM ONE PERSON TO ANOTHER.&lt;br&gt;&lt;br&gt;SPECIAL PRECAUTIONS FOR STORAGE&lt;br&gt;&lt;br&gt;TO MAINTAIN POTENCY, M-M-R II MUST BE STORED BETWEEN 15°C AND 18°C (59°F TO 65°F). USE OF THE DILUENT MAY AFFECT M-M-R II TO A TEMPERATURE COLDER THAN 15°C (59°F). PROTECT THE VACCINE FROM LIGHT AT ALL TIMES, SINCE SUCH EXPOSURE MAY INACTIVATE ITS VIRUSES.&lt;br&gt;&lt;br&gt;BECFORE RECONSTITUTION, STORE THE LYOPHILIZED VACCINE AT 2°C TO 8°C (36°F TO 46°F). THE DILUENT MAY BE STORED IN THE REFRIGERATOR WITH THE LYOPHILIZED VACCINE OR SEPARATELY AT ROOM TEMPERATURE. DO NOT FREEZE THE DILUENT.&lt;br&gt;&lt;br&gt;COMBINATION PACK CONTAINING LYOPHILIZED 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. SOME RECONSTITUTED VACCINE IN THE VIAL IN A DARK PLACE AT 2°C TO 8°C (36°F TO 46°F) AND DISCARD IF NOT USED WITHIN 6 HOURS.&lt;br&gt;&lt;br&gt;PRIOR TO RECONSTITUTION THE VACCINE HAS A SHELF LIFE OF 24 MONTHS WHEN STORED AT 2°C TO 8°C AND PROTECTED FROM LIGHT.</td>
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